Beyond the Details of Meaningful Use Stage 2: Implications for Stakeholders

By Tony Schueth, Editor-in-Chief

May 7th was the deadline for public comments about the Notices of Proposed Rulemaking (NPRMs) for meaningful use (MU) stage 2.\(^1\) It will take several months for the government to digest them and issue final regulations. Past experience with the government’s regulatory process suggests that most of what we’ve seen in the two NPRMs is what we will have to live with. To be sure, there will be some changes in response to the comments. Although the details will not be known until sometime this summer, we can make the following quick observations about MU stage 2 and how it will affect stakeholders going forward.

Providers. At the end of the day, the impact of MU falls heavily on providers. Readiness for stage 1 has grown but is not where many would like it to be: 42% of eligible hospitals and not quite 10% of eligible professionals have received incentive payments…

BioIT World 2012: Toward Personalized Medicine

By Tony Schueth, Editor-in-Chief

Do you think the BioIT World Conference and Expo organizers ever thought of calling their event “Toward Personalized Medicine?” The conference, which was held April 24-26 at the World Trade Center in Boston, felt a lot like the “Toward an Electronic Personal Record (TEPR)” conferences of days gone by. Beginning in 1984, TEPRs were an annual event until 2009 and, probably not coincidentally…

MIPPA ePrescribing Incentives: the Good, the Bad, the Ugly, the Future

By Kurt Andrews, PhD, Senior Consultant

The federal government just released results of the ePrescribing incentives available under the Medicare Improvements for Patients and Providers Act (MIPPA). As with all such initiatives, there was a mixed bag of results.

The Good. The good news is the incentive program seems to be driving ePrescribing adoption…
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according to new data from the Centers for Medicare and Medicaid Services (CMS), available here.

By nearly all accounts, neither group will be ready for stage 2, regardless of whatever those requirements will be. Provider associations have been successful over the years in beating back various federal implementation deadlines; many are asking for a delay in MU compliance dates in their comments about stage 2. (See the sign-on comment letter from more than 70 medical specialty societies and state medical associations here and the American Hospital Association’s comment letter here.

Even if they get their wish, providers should not delay making their implementation plans. The future is now. For example, older providers have been one group that has been ignoring MU. Many have vowed to retire rather than get on board with MU and “all this new-fangled computer stuff.” However, they may want to revisit this strategy. Because of the economy, some may be unable to retire early or when originally anticipated (or may choose not to), which means they will have to comply with MU and computerize their practices. If they don’t, they may unable to absorb the drop in their Medicare reimbursements when the MU noncompliance penalties kick in. MU will push providers into uncharted territory: using technology to engage patients in their health care. Providers will need help developing patient outreach and education programs and with training in the use of patient-centric applications.

Vendors. Like providers, vendors want tweaks in stage 2 reporting requirements and implementation timelines. (See comments submitted by the EHR Association here and here.) Not surprisingly, vendors want – and could use – extra time to build to the requirements as well as make plans for installations and training, as vendors have physical limitations on staff that would be made available for handling the large number of such requests that will be coming their way all at once from providers. Going forward, there are three sets of requirements that – because of their scope – vendors should proactively address in their product plans now:

● **Patient engagement.** MU will make providers responsible for some patient behavior, such as making them use secure messaging to contact their clinicians. This means that vendors will now have to satisfy their provider clients and make sure they have the appropriate patient-facing applications for the right client base. “Stickiness” also is a problem for patients. As a result, vendors will need to make sure their applications meet patient needs and will entice patients to keep coming back to the EHR.

● **Standards.** Now is the time for vendors to get ahead of the curve with respect to standards. For example, the government has made it clear that metadata and
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- the Direct Project standards are here to stay, regardless of whether they make it into the final MU stage 2 or 3 criteria. Savvy vendors will be figuring out sooner rather than later how they should be baked into product offerings. Going forward, there will need to be robust support for HL7’s consolidated clinical document architecture CDA, particularly segments for imaging, procedures and advance directives. The continuity of care document (CCD), a constraint on the DCA, is viewed as a lever to promote health information exchange, which vendors also need to take into account.

