HIT Perspectives

Perspectives and Updates on Health Information Technology

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HIT Legislation

Supreme Court Ruling on the ACA: Momentum Plus Opportunities for HIT

By Tony Schueth, Editor-in-Chief

The widely awaited Supreme Court ruling on the Affordable Care Act (ACA) was like a lot of things in life: it wasn't what was done but how it was done. Few foresaw the legal argument Justice Roberts would use to uphold the law.

Regardless whether the Supremes upheld the law (on a surprising rationale), struck it down altogether or only upheld certain pieces, the whole exercise was largely immaterial for health information technology (HIT). Why? First and foremost, as we predicted in the March issue of *HIT Perspectives*, because so many of the act's provisions are already being implemented — all depending on health information technology (HIT) — that there would be considerable momentum going forward regardless…

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HIT Regulations

Will the FDA Regulate HIT? Yep, and It's a Done Deal

By Ed Daniels

You'd never know it from the title, but reauthorization of the user fee program for the Food and Drug Administration (FDA)— the Food and Drug Administration Safety and Innovation Act — contains language that could change the face of health information technology (HIT) and how it is regulated. It's a done deal and a law of the land.

Hidden away in Section 618 comes this nugget that has been flying under the HIT radar...

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Electronic Health Records

Feds Tout EHR Adoption and Incentive Payouts, but Is It Time to Claim Victory?

By Kurt Andrews,PhD

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Prescription Drug Monitoring Programs

Feds Try New HIT Approach to Stop Prescription Drug Abuse

By Mihir Patel, PharmD

The federal government recently announced two pilot programs in Indiana and Ohio that will use electronic health record (EHR) data in new approaches to identify prescription drug abuse at the point of care.

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of the decision handed down (see March 2012 *HIT Perspectives*).

Despite the Supreme Court's decision or how it was reached, new HIT opportunities would be created through the marketplace. For example:

- **Insurance Exchanges.** The ACA helps create a competitive private health insurance market through the creation of health insurance exchanges. These new entities will function as a marketplace for the uninsured and underinsured by offering health plan and coverage choices for those needing insurance or seeking better coverage or lower cost. Some 23 million uninsured people are expected to gain coverage through exchanges, according to the Congressional Budget Office. As of June 5, 2012, 41 states and the District of Columbia e have either created exchanges or introduced legislation establishing a state exchange program. HIT will be critical in sharing administrative and other data within and across plans and exchanges, as well as communicating information to enrollees and explaining offerings to potential buyers. In addition, pharmacy benefit managers handling the drug benefit for these plans will depend on ePrescribing functionalities to ensure beneficiaries are prescribed drugs that are on the myriad formularies that will evolve.

- **Medicaid Expansion.** While it is not clear at the moment which states will move forward with the act's Medicaid expansion (which was unexpectedly made optional under the court's ruling), large-scale increases in Medicaid programs will only heighten the need and urgency for revamping and expanding Medicaid HIT. Financial incentives will encourage use of medical homes, home health services, and telehealth to care for Medicaid beneficiaries, requiring significant changes to the Medicaid HIT infrastructure. Medicaid must create infrastructure to enable health data exchange within and outside the state to a variety of stakeholders—especially connectivity and data exchange with health information exchanges, which were created by the ACA and upheld by the court. Aside from the ACA requirements, federal and state officials also are looking to Medicaid HIT to help bend the cost curve in the face of current fiscal hardships while improving the quality of and access to care for Medicaid beneficiaries.

- **ACOs.** The ACA called for the creation of Medicare accountable care organizations (ACOs), which are networks of physicians and other providers that work together and share risk while improving the quality of health care services and reducing costs for this defined patient population. So far, 150 are up and running, but it doesn't stop there. Even without a legislative requirement, ACO formation is forging ahead in the private sector as well. According to a June 2012 report, there are 221 ACOs in 45 states, nearly double from six months ago. About two-thirds are sponsored by single-provider organizations while 19% percent are sponsored by multiple-provider organizations, 8% are insurer-

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sponsored and 6% result from insurer-provider coalitions. In order to meet their cost and outcome targets, minimize shared risk and maximize shared savings, ACOs will depend heavily on HIT and an HIT infrastructure. These will be needed, for example, to facilitate population health and chronic care management; provide decision support, business intelligence and predictive analytics; optimize revenue cycle management; and share administrative, clinical and claims data across multiple providers to support these functions.

