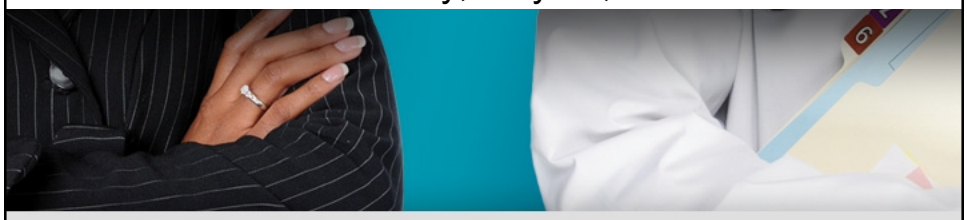
EHRs in 2013:
A Holistic View of Issues Facing Providers

Wednesday, May 15, 2013



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FOLEY & LARDNER LLP

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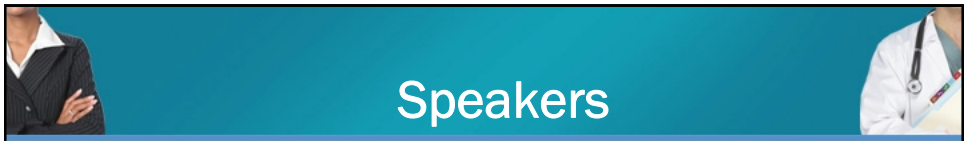

Speakers

Rick Rifenbark
Partner
rrifenbark@foley.com

Ralph Oyaga
Associate Counsel
HITEC-LA
ROyaga@lacare.org

Adria Warren
Senior Counsel
awarren@foley.com

Jim Kalyvas
Partner
IT & Outsourcing - Chair
jkalyvas@foley.com

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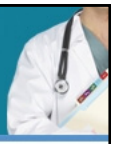
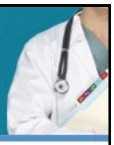
Recent Fraud and Abuse Guidance Regarding Donations of EHRs



- Proposed Stark/AKS EHR Regulations
- State Law Limitations on EHR Donations
- Office of Inspector General (OIG) Advisory Opinions on EHR donations

EHR Donation Refresher



- AKS/Stark Safe Harbors adopted in 2006
- Permit donations of EHR software and services
- EHR must be “interoperable” with e-prescribing
- At least 15% cost sharing by recipients
- Documented in written agreement
- Eligibility must not directly take into account referrals
- Recipient cannot already have equivalent EHR
- Scheduled to “sunset” December 31, 2013

Proposed Update to EHR Regulations

- CMS and OIG recently proposed to extend the EHR regulations until December 31, 2016
- Other proposed changes and areas of interest
  - Elimination of e-prescribing requirement
  - Changes to deemed interoperability
  - Potential limitation on types of donors
  - Data lock-in and exchange
  - Covered technology

State Law Limitations on EHR Donations

- Don't forget to check your state laws!
- Stark and AKS EHR regulations provide that state laws are not preempted
- States with restrictions on EHR donations:
  - Missouri
  - New Jersey
  - New York
  - Pennsylvania
  - Tennessee
  - Washington
  - West Virginia

OIG Advisory Opinion 12-19

- Pharmacy company's proposed software arrangements with community homes
  - Proposal #1: Sale of discounted software sublicenses to all interested community homes
  - Proposal #2: Donation of software to certain community homes
- OIG approved proposal #1 but not #2
  - Lack of interoperability
  - Selection of community homes
  - Independent value of technology

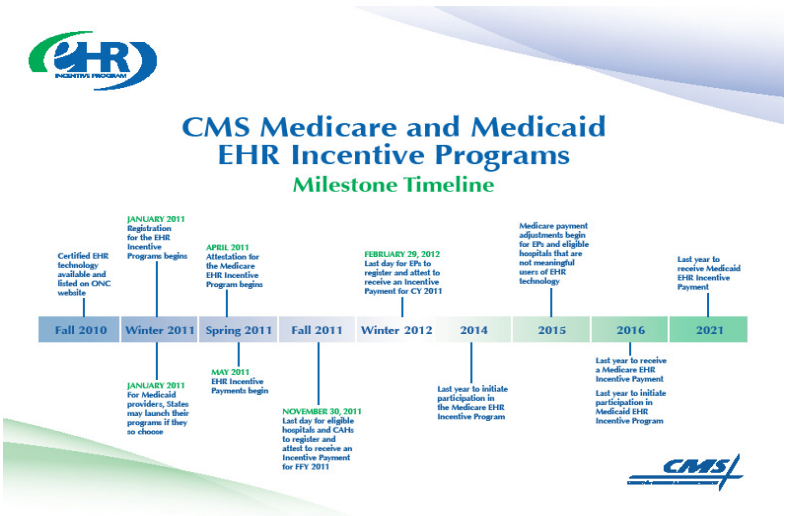
OIG Advisory Opinion 12-20

- Hospital proposal to provide free access to an electronic interface (and support services) to MDs
- Interface would facilitate transmittal of orders for certain services to, and receive the results of those services from, the hospital
- OIG concluded that the interface had no independent value to MDs and therefore did not constitute remuneration
- Consistent with CMS/Stark guidance

