HIT Perspectives
Perspectives and Updates on Health Information Technology

HIMSS11

ONC Proposes Use of Metadata for Possible Meaningful Use Stage 2 Certification Criteria
By Tony Schueth, Editor-in-Chief

In a shot across the bow to the health information technology (HIT) industry, the Office of the National Coordinator for Health Information Technology (ONC) has issued an "advance notice of proposed rulemaking" (ANPRM) to solicit public comments regarding the use of metadata (and associated standards) for patient identity (data elements about a patient), provenance (data elements about the source[s] of the clinical data), and privacy (data elements about the type[s] and sensitivity of clinical data included). It also solicits suggestions as to how these might be implemented in first-in-kind use cases: patient download of a summary care record or a request to transfer the data to patient health records (PHRs).

More importantly, ONC noted that public input on this ANPRM will be used to develop a rule that will set the stage for inclusion of metadata in meaningful use (MU) stage 2 certification requirements. If that happens, electronic health record (EHR) technology will need to be capable of applying metadata standards in the context of the use case in order to become certified.

This announcement has largely gone unnoticed by the HIT industry…

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Health Information Exchange

HIEs: Back From the Dead?
By Ed Daniels

There's been a lot of buzz lately about the importance of health information exchanges (HIEs) and concerns about their sustainability. At a recent industry meeting, for example, one cynic characterized HIEs as "dead men walking."

However, to paraphrase Mark Twain, reports of the demise of HIEs may be greatly exaggerated. According to a recent survey by the eHealth Initiative, the past year has seen a net growth of 9% in the number of HIEs, which now total 255. Twenty-four HIEs reported having sustainable business models, up from 18 in 2010...

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eMedication Management

Adding More Clinical Data to ePrescribing May Increase Niche Use Cases
By Mihir Patel, PharmD, RPh

As ePrescribing grows into adolescence, some analysts are taking a longer view to see where the industry may move in the face of market and technological evolution and maturity. The increasing demand for more and better clinical data — and increasing ability to handle it technically — will be key to the future of ePrescribing.

Increased demand for clinical information could lead to the rise of ePrescribing in a growing number of use cases as more payers and providers demand additional clinical data to make more therapeutically appropriate and cost-effective prescribing and treatment decisions. This can be seen in three niche use cases.

- **Specialty ePrescribing.** To be sure, specialty drugs are definitely a niche market. They treat rare and hard-to-manage conditions, including hemophilia, multiple sclerosis, immune deficiencies and certain cancers; require complex and expensive manufacturing conditions; and can cost payers (and often consumers) tens of thousands of dollars per patient. On the other hand, specialty drugs represent a very lucrative...

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Meaningful Use

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which is preoccupied with MU, *International Classification of Diseases*, 10th edition (ICD-10) implementation and summer vacations. We believe this ANPRM is a harbinger of things to come — possibly sooner rather than later — and the industry needs to pay attention.

The genesis of this ANPRM is a report by the President's Council of Advisors on Science and Technology (PCAST) that set the industry reeling last December with its far-reaching, transformative suggestions to quickly transition HIT to an invisible but powerful Internet-based world similar to that of Apple's App Store, the Android market and Amazon.com. The government solicited comments from the industry early in 2011 and then turned to analysis and input from the HIT Policy Committee and HIT Standards Committee in the spring. Their recommendations, delivered in late June, were rolled into this ANPRM, which was cranked out in record time, barely a month later.

The impact of this ANPRM and government follow-up could play out in several ways based on the fundamental question: Is this the right thing at the right time?

Certainly, a case could be made that this might be too much too soon. This undoubtedly will be the response from the majority of the industry. In comments submitted on the PCAST report, the health care software industry called for an incremental approach and noted that MU and ICD-10 implementation were already consuming resources and that something new like this could push vendors to the point of failure. The industry is not uniformly able to meet the MU stage 2 criteria at this point, much less address metadata — or even a small subset of metadata elements and standards — in any significant way. It also goes without saying that this shift could be too radical and costly while the industry is battling to keep afloat in the face of numerous additional federal requirements, market consolidation and difficult economic conditions.

On the other hand, is this a well-needed nudge to the industry? Involvement of consumers through use of patient portals, PHRs and mobile devices has been stifled by their inability to access their personal data in digital form. We have observed the slow adoption of PHRs and failure of Google Health. Making clinical data and metadata accessible could foster a new wave of entrepreneurial innovation, which would this time be driven at the remarkable pace of consumer innovation rather than the much slower pace of health care software adoption. This push by the government might be exactly what is needed to help consumers become more involved and motivated to better manage their own health care. It could also create jobs in new entrepreneurial ventures.

Is this just another case of hasty regulation that will create even more government mandates for an already overburdened industry? Over our years of involvement it seems that not much gets done in the HIT world without a federal regulatory requirement. Perhaps this is the starting point for an exciting, transformative process. This train certainly is starting down the track very quickly, with the government pushing the introductory use of metadata under world-record timeframes. Meaningful Use started at this pace, and look how fast the HIT world changed as a result.

It's too soon to tell whether this ANPRM will have staying power. Will it disappear only to return in some other iteration (as some issue management models suggest might happen)? Or will it simply go away; another flash in the pan? The fact that this ANPRM has been issued and is being fast-tracked by the government is usually a signal that the winds of change are blowing and we should take heed!

Meaningful Use

Point-of-Care Partners has been following this issue, along with MU implementation, ICD-10 implementation and other key industry requirements. Let us know if we can help you identify what this may mean to your business or if we can assist you with developing comments, which are due September 11, 2011. The ANPRM is available at http://www.ofr.gov/OFRUpload/OFRData/2011-20219_PI.pdf.