These are some of the analyses and insights available in Point-of-Care Partners' *Sentinel Event Alert* on the Supreme Court decision. *Alerts* are available on a subscription basis and customized for individual clients. We'd be happy to get you started with this valuable service.

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the Department of Health and Human Services (HHS) would have 18 months following enactment to publish a report "that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health information technology, including mobile medical applications, that promotes innovation, protects patient safety and avoids regulatory duplication." The report would be based on input and recommendations from a working group of external experts and stakeholders, convened by the HHS Secretary. The regulatory strategy and recommendations would be published on the Web sites of the FDA, Federal Communications Commission (FCC), and Office of the National Coordinator for Health Information Technology (ONC) (see the text of the bill here).Congress passed the conference version of the legislation (S.3187) on June 26. It was signed into law on July 9 by President Obama.

Regulation of medical devices by the FDA is nothing new. It has the statutory authority to regulate medical devices and has been doing so for years. It has recently been pushing regulation of some aspects of HIT, mostly under the auspices of protecting patient safety. This desire to expand its scope has high-level support in Congress and other such key stakeholders as the Institute of Medicine (IOM).

The wording of this bill is broad enough to cover all kinds of HIT — from ePrescribing to electronic health records to mobile Health. While some of these are regulated on a statute-by-statute basis by federal agencies, the vast majority are not. Moreover, the language is so broad that it may cover health information exchanges, even though they are not specifically identified.

This all gives rise to a number of suppositions and critical questions. Here's a summary of what we think we know and what we don't know.

What We Think We Know

Based on what we know so far, we can surmise the following.

Although fewer than 20% of bills have been signed into law this year, the President was to sign S.3187 once it reached his desk because:

- FDA user fee reauthorization had bipartisan support coming through the House and Senate. The administration also posted a supportive policy position.
- Without its passage, the current review process for pharmaceutical, medical device and biotech companies — which is said to cut review times in half — will expire in September. Neither the government nor the companies involved want this to happen.

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- Reauthorization would generate about $720 million in FY 2013, according to the Congressional Budget Office. Without these funds, the FDA would need to lay off as many as 4,000 employees (Source).

- It also contains provisions addressing other key issues related to pharmaceuticals, including several steps to combat drug shortages; enabling delivery systems to repackage drugs in shortage and distribute them to affiliate hospitals; creating new user fee programs for biosimilar biological products and generic drugs; increasing incentives for the development of new antibiotics; renewing and enhancing mechanisms to ensure that children's medicines are appropriately tested and labeled; and expediting the development and review of certain drugs for treatment of serious or life-threatening diseases and conditions.

The HIT aspects of this legislation seem to be a direct outgrowth of recommendations of an IOM working group in November 2010 that the HHS Secretary should direct the FDA to exercise all available authority to regulate electronic health records (EHRs), health information exchanges and patient health records, and that the FDA should develop the necessary framework for regulation.

This legislation reflects a maturation of the HIT industry. The lines are blurring as medical devices are becoming more HIT-like and HIT applications are becoming more like medical devices.

What We Don't Know

If you, the reader, are not already paying attention, you will be as you ponder these questions:

- What will be the scope of FDA's regulatory oversight of HIT?
- Will this create a regulatory turf battle within HHS? Although the recommendations of the workgroup would presumably sort that out, it puts the FDA in a new arena with other HHS agencies and the FCC. The FDA surely is the biggest dog on the porch.
- Is this really a move to protect patient safety or is it a power grab to expand the reach of the FDA?
- Will FDA have the resources and expertise to undertake regulation of current and future HIT applications? Will the user fees be enough to cover it all?
- Will FDA regulation and imposition of user fees stifle innovation and time-to-market for HIT applications?
- Will the workgroup truly represent the broad spectrum of HIT interests? How will it be convened and staffed?
- What harmonization will be needed down the line to align the FDA's potential HIT regulatory activities with those for standards, privacy, security and Medicare Part D?
- What will FDA regulation mean for the ONC's Permanent Certification Program for Health Information Technology (EHR certification)? What challenges will arise from potential overlap and even conflicting requirements?