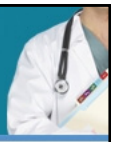
EHR Incentive Program

- Triple Aim
  - Improve Care
  - Improve Population Health
  - Reduce Per Capita Cost of Health Care

EHR Incentive Program

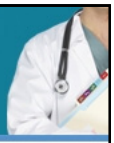


EHR Incentive Program



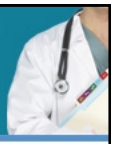
- Medicare v. Medicaid
  - Timelines
    - Jan 2011 Mcare Launch (Medicaid varies by State)
  - Payment Differences
    - Mcare: Up to $44,000 (% of Part B billing)
      - 18K Year 1,12K,8K,4K,2K
      - Penalties: 1% to 3% beginning 2015
    - Mcaid: $63,750
      - 21,250 Year 1, 8,500 subsequent years

EHR Incentive Program



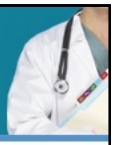
- Medicare v. Medicaid
  - Tail Periods
    - Mcare: Feb 29th
    - Mcaid: Varies by State
  - Last Year to Initiate / Last Payment Year
    - Mcare: Initiate by 2014 / Last payment year 2016
    - Mcaid: Initiate by 2016/ Last payment year 2021
  - Skipping Years allowed in Mcaid Program

Registration Issues



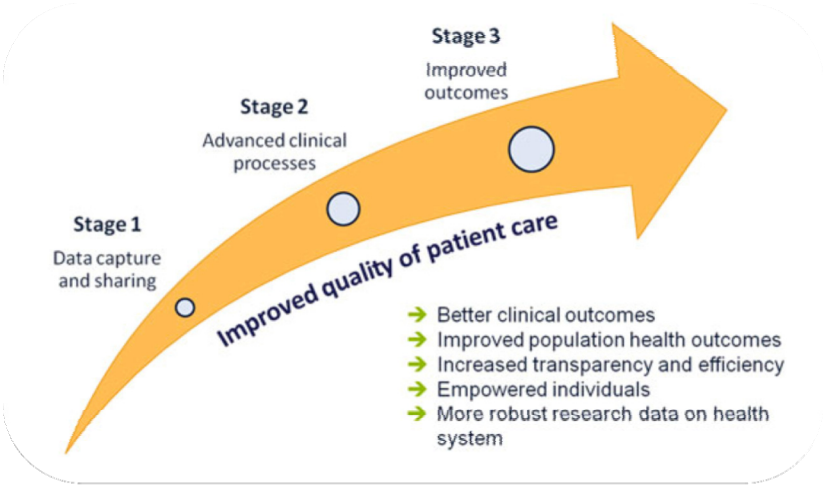
- Payment Reassignment
  - To employer or entity with which EP has a contractual arrangement allowing the employer or entity to bill and receive payment for the EP's covered professional services.
  - An entity promoting the adoption of EHR technology (Medicaid EPs)
  - Each EP may reassign the entire amount of the incentive payment to only one employer or entity

Registration Issues



- National Level Registry (NLR)
  - Identity and Access (I&A) System
    - Set up "proxy" account
    - EP approval (account access issues)
  - PECOS issues
- State Level Registry (SLR)
  - State Medicaid Office (subcontractor)
    - Time is of the essence
      - Case reporting/resolution

Meaningful Use[2]



What's Next?

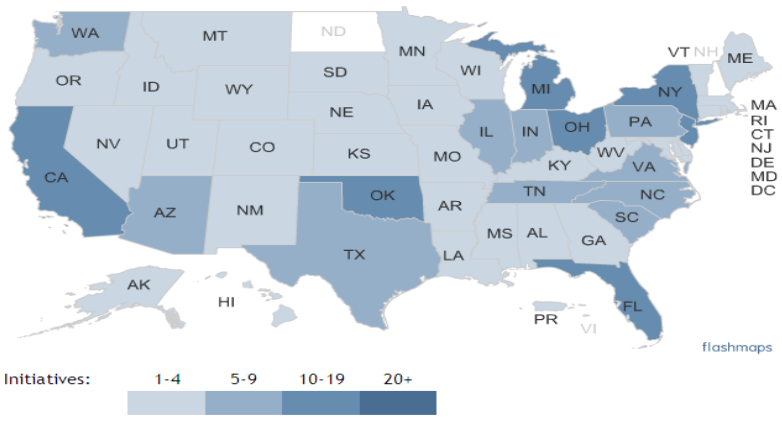
- ARRA Funding Ends
  - Regional Extension Center will no longer provide subsidized technical assistance to PPCPs
  - Stage 2 thresholds raise the bar for Providers (and EHR Vendors?)
  - HIEs, ACOs, PCMHs, and Other

What is HIE?

