BY ROBIN ROBINSON

HITECH: High Stakes

The pharma industry could come out a winner in the new HITECH game, if companies can come up with the right ante.

The American Recovery and Reinvestment Act (ARRA) has set forth $30 billion to make industrywide health information exchange a reality. As part of ARRA's provisions, the Health Information Technology for Economic and Clinical Health Act (HITECH) has implemented new regulations around HIPAA privacy laws, security breach notifications, and utilization of the grant dollars. But our experts say the healthcare industry as a whole, and the pharma industry in particular, is lagging in its preparation for this new age.

By 2015, more than 70% of patients will have electronic medical records.

PAUL CEVERHA
PricewaterhouseCoopers

Preparation is Key

The entire healthcare industry — pharma included — needs to prepare for the day interoperability becomes a reality.

VENKATESWARAN. SOLAR ENTERPRISE SOLUTIONS. Eventually, companies will have to be prepared to use an electronic system to record the diagnosis, request lab-tests, and order prescriptions on a computerized provider order entry (CPOE) system. CPOE, also sometimes called computerized physician order entry, is being touted by many groups as a perceptible milestone for the initial phase toward embracing HITECH at the provider end. Achieving CPOE would be an important watermark in this initial phase. Considering that HITECH, when looked at its full level of integration, will involve other externally involved entities, it is clear that such a system would help streamline some of the downstream activities such as the claims processing, for example, and reduce processing times, errors, and resources spent on paperwork. Ideally, the goal is to be totally paperless, but the industry is far from that. From a scientific perspective, such a comprehensive system with huge amounts of health data can offer a platform for forecasting disease occurrence; it would also help plan effective disease control measures and back the evolving field of practicing evidence-based medicine. These are all aspects of meaningful use, but the road map to achieving integrated health technology is a very complex one.

CEVERHA. PWC. The majority of payers, providers, and pharma companies are focused on the incentives and penalties associated with the stimulus package and the "meaningful use" clause and what these mean to their operations. Providers are especially concerned with the potential reimbursement penalties, which start rolling out in 2015. The most forward-thinking companies realize there needs to be transparency and interoperability of data, which is going to require a new infrastructure and competencies. The healthcare industry will require stakeholders to exploit and manipulate data in ways they never have before. This will require more tools and more expertise than they currently possess, but will ultimately lead to better business intelligence, efficiency, and patient safety. There are a couple of factors that might catch some by surprise and provide a significant burden, such as the breach notification requirement and the ability to document who has access to patient records. This last requirement was firmed up in the HITECH law. If a patient walks in to any facility that has his or her record on file, that entity needs to be able to tell the patient who has had access to the record and when it was accessed. Not many facilities can do that right now. The security breach issue pertains to protected health information. If a system is hacked or breached, or patient records

Instead of stimulating the industry, the HITECH law has frozen it.

DAVE GARETS
HIMSS

are inappropriately accessed, the facility is required to notify the patient and HHS. And if more than 500 patients from a state are affected, the facility is required to alert the affected individuals, as well as the HHS and the media. The regulations also require business associates of covered entities to notify the covered entity of breaches at or by the business associate.

SLOCUM. KDS CONSULTING. First, the pharma industry has to understand what HITECH means and why it could be a classic disruptive innovation for some of the elements of the industry's business model, particularly in clinical development, health economic outcomes research, and the commercial sphere. These will be the three sectors most impacted by how this all rolls out. The biggest problem is that for the most part the pharma industry is unaware of the HITECH bill, which was signed to law February 2009, and its implications. Pharma has been treating it like a parallel universe and only a handful of people involved in the pharma space have paid any attention to it. That being said, there are a few companies that have done an excellent job preparing: Pfizer, Lilly, and Johnson & Johnson are the three most sophisticated companies at the corporate level.

LEWIS-HALL. PFIZER. We believe that HITECH will benefit everyone with an interest in better healthcare. This includes Pfizer and we're aiming to do what we can to make HITECH work on America's behalf. While the pharmaceutical industry isn't specifically addressed by HITECH, we expect the fundamental changes envisioned by this law will have an effect on us and will open up new opportunities for us. We are working closely with our partners and clients to better understand the effects that HITECH will have on us and all the stakeholders we serve. We're also actively engaged in discussions regarding meaningful use and the importance of certifying and using EHRs to improve clinical research and advance patient safety. Because we work with everyone who mediates the use of a medicine, from reg-

Interoperability will present a new opportunity to improve healthcare diagnosis and treatment options.