- **New requirements.** There were two patient-facing, sleeper requirements in the MU stage 2 proposal for certified electronic health record (EHR) technologies: compliance with Web content accessibility guidelines (WCAGs) to support the disabled and using the HL7 Info button standard to deliver context-sensitive health education material to patients. Providing meaningful health education to patients will contribute to the “stickiness” goal described earlier. With respect to the WCAGs, these have been used in other industries for some time, and it is time they are fully embraced by the health information technology industry. Both of these requirements are essential building blocks to certified EHRs that are designed to attract patients to effectively use tools provided by a certified EHR.

**Payers.** With the exception of a very few Medicare Advantage plans, payers are exempt from MU requirements. But that doesn’t mean they can or will be watching the show from the sidelines. A handful of payers already are leveraging MU criteria. Some plans with significant market share and better relationships with their provider populations, such as Blue Cross Blue Shield of Michigan and the Capital District’s Physician Health Plan, have been using MU to help promote better payer-provider cooperation and integration. This has given them some advantages relating to initiatives for patient-centered medical homes (PCMHs) and accountable care organizations (ACOs). It also has paid off in better data exchange between the parties to the benefit of all constituents. Some plans also are working MU criteria into their own pay-for-performance programs.

All payers, however, will need to better align their quality and cost-savings requirements with MU. Smarter payers will do this sooner rather than later because in the end, Medicare regulations eventually drive private payer behavior. Those on the MU bandwagon early will benefit from improved performance in existing programs and competitive advantage. Widespread interoperable EHR adoption can help payers, ACOs and PCMHs improve their disease and case management programs by allowing them to add clinical information to their claims data. The patient as an integral user of EHR technology has major implications for payers, such new delivery models as ACOs, and the health insurance exchanges that are being set up by the public and private sectors.

**Pharma.** While pharma has been largely absent from the MU fray, there are requirements that are of interest to it. For example, raising the minimum ambulatory ePrescribing thresholds and requiring ePrescribing of medications for patients being discharged from a hospital will bolster ePrescribing rates. However, ePrescribing quality issues, such as eFormulary accuracy and timely drug database updates, are likely to remain unaddressed in stage 2. ePrescribing of controlled substances is also conspicuously absent in stage 2. The increased overall emphasis on quality and clinical
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decision support is an indication of the future direction of health care. Therefore, care guidelines and clinical decision support will have more influence on the prescribing process going forward. MU strongly encourages data exchange and care coordination, which will bolster the new accountable care delivery models and possibly affect the traditional payer-based formulary contracting process. Lastly, continued emphasis to increase patients’ involvement in their health care may increase the importance of direct-to-consumer efforts.

Patients. Patients are coming front and center in health care. Although they are not subject to MU, its requirements will continue the impetus to give patients access to their data and engage them in their own care. Final stage 2 regulations are still expected to require eligible hospitals and providers to give patients electronic access to their records (or some portion of them) within a specific time frame. Patient Web portals will be one way of addressing MU requirements, such as giving patients direct and secure access to parts of their health record, creating reminders and updates, as well as providing patient education. Mobile applications will be developed to do the same things. However, patients’ ability to participate will depend on technological access and other factors. For example, there is a digital divide among the elderly (especially for mobile health) and for certain minority populations that needs to be solved. Other patient-centric issues also need to be addressed for successful patient engagement. They include health literacy, language barriers, assistance to caregivers, and developing ways to help providers and pharmacists effectively communicate with clients representing very diverse demographics.

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Point-of-Care Partners already is doing deep dives with numerous stakeholder clients to strategically position them for implementing MU stage 2, looking ahead to stage 3 and preparing for upcoming changes in standards and processes required under the Health Insurance Portability and Accountability Act and the Accountable Care Act. We’d be happy to do it for you.

BioIT World 2012: Toward Personalized Medicine

By Mihir Patel, PharmD, RPh, Consultant

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passage of the American Reinvestment and Recovery Act of 2009 (ARRA) and the $29 billion it made available for adoption of electronic health records (EHRs).

The comparison to TEPR is not a bad thing. Despite the persistent jokes around how many years we’d been working toward the electronic patient record, I thought the conferences made a positive contribution in the evolution of EHRs. I bet a lot of you attended a TEPR or two.