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Looking Ahead

To be sure, these questions will be answered as this all unfolds — which could take four years or more. The most immediate issues concern the convening of the workgroup and membership selection. After that, it should it should take nearly two years for the workgroup to hold hearings and issue recommendations, per the legislation. Resulting regulations would take at least another couple of years to promulgate. Point-of-Care Partners is monitoring this for both our pharma and HIT clients. Let us know if we can help you determine what it means for you.

Electronic Health Records

Feds Tout EHR Adoption and Incentive Payouts, but Is It Time to Claim Victory?

By Kurt Andrews,PhD

(continued from p. 1)

The federal government is loudly patting itself on the back for recent rises in electronic health record (EHR) adoption and incentive payments under the meaningful use (MU) program. Among the statistics touted in recent press releases and blogs:

- As of the end of May, 110,000 health care providers have been paid for meaningful use of EHRs. Some 2,400 hospitals (mostly in urban areas) have received incentive payments as well (Source).
- In a matter of two months, the uptake exceeded the government's self-proclaimed "ambitious" goal of having 100,000 health care providers adopt or meaningfully use EHRs by the end of 2012. This goal was articulated in a March 23 blog co-authored by Marilyn Tavenner, acting administrator for the Centers for Medicare and Medicaid Services (CMS), along with Farzad Mostashari, MD, head of the Office of the National Coordinator for HIT, who declared 2012 the "Year of Meaningful Use" (Source).
- More than $3 billion was dished out under the Medicare EHR incentive program between May 2011 and May 2012 to both hospitals and eligible providers. More than $2.8 billion was paid under the Medicaid EHR incentive program during the window from January 2011 to the end of May 2012. That adds up to about a third of the $19 billion in MU incentive money authorized by the 2009 economic stimulus legislation, which created the MU program.
- Collectively, regional extension centers (RECs) are now working with 132,000 primary care providers — more than 40% of all the primary care providers in the country. RECs are now in every state, reaching more than 70% of small practice providers in rural settings and more than 75% of federally funded health centers (for REC statistics, see here).
- Over 12,000 providers working with RECs have received their EHR incentive payments.
- In 2010 and 2011, the Office of the National Coordinator for Health Information Technology (ONC) provided an additional $30 million to RECs to help increase EHR adoption rates in critical access and rural hospitals — important providers

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who are struggling to achieve MU. The RECs are currently working with 963 critical access hospitals and 85 small rural hospitals.

To be sure, those numbers are encouraging. It is clear incentive payments are driving initial adoption. The total payments are heartening and the payouts to individual eligible professionals, hospitals and practices are not exactly chicken feed. The RECs are gaining traction and showing proof of concept, especially as related to helping small practices and hospitals in rural areas achieve meaningful use so they can ultimately collect incentive payments.

Before we break out the bubbly, we should step back a little. While adoption has definitely come a long way in a short time, it seems obvious incentive payments really went to those were already up and running or well on their way. What about the rest? For example, incentive payouts for MU went to 20% of eligible professionals and 48% of eligible hospitals and critical access hospitals. That really isn't much for eligible professionals. Although the finish line is some years away, what is it going to take to get the rest up and running? Will penalties for non-adoptors do the trick or will RECs really have their work cut out for them? Will the extra attention the RECs are paying to rural hospitals be enough to get them toward — and ultimately over — the finish line?

It's hard to understand the government's short-term goal of having 100,000 providers qualify for MU incentive payments by the end of 2012. For one thing, it is a pretty low bar. Creating milestones is important and they should be a stretch, but achievable. This one was a no-brainer. CMS reported 176,049 active registrations for MU in December 2011, so it's not hard to imagine that 100,000 or more would qualify for MU payments by the end of the 2012, not to mention the thousands that would additionally qualify in 2012 alone (see the January 10, 2012 testimony by CMS staff to the HIT policy committee here). Secondly, it's a little hard to understand how a goal could be set in March 2012 for minimal activities that mostly happened in 2011. All providers had to do was submit their attestation — as early as April 2011 — for 90 days' worth of usage. Granted, the government's metrics could have taken into account work that was done in the first quarter of 2012, but again, the majority of the work that was counted toward the goal was already done between April and December 2011. In sum, CMS may need to develop more meaningful milestones. It will be interesting to see the numbers for this year, when many eligible professionals and hospitals will be evaluated for a full year in order to qualify for incentive payments.