DR. TANUJ GUPTA
AstraZeneca

THOUGHT LEADERS

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Pfizer expects the fundamental changes envisioned by HITECH to have an effect on us and to open new opportunities for the industry as a whole.

DR. FREDA LEWIS-HALL
Pfizer

ulators to payers to pharmacists, we're hard at work trying to understand how things might change so that we can participate even more fully in the improvement in healthcare in our country. To prepare and advance the complete HIT interoperability scenario, members of the pharmaceutical industry should recognize and plan for HIT standards created by the ARRA/HITECH committees. These standards are vital for the success of HIT interoperability as they ensure that all groups collect and format data in a compatible, secure way. The industry has to ensure the full protection of health information data through the use of approved, secure systems and protocols. Pfizer recently took a step in that direction by signing a non-exclusive alliance with Private Access, a company offering a technology platform that allows patients to control who sees what in their personal medical information. We're opening the door to other pharma companies to join an alliance that would help patients overcome their No. 1 fear in volunteering for clinical trials, which is that their private information will be compromised or misused. On a larger scale, only by developing and using common HIT standards and strong security measures can we realize full HIT interoperability.

GARETS. HIMSS. There is a lot of planning going on, but I don't think there is a lot of buying going on. Ostensibly, we are a year away from the first money rolling out. It seems the stimulus law has had the opposite effect of what it was supposed to have; instead of stimulating the industry, it has frozen it, because people in healthcare organizations are waiting for the final meaningful use regulations to come out before they get in gear. By the time many organizations get ready to spend the money, they will be joining a long line of other hospitals and clinics and there won't be enough resources from the vendors and consulting firms to service them all, which means they may not be eligible for the first rollout of the money in 2011. Somewhere in the vicinity of 60% to 85% of clinics are going to need to make some type of technology purchase and implement solutions before qualifying, and with a finite human resource pool to accomplish this I think we are headed for a train wreck. According to our data, as of June 30, 2009, 91.6% of hospitals are not going to have all applications in place that they'll need to qualify for the current meaningful use specs. We don't know what the final regulations will be, but so far they state a hospital needs to have at least 10% of orders performed via CPOE. By October 2010 there may be 40% that have that ability, still leaving 60% that will be scrambling to find the resources to help them implement the technology and do the change management work with their clinicians.

DEVINE. PATNI LIFE SCIENCES. For interoperability to be effective, the process has to be an evolution, not a revolution. Companies need to start making strides where they can, but some pharmaceutical companies don't even know about HITECH yet, which troubles me a bit. When the regulation goes into place they will be out of compliance immediately. With this law, pharma companies fall under the HIPAA regulations and the industry doesn't have its ducks in a row to comply. The most daunting, technical task is getting pharma companies to rationalize their data models to allow people on the outside to map the way they are storing the information. To make the model effective, there is going to have to be a more collaborative approach to data sharing and a real commitment to knocking down silos. Also because of the economy, a number of companies are pulling back on long-term IT initiatives and this puts everybody behind. Companies that are not taking regulatory compliance seriously are going to be in jeopardy and those that start later are going to find themselves behind the power curve. By 2011, every provider that is receiving government money has to have an EHR system.

Paradigm Shift: Business Model Changes

The switch to interoperability will not take place overnight. In fact, it is sure to be a long, slow process that will bring major evolutions to business models industrywide.

CEVERHA. PWC. Pharma companies can prepare by becoming very familiar with the capabilities of electronic medical records and pursuing partnerships with large healthcare systems or medical centers in order to have access to EMR data. From a pharma perspective, there will be the opportunity to significantly shorten the R&D life cycle. If patient data are available and interoperable, it will be much faster to recruit patients for trials and much easier to document the trial results. The other potential impact is greater transparency of the comparative effectiveness of a product. The data collected could also help pharma companies better understand how drugs and devices are being used and if they are being used as directed. Transparency related to comparative effectiveness of medication, therapies, and diagnostics could have a major impact on the market for therapies. Pharma companies will not be the only entities mining the information and looking for efficacy — this information will also be available from EMR-derived data sources and reported beyond any control of the manufacturer.