This is BioIT World’s 10th anniversary. Like TEPR, the BioIT World event had a number of different tracks, thought-provoking speakers and exhibitors, although it seemed to be better organized and keynotes more “heavy-hitting.” Well, “seemed” is the operative word. The truth is, despite their impressive credentials, I had never heard of any of them.
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In fact, I found myself to be a “fish out of water,” as I knew only two other attendees and was aware of just a handful of the 143 exhibitors, although the tchotchkes and candy looked familiar.

I attended the event because I believe personalized medicine is the future of health care. Nine years after the first complete genome was published from the 13-year, $2.7 billion Human Genome Project (HGP) (click here for more information), I was only beginning to see traces of genomics touching on health information technology (HIT). If personalized medicine was part of the Health Information and Management Society (HIMSS), I missed it among the 39,000 attendees, miles of exhibitors, sunup to sundown events, interest group meetings, and the like, despite the push toward patient-centric care manifested in patient-centered medical homes and health reform-driven accountable care organizations.

My key takeaway from BioIT World is that HIT and personalized medicine have only converged in academia and pharmaceutical research, if the speakers are any indication. No one from a major insurance carrier spoke, though it was noted that Medco (now part of Express Scripts) and Humana had shown some interest in diagnostic deoxyribonucleic acid (DNA) tests. The only commercial EHR company I heard mentioned was McKesson, unless you count the Veteran Administration’s open-source EHR, VistA (which has had its ups and downs).

The personalized medicine vision is that the EHR of the future would support patient-specific (vs protocol-centric) treatment plans based on a patient’s DNA. Clinicians would use genetic data for diagnosis and risk assessment, and linkages to drug metabolism, efficacy and toxicity information.

Personalized medicine, however, will need to draw from more than DNA. It’s based on “the recognition that unprecedented types of information will be obtainable from genetic, genomic, proteomic (protein), imaging technologies, etc., which will help us further refine known disease into new categories, managing the person’s health care based on the individual patient’s specific characteristics vs standards of care,” said Zhaohui (John) Cai, PhD, AstraZeneca Pharmaceuticals, LP, one of the speakers.

While there’s an element of personalized medicine that one might argue wouldn’t need EHRs – for example, labs today produce paper reports that physicians can review – clearly EHRs – with alerts, relevant demographic information, beefed up clinical decision support, physician observation, and other features – will be a boon to personalized medicine.

Dr. Cai goes a step further in linking HIT, suggesting that personalization can be taken to the level of health care, where “therapies are linked to diagnostics and tools (e.g., home monitoring devices, patient-managed or reported data) to deliver superior outcomes.” Such a model would link innovative tools, personal health management systems, external data sources and other elements of HIT and leverage clinical decision support, both for clinicians and payers. With the evolution of mobile health, this could be done at the bedside, in the patient’s home, in the long-term care facility and other remote places.
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The challenge, as speaker Michael Cantor, MD, of Pfizer pointed out, is “how do you make personalized medicine valuable to physicians practicing in the community, not just in academic settings?” The answer wasn’t really posited by any of the conference speakers but by Intermountain Healthcare’s chief medical informatics officer, Stanley Huff, MD. In a separate, post conference conversation, he explained that software could be written that would take information and suggest to clinicians the best personalized health care for each individual, based on genes. “A physician need not be an expert in family medicine and genetics,” Dr. Huff said.

While software programs that translate genetics and cross-reference it with other EHR data are, well, a no-brainer, it strikes me that what’s still missing is what had been missing for most of the 25 years of TEPR – a strong driver.

That driver could be employers, whom insurance companies have said are pushing them to at least perform the diagnostic testing to determine if expensive therapies are appropriate and effective. It could also be the federal government, in its role as the nation’s largest payer and insisting on increasing levels of clinical decision support in subsequent stages of meaningful use. Or it could be patients, as suggested several BioIT speakers and Dr. Huff. “How’s that?” you might be asking.

In September 2010, one of the event’s organizers, Kevin Davies, published the groundbreaking book The $1,000 Genome, in which he suggested that the cost of doing a complete genomic scan could be as little as $1,000 by 2014. The first preliminary analysis cost $1 million. Well, we learned at BioIT World that the timetable for the $1,000 complete analysis has accelerated to this year. Furthermore, one of the keynotes noted that at the pace of cost reduction, the price of a full genomic scan could be $100 by 2014.