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With funding from the National eHealth Collaborative, Point-of-Care Partners (POCP) recently conducted an in-depth profile of 12 successful HIEs: Availity, Big Bend RHIO, Health Bridge, HealthInfoNet, Inland Northwest Health Services, Med Virginia, Quality Health Network, Rochester RHIO, Sandlot, SMRTNET, THINC, and the US Department of Veterans Affairs.[1] While these and other successful HIEs are alive and well, another group of HIEs are on the edge or having trouble getting started. Some of these efforts will die but there will be survivors, with some are destined to become significant players on the health information technology landscape.

What makes certain HIEs thrive? Through innovative strategies and business models, successful HIEs can benefit multiple stakeholder groups and, in the process, grow and become self-sustaining. Among critical success factors: embracing an intensive and ongoing effort to align stakeholders with HIE priorities.

POCP believes payers are a key stakeholder group for HIEs. So far, however, we have observed that, with a few significant exceptions, payers have failed to understand how their interests align with HIEs. For one thing, payers may have the misperception that HIEs are on their way to extinction. Another reason for failing to engage is that payers are used to having the upper hand with stakeholders at whatever point they choose to engage. This might not be the case with HIEs because as they get bigger, stronger and more financially sound, they will realize a much stronger negotiating position. As a result, payers will find themselves being more reactive. To quote from page 3 the report, "…a common view of the HIE organizations…is that the longer payers…stay on the sidelines, the less leverage they will have when they finally realize the significant value of the health information available from the HIEs…"

POCP is proud to have played key roles in a number of multi-stakeholder health care initiatives. From building HIE strategies and advising on execution to serving in a managerial role, we provide a broad range of HIE consulting services. Give us a call or drop us an e-mail for more information about how POCP can provide the guidance and experience necessary to steer your multi-stakeholder initiative toward success.

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[1] You can access the report at http://nationalehealth.org/SecretsofHIESuccessRevealed.pdf.

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- and rapidly growing market segment. According to Medco's 2010 Drug Trend Report, specialty drug prices rose 14.7% last year, compared with a 9.2% jump for traditional drugs. The number of patients requiring specialty medications also is rising due to better diagnostics and changes in patient demographics. ePrescribing with enhanced clinical information definitely will be useful in this space. It can help payers improve their clinical documentation requirements for specialty drugs and streamline justification of prescribing these expensive medications. ePrescribing with enhanced clinical data can help providers better manage patient treatment and compliance, monitor outcomes and more quickly identify when alterations in therapies are needed as patients' clinical conditions change over time. It also could help manufacturers obtain more consistent, current data to monitor prescribing patterns, adjust inventories and forecast demand for these niche drugs. In addition, specialty pharmacies could become more efficient dispensing these drugs since the additional clinical information would be provided with the prescription electronically, thus reducing faxes, paper forms and telephone callbacks.

- **Risk Evaluation and Mitigation Strategies (REMS).** The REMS program is part of an evolutionary process put in place by the Food and Drug Administration (FDA) to help ensure additional safeguards are in place when the benefits of drugs do not overwhelmingly outweigh their risks. Both the FDA and manufacturers evaluate risks vs. benefits both before a drug is approved and throughout its lifecycle. While risks are communicated in package inserts, some drugs merit special attention because of potentially - serious adverse effects. In such cases, the FDA and even manufacturers will determine whether REMS are needed to better inform prescribers and patients about the risks of a drug and make sure it is used appropriately. Proposed REMS may contain a number of elements, including a medication guide; communication plan; "elements to assure safe use" (ETASU), in which controlled systems or requirements, such as periodic blood tests, are put in place to enforce appropriate use of a drug; ETASU implementation plan; and submission timetable. While REMS evolve, they represent an untapped area for ePrescribing. For example, ePrescribing with lab values could help ensure patient compliance and ETASU compliance, such as ensuring a blood test has been completed before a drug is prescribed. ePrescribing also could help manufacturers track side effects and potentially provide an information channel for pharmacies and prescribers. In addition, ePrescribing can help remind prescribers and pharmacists of REMS requirements at the point of prescribing and dispensing.

- **ePrior Authorization (ePA).** At best, ePA joins a number of support management services for patients with rare and hard-to-manage conditions. At worst, it is a nightmare for providers and patients to provide the varying array of clinical information required by payers. Recognizing this situation, the National Council on Prescription Drug Programs (NCPDP) created a standard for ePA, with which Point-of-Care Partners was heavily involved. With the standard in place, and the growing ability to add clinical information on the software application side, ePrescribing can satisfy many more payers' upfront needs for clinical information and requests for additional data at the back end in order to justify use of expensive medications or determine the need for step therapies. This could reduce the "hassle factor" of prior authorization for all parties and help providers and patients get the correct medications more quickly. Having clinical data paired with ePrescribing will also provide payers and pharmacy benefit management companies the most complete picture available of a patient's situation in order to make better, quicker, therapeutically appropriate

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and cost-effective medication decisions.

As ePrescribing adoption continues and it becomes the dominant form of prescription transmission between prescribers and pharmacies in the next few years, additional clinical data and functionality will need to be supported by these systems. And, similar to the ways ePrescribing has improved efficiencies among prescribers and pharmacists, other such stakeholders as payers and pharmaceutical manufacturers will benefit from more streamlined administrative activities supported by the addition of clinical data transmitted along with ePrescriptions.