DEVINE. PATNI LIFE SCIENCES. HITECH will drive the industry toward a true outcomes-based analysis determining if the total treatment regimen for a patient was the best choice based upon the eventual outcome. For example, it's not just how a patient coped with the flu but tracking if he or she had the flu shot for the preceding three years and if there were complications and then adding meta analysis and data sets. Before this happens, however, there needs to be significant work done in terms of standards. Just the fact that MedDRA (Medical Dictionary for Regulatory Activities) isn't standard worldwide is very telling.

GARETS. HIMSS. Hospitals have been trying to implement health information technology (HIT) for more than 30 years. There has been significant progress in many different areas since 2004, but there has yet to be the right set of incentives or the technology for full implementation. There also hasn't been a great business case, especially for clinics to spend the money, so there hasn't been good technology

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adoption until relatively recently. A major improvement is that organizations are creating electronic record systems that are replicable. Many large hospitals with significant resources, such as Brigham and Women's Hospital, have great systems but until recently these weren't able to be replicated in other organizations. Today, there is a 72-bed hospital in Missouri that has implemented a replicable EMR system and if it can do it, then ostensibly, other hospitals of similar size and resources can. And now, hospitals and clinics have the incentives — to the tune of $40 billion — to get it done. But organizations need to get moving. There are healthcare informatics certificate programs popping up in universities in anticipation of upcoming staffing needs. A study done by Bill Hersh of Oregon Health & Science University showed that the industry is facing a 40,000-person shortage for implementation of HIT. There aren't enough people to get this done and I wouldn't want to be the hospital or clinic that is 92nd in line.

LEWIS-HALL. PFIZER. We have already seen a good model demonstrated in the ASTER study — a recent pilot project involving Pfizer, Partners Healthcare (Brigham and Women's Hospital Boston), and CDISC. In the pilot, we created a reporting system that took only minutes to deliver high-quality medical information on specific adverse events directly from the doctors wishing to report to the FDA, the ultimate recipient of these reports. The key to success of the pilot was using the electronic medical information found in the Partners EHR and in finding ways to connect the practice of the doctors and the standards of the EHR to the needs of FDA and the standards used in receiving and processing the reports. We believe this could be a template for how the industry can take advantage of the coming changes from the rollout of HITECH and work to improve the healthcare system.

GUPTA. ASTRAZENECA. Once the bulk of health records becomes electronic and health information exchange is enabled, there may be a new opportunity for healthcare providers, researchers, and companies focused on innovation to learn how to improve healthcare diagnosis and treatment options. The secondary use of health information data for research purposes could also provide a feedback loop to all healthcare system stakeholders so they can measure the quality of their services or products and improve on them.

LEWIS-HALL. PFIZER. The potential of HITECH can be visualized just by walking into a doctor's office. It's unbelievable in this Internet era that patients are still sitting around with clipboards filling out paper records. HITECH can serve as the catalyst for a fully integrated health information system that can improve many areas in clinical and health systems research and safety surveillance. Faster, better clinical trials are the low-hanging fruit of HIT interoperability,

CPOE is being touted as a milestone toward embracing HITECH at the provider end.

LAKS VENKATESWARAN
Solar Enterprise Solutions

10 HITECH THINGS COMPANIES NEED TO KNOW

On Feb. 17, 2009, President Obama signed into law the economic stimulus bill — the American Recovery and Reinvestment Act of 2009 (ARRA). Enacted as a part of the ARRA, the Health Information Technology for Economic and Clinical Health Act (HITECH Act) expands HIPAA to impose new privacy and security requirements on covered entities, business associates, and personal health record (PHR) vendors and related entities. Among other things, the new law:

- Strengthens and expands the scope of the HIPAA privacy and security rules.
- Increases penalties for HIPAA violations.
- Extends potential liability for HIPAA civil and criminal penalties to business associates.
- Establishes a federal data breach notification law for protected health information.