Speaking of attestation, do the numbers make sense? The payouts touted by CMS and ONC are based on attestation of usage for 90 days, and there seems to be a pretty high success rate. According to CMS testimony to the HIT Policy Committee in January, all 842 hospitals attesting to MU under the Medicare program did so successfully as of December 2011; of the 33,595 eligible professionals who attested by then, only 355 were unsuccessful. CMS staff also acknowledged that, on average, attesters were reporting performance benchmarks that "greatly" exceeded the MU thresholds. Although the attestation is a legal document, there has been skepticism that some of the undeserving still slipped in under the radar. Down the line, it is likely that some of those attesting now may be unable to meet targets for a full year of use.

Before we start the next round of high fives, we should remember that adoption does not

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always translate to improved quality and reduced costs, primarily through changes in doing business that cut overhead. Despite the adoption numbers, we are still hearing many reports of offices implementing HIT but not changing work flow to take advantage of it. For example, we still hear about practitioners writing a prescription on a piece of paper and then handing a fistful of them to an office assistant, who then enters the stack.

Yes, we've come a long way but still have a long way to go. Point-of-Care Partners is staying on top of the ever-shifting MU landscape to identify business opportunities and strategic positioning for clients. Let us know how we can help you achieve MU or understand its implications.

Prescription Drug Monitoring Program

Feds Try New HIT Approach to Stop Prescription Drug Abuse

By Mihir Patel

(continued from p. 1)

The federal government recently announced two pilot programs in Indiana and Ohio that will use electronic health record (EHR) data in new approaches to identify prescription drug abuse at the point of care.

According to federal statistics, prescription drug abuse is a national epidemic. Abuse of prescription pain killers now accounts for more deaths than cocaine and heroin combined. Over the past decade, prescription drug-induced deaths have approached motor vehicle fatalities as the leading cause of all injury deaths. Prescription drug abusers often end up in emergency departments, resulting in millions of preventable visits and billions of dollars in excess costs each year (learn more from the Centers for Disease Control).

Currently, states are trying to identify prescription drug abuse through prescription drug monitoring programs (PDMPs), in which pharmacies report controlled substance prescriptions to an in-state database that can be checked by prescribers and pharmacies before a prescription is written or filled. However, these databases are outside the ePrescribing process and have limited interoperability across states. Currently, most PDMPs are not operating in real time; because most data are transmitted from pharmacies every two weeks, there is no way to rely on PDMP databases to obtain current information. Some PDMPs depend on fax and snail mail to respond to requests. What's worse, PDMPs—which receive funding totaling $7 million each year—are grossly underused. Although there is wide variation among states, the federal government says that less than 20% of authorized physicians utilize the PDMP in their state.

Flaws in PDMPs were recognized as early as 2006, when the Drug Enforcement Agency was considering whether it would permit ePrescribing of controlled substances. Point-of-Care Partners (POCP) was among a number of stakeholders urging the agency to take a different approach and work with the ePrescribing industry to leverage ePrescribing technology — including its real-time ability to provide medication history — to help identify prescription drug abuse at the point of care. This plea fell on deaf ears.

Times have changed and new pilots are taking a fresh line of attack using today's health

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information technology (HIT). The project in Indiana will pilot how emergency department staff can receive a patient's controlled substance prescription history directly through the Regenstrief Medical Record System (RMRS), a care management system used by Wishard Health Services, a community health system in Indianapolis, and other hospitals. The project is a collaboration between the federal Office of the National Coordinator for HIT (ONC), Regenstrief, Wishard, the National Association of Boards of Pharmacy, Appriss Inc. and the State of Indiana. In some states, emergency departments are responsible for almost 25% of all controlled substance prescriptions.

The Ohio pilot project will test the impact of having a drug risk indicator in the EHR and how that affects clinical decision making. The Ohio project is a collaboration of the Springfield Center for Family Medicine, Eagle Software Corporation's NARxCHECK, the State of Ohio and MITRE.

The new pilots are being funded as part of a current push to bring PDMPs into the interoperable electronic age, principally by agencies in the Department of Health and Human Services. The pilots stem from their recommendations, which were recently published in a new **Action Plan For Improving Access To Prescription Drug Monitoring Programs Through Health Information Technology**, which is available here.

POCP applauds the government's efforts to leverage HIT to fight the nation's drug abuse epidemic. Stay tuned to *HIT Perspectives* for results.