Responding to 'Meaningful Use' Regulations:

Implications for Provider, Payers Vendors, and the Government

William R. "Bill" Braithwaite, MD, PhD, FACMI
Chief Medical Officer
Anakam Inc.

700+ pages of CMS and ONC rules

- **HHS is obliged under the stimulus law to:**
  - adopt standards, implementation specifications and certification criteria that will "enhance the interoperability, functionality, utility and security of health information technology."
- **Providers must document "meaningfully use" of their subsidized EHR systems**
  - which must be "qualified" under a definition in the stimulus law
  - and then "certified" against criteria established through federal rulemaking
  - by a certification organization "recognized" by the ONC.
- **The key EHR certification process is unknown**
  - Waiting for new rules to cover how certification bodies will be selected and "recognized".

Medical Group Management Association (MGMA)

- **“Significant barriers" for physicians trying to achieve meaningful use of EHR data include:**
  - Unreasonable thresholds for some meaningful use criteria, including computerized prescription order entry, electronic claim submission and electronic insurance eligibility verification;
  - members say it's unrealistic to require office-based physicians to produce 80% of their orders using CPOE.
  - Potentially difficult meaningful use attestation after the first year; and
  - Requirement that physician offices provide patients and others with electronic copies of medical records.
- **Physicians must furnish a patient an electronic copy of his or her medical record within 48 hours of a request.**
  - HIPAA gives providers up to 30 days to compile the records
  - Many practices have different systems and to compile it within 48 hours looks to us to be overly burdensome.
  - Patients hardly ever ask for an electronic copy of their record
  - The quick delivery capability would be “good to have, but they have to be practical. If they expanded that time frame, we'd be a lot more comfortable.”
- **CMS needs to keep two words in mind: “achievable and practical”**

KLAS Survey - "Ambulatory EMR: On Track for Meaningful Use?"

- **Eighty-five percent of healthcare providers believe their ambulatory electronic medical record software will enable them to meet the 2011 meaningful use deadlines.**
  - But many respondents say their technology lacks adequate reporting functionality.
- **Most respondents believe their EMR will help them meet the proposed government requirements,**
  - with Epic, NextGen and athenahealth customers expressing the most confidence and SRSsoft and Amazing Charts clients expressing the least.
- **Providers also noted a number of functional areas that are still lacking. Foremost among these were:**
  - EMR reporting tools, patient access to medical records, and the ability to share clinical data.
- **17 percent of providers say reporting is difficult or impossible with current tools**
  - 24 percent report needing specific technical expertise to manipulate the tools provided.
  - Many vendors will need to increase the number and complexity of their canned reports, provide a stand-alone reporting application, or add a third-party tool that can pull the required data
- **Only Allscripts Enterprise had 100 percent of interviewed clients able to digitally transmit qualifying pharmacy orders. Greenway and e-MDs earned the highest marks for functionality in this area, while MED3000 was considered the most challenged.**
  - Biggest obstacle to date has been pharmacies' lack of ability to receive digital transmissions. Most large pharmacy chains are now using systems that can receive transmissions, but many smaller or independent pharmacies lack either the means or the inclination to go digital.

American Hospital Association (1)

- **“The time frame that they've put forward and that all-or–nothing approach is really out of step with the way hospitals and physician offices implement health information technology,”**
- **The rulemakers clearly tried reach a balance between,**
  - on the one hand, ensuring that the huge government investment in EHRs would go to buying tools that would be used to improve healthcare performance and,
  - on the other hand, to be mindful not to set performance goals and measures so high that adoption of the EHR systems—even those subsidized as much as 85% of cost—would be impeded.
- **CMS called for a “phased approach” to compliance, promising to develop even more stringent meaningful-use criteria in the future.**
- **Federal officials spent not enough time querying providers in the field on how these proposed rules might affect their day-to-day operations.**
- **“They did a lot of detailed work very quickly and I think they've come up with a pretty good ideal system, but we don't think it's a starting system,”.**
- **“This rule may actually provide a disincentive for those hospitals that are on the wrong side of the digital divide.”**

American Hospital Association (2)

- **The proposed rule provides for the creation of three, increasingly more stringent stages of meaningful-use criteria, with details of the first stage covered by the new rule.**
  - Even the just released first-stage rules that cover the program startup in 2010 and 2011 may prove too big a step up for many hospitals.
- **For example, one meaningful-use criterion requires hospitals to measure and attest that 10% of all physician orders are entered into a computerized physician order-entry system.**
  - The first problem is that only about 30% of hospitals have some form of CPOE up and running in at least one department. Technically, CPOE is one of the highest-level clinical IT systems a hospital can install. Plus, they require physicians to change their workflows. For those reasons, typically, CPOE is brought online last in an IT implementation.
- **The meaningful use requirement for CPOE also calls for hospitals to count how many orders they process—both on paper and electronically.**
  - The hospital has to count all of the physicians' orders and not just the ones in the EHR, so they're going to have to create a process that doesn't exist today
- **There are 15 meaningful-use measures of EHR functionality in the new rules—including CPOE use—that require hospitals to make such calculations, creating both numerators and denominators; physicians and other medical professionals have 17 such measures.**
  - We have some real concern with these denominator issues.
  - Under the CMS rule, hospitals and physician offices have to comply with all meaningful-use requirements to be eligible for payment, creating the “all or nothing” problem.
- **AHA says: 80% of hospitals surveyed recorded patient demographics electronically; 60% were able to view electronically the results for radiology and laboratory reports.**
  - But when you look at how many hospitals have all of those functions up and running, you see all of those great numbers drop.
  - Less than 2% of hospitals in the survey had all 24 functions of a so-called “full-featured” EHR.
- **While hospitals have done a lot, not a lot of them have done everything**