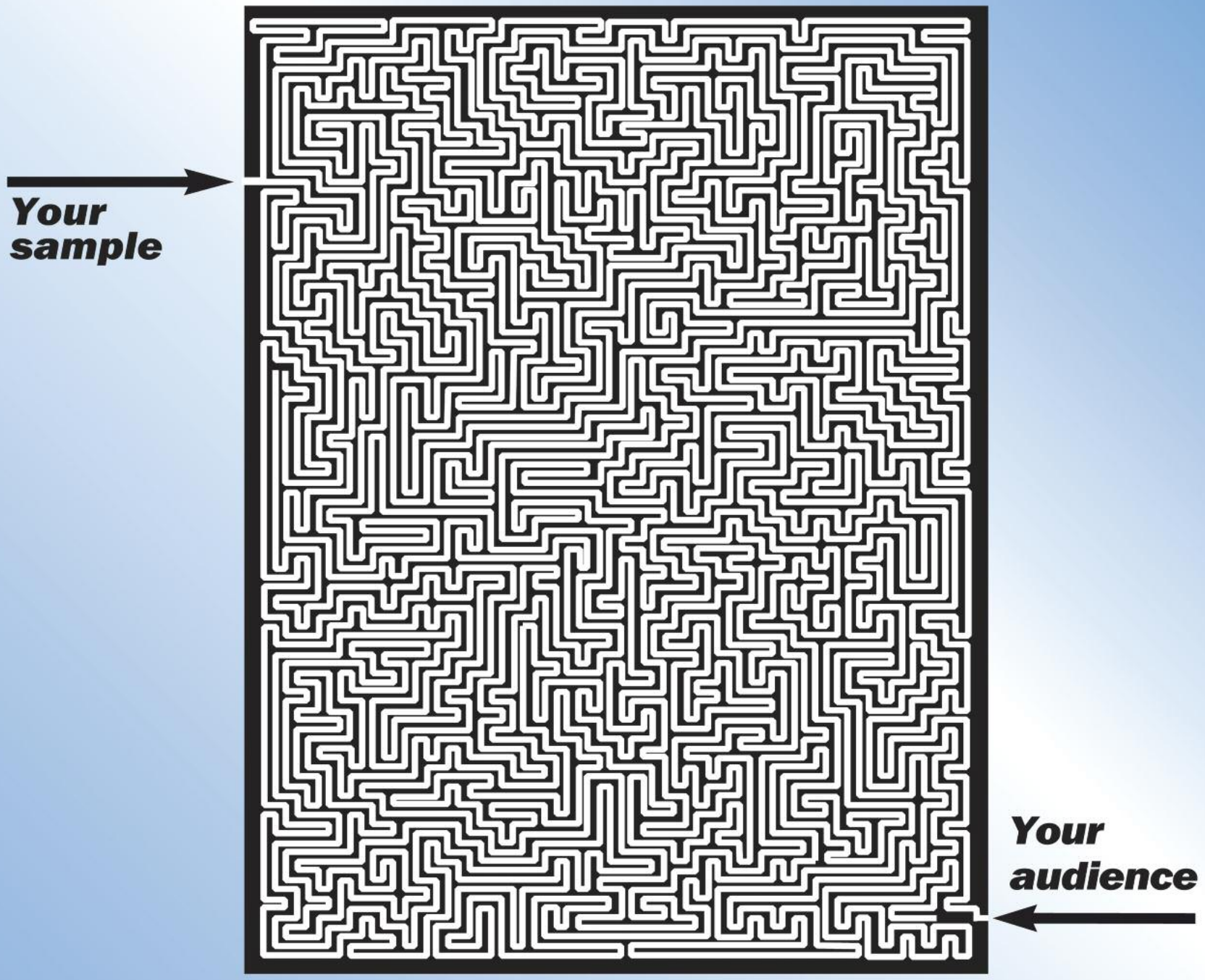
It's not just the HITECH Act pharma and the rest of the healthcare industry needs to worry about, reports PricewaterhouseCoopers. There are numerous other new privacy and data protection laws in the United States and globally that have impacted HIPAA and non-HIPAA organizations alike.

Organizations that simply address the new HITECH provisions, without consideration of the many new privacy and security rules and regulations, risk creating their own patchwork of privacy and security processes and controls that will ultimately prove less effective and unnecessarily expensive to build and maintain.