Definition:

The electronic movement of health-related information among organizations according to nationally recognized standards

HIEs reported, by State



Source:http://apps.himss.org/statedashboard/

Drivers

- Patient Protection and Affordable Care Act
- New delivery and payment models, i.e., accountable care organizations (ACOs), bundled payments, health and medical homes, and push for reductions in hospital readmission
- HITECH Act
- Meaningful Use Stage 2
- Technical Standards for Certified Electronic Health Record Technology
- State Laws
- More to Come?

  HHS Request of Information (comments due April 22, 2013): http://www.regulations.gov/#!documentDetail;D=CMS-2013-0044-0001

  > "We introduced many concepts of interoperability in Stage 2 and expect that the Medicare and Medicaid EHR Incentive Programs criteria for Stage 3 of meaningful use will include requirements for advanced interoperability. As other value-based payment programs evolve, they might include a greater emphasis on HIE as either a *requirement for participation*, receipt of incentive payments, or avoidance of payment adjustments."

Meaningful Use Stages

Stage 1: Meaningful use criteria focus on	**Stage 2:** Meaningful use criteria focus on	**Stage 3:** Meaningful use criteria focus on
Electronically capturing health information in a standardized format	More rigorous health information exchange (HIE)	Improving quality, safety, and efficiency, leading to improved health outcomes
Using that information to track key clinical conditions	Increased requirements for e-prescribing and incorporating lab results	Decision support for national high-priority conditions
Communicating that information for care coordination processes	Electronic transmission of patient care summaries across multiple settings	Patient access to self-management tools
Initiating the reporting of clinical quality measures and public health information	More patient-controlled data	Access to comprehensive patient data through patient-centered HIE
Using information to engage patients and their families in their care		Improving population health

Meaningful Use Stage 2 and HIE

1. *Summary of Care Records* – The EP who transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 50% of transitions of care and referrals.
2. *Transitions of Care* -- For 10% of transitions and referrals, the hospital or EP that transitions a patient to another setting of care or provider of care must provide a summary of care record either:

   (a) electronically transmitted to a recipient using certified EHR (can be the same or different EHR); or

   (b) using an HIE that complies with Nationwide Health Information Network (NwHIN) specifications or is validated through an ONC-established governance mechanism to facilitate exchange.
3. *Electronic Exchange* -- Hospitals and EPs must either:

   (a) conduct one or more successful *electronic exchanges* of a summary of care record with a recipient using technology that was designed by a *different* EHR developer than the sender's (e.g., a provider with Epic as opposed to Cerner); or

   (b) Conduct one or more successful tests with the CMS-designated test EHR during the EHR reporting period (i.e., send a summary of care document to a CMS-created EHR testing site).

Meaningful Use Stage 2 and HIE

- *Transmission of Prescriptions*
  - More than 50% of all permissible prescriptions written by the EP must be compared to at least one drug formulary and *transmitted electronically* using EHR.
- *Stage 2 MU Optional Hospital Requirement*:
  - More than 10% of the hospital discharge medication orders for permissible prescriptions (for new or changed prescriptions) are compared to at least one drug formulary and *transmitted electronically* using EHR.
  - Hospital labs must send structured *electronic* clinical lab results to the ordering provider for more than 20% of *electronic* lab orders received.

National HIE Framework

- Office of the National Coordinator for Health Information Technology (ONC)
- Healtheway (NwHIN) – governance models/protocols/policies
- Health Information Handlers – the "gateways" on the nationwide health information network to CMS. Include HIEs, RHIOs (Regional Health Information Organization), ROIs (Release of Information Vendors), EHR Vendors, Claim Clearinghouse
- Nationwide Health Information Network Participant: any organization that has successfully completed the "on-boarding" process

HIE Governance

"Governance Framework for Trusted Electronic Information Exchange"

issued by the ONC on May 3, 2013

- *Organizational Principles*. HIEs should operate in a manner that is open, transparent, inclusive, consistent, and equitable. They should also have mechanisms to ensure compliance with legal requirements and provide due process to stakeholders.
- *Trust Principals*. Patients should:
  - be able to access a "Notice of Data Practices" in lay person terminology about the purposes for which both identifiable and deidentified data may be exchanged.
  - "receive" a "simple explanation" of data privacy and security practices as well as who has access to the exchanged data.
  - express "meaningful choice" about whether their data is exchanged, request limits on exchange, and electronically access and request corrections to their data, "consistent with applicable laws".
  - be "assured" that their data will be consistently accurately matched when exchanged.