John Halamka, (HITSP chairman) CIO of Beth Israel Deaconess

- **The recommendations are consistent with the work of thousands of experts over the past decade.**
  - They do not include all the detailed recommendations from HITSP or implementation profile writers such as IHE but they do include all the highly mature constructs that are deployable in 2011 without over burdening the industry.
- **At BIDMC, we have healthcare information pilots among payers, providers, government, and patients under local implementation guides, a defined architecture, and transmission standards.**
  - This means that we're in reasonable shape for implementing the IFR and NPRM as written.
  - We would appreciate clarification of the patient engagement requirements. We can send the patient summary record to Google Health and Microsoft Healthvault. We make all patient data available via our tethered PHR. We do not send unsecured email to patients nor do we make extensive use of interactive voice technology.

The Interim Final Rule on Standards

- **Lab standards are not specific enough.**
  - 100% of the optionality of the HL7 base standard is still allowed.
  - Implementation guides must be added to the rules to set a firm technical direction for Stage 2 with a minimum of 2 years advance notice for implementation, or it will not be possible for the country to achieve the policy targets of Stage 2 for structured information exchange until a later date.
- **Transmission standard needs more detail to support interoperability.**
  - SOAP or REST are both acceptable. SOAP could include any proprietary implementation of SOAP 1.2 which vendors/HIEs would like to implement. REST is an architecture so it provides great latitude to incompatible implementations.
- **Unsure how to implement the RxNorm requirement in Stage 1.**
  - Must EHRs internally have one of the RxNorm source vocabularies or is the requirement that data exchanged from the EHR include one of these vocabularies?
  - Using a source vocabulary inside an EHR and RxNorm for transmission outside an EHR requires a complete mapping.
- **Quality standards are still emerging, such as Quality Reporting Document Architecture (QRDA) and Healthcare Quality Measure Format (HQMF).**
  - These are not mature enough to require in Stage 1, but giving implementers credit for early adoption would advance quality reporting.
- **Too much optionality in the security standards.**
  - AES should be required for encryption, SHA-1 or SHA-2 for data integrity and TLS, IPv6 or IPv4 with IPsec for secure transmission should be the only choices.

The Notice of Proposed Rulemaking

- **CPOE requirement should include emergency departments. NPRM seems to exclude the ED as qualifying for the 10% electronic ordering threshold. The ED could be a good first place to implement CPOE and the transaction volume would meet 10% of hospital orders.**
- **Quality reporting requirement is too much too soon.**
- **Patient engagement requirements are too much to soon.**
  - Existing systems do not understand how to send reminders to patients per their preference (email, fax, phone call, PHR, Facebook, twitter) and since there is no standard secure API for doing this, it is not implementable.
  - Providing 80% of patients with a clinical summary of office visits or care transitions will require significant retooling of software and incremental staffing.
- **Electronic medication reconciliation at each transition of care is challenging to implement technically and requires significant workflow redesign.**
- **Submission of immunization, syndromic surveillance data or public health lab reporting is challenging to implement.**
  - Transmission standards in the IFR lack detail and there is no national reference implementation to follow.
- **Summarizing - aggressive interoperability timelines require specific implementation guides and reference implementations. This leaves a choice - either the standards need more detail, especially in the transmission area, or the NPRM goals need to reduced in scope/extended in time.**

Electronic Health Record Association (EHRA)

- **The basic EHR incentive funding for Medicare and Medicaid pathways, along with much of the specific clinical EHR meaningful use criteria, hasn't really changed from preliminary requirements published earlier in 2009.**

Healthcare Information and Management Systems Society (HIMSS)

- “There is much more to applaud than criticize,"
- "We now have clarity of what technology functions constitute a qualified electronic health record,
- we now have a multi-year road map of future expectations, and
- we have certainty about many of the standards necessary to support practitioners’ ability to improve patient care."

EHR Vendors

- **Ingenix Inc. and Allscripts are guaranteeing that their products will comply with meaningful use requirements and have also launched new financing programs.**
  - Ingenix is offering interest free loans from OptumHealth Bank. Integrated practice management software also is eligible for interest free financing. Ingenix will guarantee the EHR will comply with meaningful use requirements and will offer clients assistance to use the tools. The company will waive EHR subscription fees until clients qualify for incentives.
  - Allscripts is offering a financing program with no payments for software for the first six months of EHR purchases, as well as new procedures to speed implementation. The company will waive up to 12 months of monthly support fees if a client's EHR fails to meet certification criteria.

Questions?

William R. “Bill” Braithwaite, MD, PhD, FACMI
Chief Medical Officer
Anakam Inc.