Following are 10 suggestions from PWC for organizations to consider when planning their HITECH strategy for the short- and long-term road forward.

1. Communicate the new requirements and need for changes and resources to senior management as the stakes have changed.
2. Business associates must enhance safeguards as they are treated as covered entities.
3. Contracting companies, including business associates, are assessing vendor practices and compliance.
4. Review PHI disclosure process and access controls management and monitoring to address enhanced accounting of disclosures requirements.
5. Review design and functionality of electronic health record systems to address patient request for records.
6. Develop new processes that address additional restrictions on the use or disclosure of personal health information.
7. Update incident response plans for general privacy considerations and new federal PHI breach notification requirements.
8. Implement encryption and/or review technologies and data classification schemes based on new federal PHI breach notification requirements.
9. Conduct a data element inventory beyond HIPAA for compliance and cost savings purposes.
10. Establish and roll out an integrated privacy and security program beyond HIPAA.

For the full report, visit pwc.com/us/en/healthcare/publications/10-things-you-need-to-know-now.jhtml
Source: PricewaterhouseCoopers. For more information, visit pwc.com.



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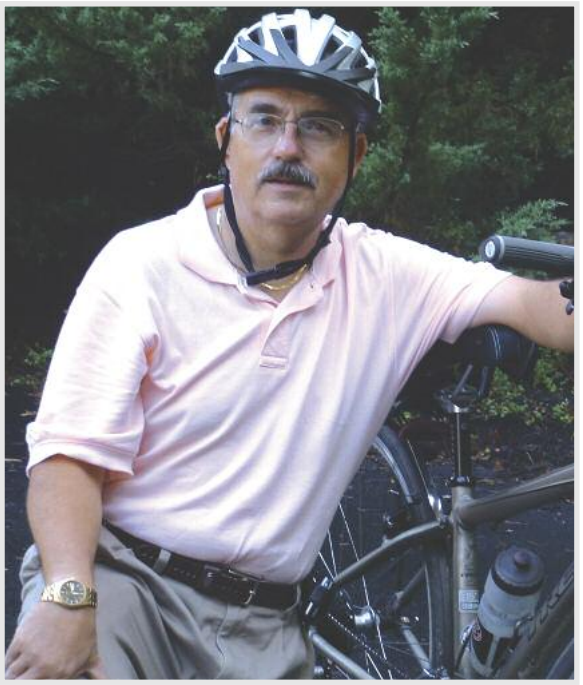
given the amount of time and money spent in executing the tens of thousands of clinical trials now on the books. With a fully interoperable HIT system, clinical data could be collected in an anonymous, aggregated manner and used for postmarketing surveillance studies and to identify populations and match patients to clinical trials. Should the market achieve complete interoperability, there is a potential opportunity to redefine how clinical trials are designed and conducted and for the FDA to change what data are collected and how information is gathered and organized. With complete HIT interoperability, healthcare providers could do a better job at every point in the care continuum. Vital patient data could be delivered to healthcare providers at the point-of-care, enabling them to make the most appropriate treatment and prescribing decisions for their individual patients. In addition, a provider could coordinate a patient's care to ensure safe, effective treatment, eliminating duplicate tests and reducing the possibility of drug-drug interactions. With HIT interoperability, the clinician could provide each patient with a "medical home" to ensure care coordination regardless of provider or patient location, time, or other factors. Safety surveillance is another area that holds great potential for improvement. Postmarketing reporting has long suffered in our country because of the lack of coordination in safety reporting among patients, doctors, pharmaceutical companies, and regulators. HITECH could help improve this situation by making it possible to directly transmit pertinent safety information from the patient and doctor to regulators and the pharmaceutical company, both of which are responsible for monitoring the safety of medicines and devices.