HIE Governance Cont'd.

- *Business Principles*. HIE governance entities should have entry standards that promote "collaboration" and exchange of information. They should provide "open access" to descriptions of the types of data that they have available for exchange, including publishing statistics about their operations. The entities should also "maintain and disseminate" information about compliance with standards, potential security vulnerabilities, and best practices.
- *Technical Principles*
  - Technology should support the "Trust" and "Business" principles.
  - Where federal standards for vocabulary, content, transport, and security exist, exclusive use of these standards should be "prioritized."
  - Where federal standards are not available, then standards developed by voluntary consensus standards organizations (VCSOs) should be used.
  - Entities should both: (1) support and work with VCSOs where technical standards have not yet been developed; and (2) support assessment and testing methods to determine compliance.

Practical Tips – Considerations and Challenges

- Interoperability/Connectivity
- Sustainability
- Privacy and Security
- State laws
-- privacy/security standards not preempted by Federal law and may be more restrictive
-- HIE standards/requirements
- Patient Consent
- Governance
- Contractual Considerations
  - Participation Agreement
  - Business Associate Agreement

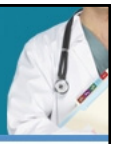
EHR Procurement and Management

- To save money and ensure system performance
  - Obtain an effective MU warranty or practical assurance
  - Address medical device and EHR convergence
  - Know the development paths of key third party systems/products and your EHR, and ensure your EHR vendor's development cycle includes consideration of such products

MU Warranty

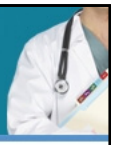
- The Licensed Software has been tested and certified by an ONC-ATCB as Certified EHR Technology for use as a Complete EHR in the ambulatory and inpatient practice settings, as applicable based on the intended primary practice setting use of the Licensed Software, pursuant to the HITECH Technical Standards. Further, Vendor represents and warrants, during the Support Term, Vendor shall provide to Customer at no additional charge: (a) software updates or replacement software, and Revisions thereto, if required, ("**HITECH Modifications**"), so that the Licensed Software meets the requirements of Certified EHR Technology for use as a Complete EHR in the ambulatory and inpatient practice settings, at each stage of the Meaningful Use requirements(referred to as the HITECH Technical Standards as defined below), as that term is defined by the Health Information Technology for Economic and Clinical Health Act of 2009 (the "**HITECH Act**"); (b) Vendor will provide the HITECH Modifications sufficiently in advance of the beginning of the first applicable reporting period identified under the HITECH Act or its implementing regulations as to each stage of the Meaningful Use requirements in order for Customer to receive the full amount of incentive payments, and to permit a reasonable period for Customer's implementation of the HITECH Modification.

Address Convergence



- Medical devices have been getting “smarter” (software driven/network capabilities) for years
- EHR capabilities for decision support and analytics are significantly enhanced by direct input from medical devices
  - Highly relevant
  - Accurate/continuous
- EHR systems are increasingly designed to process direct input from medical devices
- EHRs and smart devices can operate on the same network infrastructure
- The blurring of the line between data input to the EHR and processing the data is causing the convergence

Address Convergence



- Align investments in EHR, medial devices, and network, with the convergence strategy
  - Modify agreements and procurement documents (RFPs) to address convergence
  - Address warranties
  - Confidentiality – EHR and medical device suppliers must be able to access each system
  - License rights – ensure you understand how device connections to your EHR will be treated
  - Ask about the interoperability of devices with your systems and vice versa in your RFPs
  - Have accurate descriptions/lists of medical devices and systems so you can get specific responses
  - Budget for the cost of integration and additional network capacity

Key Third Party Software

- EHR Vendor will collaborate with Third Party Vendor in the development and testing process of both the EHR and Third Party software, to maintain the Software as Compatible with the Third Party Software. For purposes of this Section __(Compatibility), "Compatible" means the EHR Software will operate together with the Third Party Software such that there is no diminution of performance or function of either software caused by the other.

Q&A Session

A survey will appear on your screen at the end of the Q&A session, please take a few moments to complete the it and provide us your feedback on today's program.