When such analysis becomes that inexpensive, insurance companies may be more likely pay for it. If they resist, the price point would be where people could afford the test themselves, should they choose to have the tests performed. From a research perspective, this could be a boon because as the number of samples increases, the easier it will be to make genomic-to-disease connections. Clinically, it should be part of everyone’s medical record, making links meaningful. The possibilities are endless.

However, there’s a divide among patients. Some want to know the results while others don’t. While my wife and I have discussed it and would want to know, we’re in one camp. We know a number of women in whom breast cancer has run in their families for decades, but they resist having a blood test done for mutations in the BRCA 1 and 2 genes, which indicate susceptibility to breast and ovarian cancers, because they fear what might be uncovered. There’s also concern that undergoing such analysis might make you uninsurable, creating a difficult dilemma.

To be sure, there are no easy answers. So, nine years after the HGP and 10 years into BioIT World, you have to wonder where we are on the personalized medicine timeline and if it’s the 25 years of TEPR, shorter or longer.
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according to a new report from the Centers for Medicare and Medicaid Services (CMS). [See the report here.] The agency paid out $270.9 million in 2010—83% more than in 2009, which was the first year incentives were available. Nearly 66,000 eligible professionals (mostly physicians) and 18,713 practices received incentive payments. Program participation among eligible professionals rose 26% from a year ago; based on preliminary 2011 data, the number is expected to jump by 42%. That’s good news for eligible professionals because those who do not receive incentives—or report minimum usage—will start being monetarily penalized.

The Bad. A closer look at the numbers reveals that program participation and qualification rates have a long way to go. Only 16% of eligible professionals participated and less than 60% of those who applied for incentives received them. This is due to a host of factors, including: 1) problems communicating what is needed to qualify for incentive payments by CMS and medical specialty groups; 2) complicated qualification requirements; 3) complex reporting requirements; 4) misunderstandings about meaningful use and how its requirements and incentives relate to those for MIPPA; 5) technology issues; and 6) confusion by the provider community about how and when it is supposed to deal with the onslaught of other technology issues coming their way, including the switch over to the International Classification of Diseases, 10th edition (ICD-10) and new state requirements, such as increased immunization registry reporting.

The Ugly. Eligible providers could try to beat the penalties by applying for MIPPA hardship exemptions, if they meet the criteria. However, some eligible professionals were denied exemptions for 2012 because of the backlog due to processing the expanded MIPPA hardship exemptions, which were put in place to help prevent noncompliant providers from being caught short by the start of penalties. Compounding provider confusion and frustration, CMS ended up imposing the 1% penalty even in instances in which an exemption application was received but not processed. In those instances when an exemption is eventually approved, those claims will have to be reprocessed, adding to physicians’ aggravation and incentive payment delays. There is no appeals process.

The Future. As health care evolves, there will certainly be bumps along the way—it’s unavoidable. But, there are things that can be done. Hopefully, more eligible professionals will qualify for the MIPPA incentives as they become better familiar with the requirements—especially because the incentives end in 2013, but the penalties continue for several years thereafter. Hopefully, both CMS and medical specialty societies will do a better job of getting the word out and working with confused providers as to what needs to be done—both in terms of minimum usage and technology requirements in order to qualify for incentives and avoid penalties. For starters, CMS could improve the user friendliness of its of its MIPPA Web site by streamlining and simplifying (see here). Hopefully, CMS will allocate additional resources to quickly eliminate the hardship exemption backlog and prevent it in the future. In the meantime, the American Medical Association is lobbying CMS...
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to re-evaluate penalty timelines associated with the MIPAA program, which is set up on a "carrot and stick” basis.

Eligible professionals have until June 30, 2012, to report to CMS that they sent 10 ePrescriptions since the beginning of the year – or to apply for the hardship exemption – to avoid 2013 penalties. These will be 1.5% of all Medicare claims, based on the 2013 fee schedule amounts during the year, and will rise to 2% for 2014. Exemption applications must be made online using the CMS application tool here.

As a national leader in ePrescribing, Point-of-Care Partners can guide providers through the complicated MIPPA maze and coordinate with the MU requirements. Call us or drop us an e-mail. We’re here to help.