VENKATESWARAN. SOLAR ENTERPRISE SOLUTIONS. As mentioned earlier, there are societies, groups, and organizations that are trying to come up with realistic milestones. Because of the expense involved with different pieces, it becomes clear that many of the facilities may look to have the electronic record systems established in a federated manner or in a shared/hosted manner. But the moment a federated system of working is brought into the mix, we are faced with another set of issues, and those are privacy/protection and interoperability. When interoperability is demanded among various players, the issue of standards needed for data exchange comes up. Sure, from a technology standpoint there are interoperable schemes, such as a service oriented architectures (SOA); on the business side standards such as the HL7, ANSI X12, etc. And the availability of standardized codes such as CPT and ICD-9 (now in version 10), which offer great benefit in terms of data exchange standards and data content objectives. But there is still work to be done in this area, and an interesting development is that standards organizations have also started working jointly. For example, CDISC and HL-7 are focusing on one harmonized set of standards for patient data. And for privacy/protection there are documents and suggestions available in the archives of the National Institute of Standards and Technology (NIST) to make the services secure.

HIT could be a classic disruptive innovation for the pharma business model.

KIM SLOCUM
KDS Consulting



HITECH: A Win-Win

Our experts agree the pain of implementation aside, electronic health records, interoperability, and transparency will be a win for all stakeholders, patients included.

GARETS. HIMSS. When automation is implemented in more physician practices and hospitals, it will lead to better decision support, protocols, and evidence-based medicine. Therefore, formularies will tighten up and clinicians and patients are going to make better decisions because they will have all of the data in front of them and not just what is in their own silos. Conversely, there may be less of an opportunity to sell directly to physicians under this model because they will have better access to what medications and treatments work and what don't through comprehensive evidence-based data.

LEWIS-HALL. PFIZER. We have to be vigilant that the momentum of HITECH doesn't fizzle out before we get close to the vision of a fully integrated healthcare information system. We have the need and the resources. We have to keep the will to succeed and find the best ways to use HITECH to improve health and patient care in our country. One specific challenge will be in helping ensure that physicians and all healthcare providers have access to the appropriate clinical and patient data, as well as timely health information, to make the best treatment decisions for their patients. Additionally, it is critically important to make clinical data available for clinical research to expedite clinical trials, get medicines to those in need, and use the best data available to improve patient safety.

SLOCUM. KDS CONSULTING. The big win in clinical trials is going to come when the industry can use EHR as a collector of data for case report forms. Currently, someone has to manually transcribe patient data into paper-based case report forms that don't integrate with the recording activity in the doctor's office. When the forms are electronic, then everyone will be aware that the patient is in a study and the system will automatically extract information and send it to the sponsor. Now, when a mistake is made on the reports, someone has to go to the site and reconcile the chart. This slows down trials and creates a lot of expense. These are the issues that will go away in a HIT interoperable world. There are some significant disruptive factors that HIT could have on the pharma industry. HIT has the potential to revolutionize the way managed care contracting is done as well as how quality reporting and value measurement are conducted. Granted, the industry is a long way off from being able to do this, but there are pieces that can be accomplished now because a small portion of the U.S. healthcare delivery system is highly automated. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

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BY ROBIN ROBINSON

The meaning of MEANINGFUL USE

Our experts discuss the challenges and implications of the meaningful use clause in the HITECH law.

The biggest impact to the pharma industry of the "meaningful use" clause is that it will create a pent-up demand for interoperability; it will provide incentives for healthcare providers to make data available for secondary uses.

PAUL CEVERHA
PricewaterhouseCoopers

"Ultimately, the group that will be most impacted will be the pharmaceutical companies," says Paul Ceverha, director of PricewaterhouseCoopers. "Right now there is nothing directly related to life-sciences companies in the law other than the HIPAA changes in business associate agreements but overall, interoperability will impact the pharmaceutical industry the most."

Mr. Ceverha believes the biggest impact of the meaningful use clause is the demand it will create for interoperability.

"In a sense it will incentivize a provider to make data affordable and interoperable for other uses," he says. "It is this information and the transparency around efficacy and safety that will have a positive impact on shortening the time of R&D."

Before this can happen, however, a new system for identifying patients and categorizing them will have to be created.

"Interoperability demands a certain technical component that does not exist right now and that is the ability to hook together patients from multiple databases," Mr. Ceverha says. "Right now there is no national patient identifier, so in every database where a patient exists they are being identified in different ways."

Mr. Ceverha says without a new approach to matching patients across the healthcare continuum, the advantage of interoperability collapses.

Dave Garets, president and CEO of HIMSS Analytics, has studied the meaningful use matrix in its current state and finds it to be quite reasonable, although he does have one criticism.

"The matrix for the most part makes sense but I think it's backward in one spot," he says "Nursing documentation needs to be a criterion that comes before the use of computer-based provider order entry (CPOE) system in a hospital."

Mr. Garets' theory is that nurses are the ones who document the clinical information that physicians need to help inform their decisions to issue orders in the first place.

"In the majority of hospitals, nurses are using electronic documentation and in my view that application has to be in place before CPOE is implemented," he says. "According

MEANINGFUL USE DEFINED

According to the HITECH act, qualified physicians who use a certified electronic health record in a "meaningful way" will receive incentive payments through additional reimbursements via either Medicare or Medicaid, depending upon the individual physician's payer mix. Incentive payments ranging from a maximum of $44,000 under the Medicare incentive option or $64,000 under the Medicaid option are available to each qualifying physician, regardless of group practice size. The payments will be made over a five-year period beginning in 2011. Meaningful use is defined three ways in the law:

1. Use of a certified product complete with e-prescribing capability as determined appropriate by the Secretary of HHS.
2. The EHR technology is connected for the electronic exchange of PHI.
3. Complies with submission of reports on clinical quality measures.

Source: Health and Human Services. For more information, visit hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/breachnotificationifr.html.

to our stats about half of the U.S. hospitals have electronic nursing documentation in place right now, and it would be my advice that the other half get it done as soon as possible. Physicians shouldn't have to chase down the paper chart before they're required to stand in front of a computer and key in orders."

One of the great difficulties in attempting to improve healthcare through policy changes is finding ways to make improvements and measure progress, according to Freda Lewis-Hall, M.D., chief medical officer at Pfizer.

"Meaningful use provides a framework to advance the mass adoption of EHRs nationally and gradually increase their capabilities," she says. "To gain broad EHR adoption, the meaningful use definition should evolve to promote basic adoption at first, then move on to promote more robust functionality that allows for full HIT interoperability."

Dr. Lewis-Hall says the challenge of meaningful use will be in monitoring its effectiveness in stimulating doctors and physicians to find ways to use EHRs to genuinely improve patient care.

According to Kim Slocum, president of KDS Consulting, there are 30 measures that physicians need to address in 2011 in order to qualify for the bonuses coming out of the HITECH law.

The good news for pharma companies, he says, is that many of the elements are not technology driven and are more about improving patient care.

"Meaningful use is not just about technology but about the actions the doctor takes," Mr. Slocum says. "For example, say my medical history shows that my parents have high blood pressure and cholesterol, so my doctor looks at my electronic medical record and the note about my parents reminds him that he needs to watch out for those symptoms in me. Doctors will also be asked to report how well they are controlling patient disease to qualify for the incentive money.

"Over the next five or 10 years, the bar will continue to rise and doctors may be asked to do more and more with this type of information and soon we will be paying doctors more for quality of care instead of quantity," he continues. "This could be a very positive trend for the biopharmaceutical business."

Tanuj Gupta, M.D., executive director, field medical relations, AstraZeneca, says the company continues to watch the law and is engaged in the debate through the industry association Pharmaceutical Researchers & Manufacturers of America (PhRMA).

"PhRMA has submitted comments on the definition of meaningful use of technology, which includes the use of health records to improve the selection of appropriate treatment, the use of HIT to improve patient adherence to treatment, and the use of health record data to enhance medical research," he says. ✦

RISE IN HIT OPERATIONAL INITIATIVES

The exchange of health information electronically between physicians, hospitals, health plans, and patients has increased substantially in the last year and is reducing the cost of care and positively impacting physicians, according to a survey conducted by the nonprofit eHealth Initiative.

The report, "Migrating Toward Meaningful Use: The State of Health Information Exchange," includes responses from 150 community-based initiatives and shows an almost 40% increase in the number of advanced or operational initiatives exchanging information. Responses from operational initiatives demonstrate an increasingly positive impact on the efficiency of care while showing a return on investment.

For more findings from the 2009 survey visit ehealthinitiative.org/hiesurvey.

Source: eHealth Initiative.