LETTER *to the Editor*

How the ACA Is Changing

The Management of Patient and Healthcare Data

JONAH FROHLICH
Managing Director
Manatt Health Solutions

The ACA is accelerating a reorganization of the healthcare delivery system from episodic, reactive, acute management of patients, to proactive, population-based delivery models. These changes, manifest as patient centered medical homes and accountable care organizations, require health plans and providers to aggressively manage high-risk patients, identify risk factors, manage chronic disease, and engage patients in self-management. None of these tactics are feasible without comprehensive, accurate, and timely information made securely available to providers and patients. Organizations that are more successful at managing the cost and health of large swaths of the most challenging, high-needs patients, while providing information and tools to keep less complex patients healthy, will gain more share in their markets.

Federal, state, and private insurance exchanges will fuel these delivery system changes as they create more transparent marketplaces for employer groups and individuals to shop and select plans that can accommodate their health and financial needs. Choice of provider, benefits, and affordability are key variables in their selection process. Providers able to manage the heavy flow of information required to manage health outcomes and costs will develop competitively priced benefit plan options with health plan partners to offer on these nascent exchanges.

Current medical record systems do a good job at the basics of digitizing health data and their adoption is occurring at rapid pace: from 2008 to 2012, hospitals' adoption of electronic health records increased from 9.4% to 44.4%. While digitizing health information is a necessary step, other tools are needed to support population-based care delivery models.

Registries, analytics and business intelligence systems are being deployed to identify high-risk populations, apply protocols to prompt patient outreach, assess treatment pathways that result in better outcomes, and report measures internally and externally to inform better decision-making and demonstrate value to health plans and purchasers. This requires a convergence of clinical, financial, and utilization data into a single data stream that can be mined to identify and generate value across the delivery spectrum.

This convergence of data will be critical for pharmaceutical companies. The integration of clinical, molecular, and demographic data sets, combined with advanced modeling, will drive new research and development processes, creating new linkages between pharmaceuticals, medical devices, and providers with clinical data. These data will increasingly be used to identify safety concerns and evaluate cost effectiveness.

Different actors in the healthcare system are custodians of different data streams — providers manage clinical data, health plans administrative data, labs, pharmacy benefit managers, consumers, and others host, or have access to pieces that together represent an ocean of information. Processes to integrate these data require trust, and a rationale, amongst the parties to share it. Financial alignment and regulatory changes following the ACA are creating some of that rationale for actors to be more collaborative.

However, to automate the integration of data so that it becomes an actionable part of the healthcare planning and delivery processes, two areas must be addressed: data standards and data governance.

First, data liquidity has been hampered by the slow pace of the development of interoperability standards. Seamless exchange and integration of data will require faster and broader adoption of standards specifications, and systems that can handle the extraction, translation, and loading of large data sets from a variety of systems to a normalized data repository.

Secondly, organizations seeking to access, integrate, and utilize existing and emerging data sets must fully understand the laws, rules, and general practices governing data use. Many organizations find it daunting to navigate the complex patchwork of federal and state privacy and security laws that restrict the use and

disclosure of individually identifiable health information by healthcare providers and others. Organizations with a clear understanding of rules and have developed robust privacy and security policies in alignment to them will be better prepared to manage the onslaught of data from all trading partners.

The 2009 Recovery Act created a forum for the development of national interoperability standards. Through a series of federal advisory committees and resulting regulations, these standards are slowly making their way into electronic health record and health information exchange systems and becoming requirements for clinical data exchange. While there is much left to do, and gaps in privacy and security policies that would enable more widespread data exchange, the industry is beginning to make progress.

As the healthcare regulatory, delivery, and payment systems shift from a focus on volume to value, more participants in the healthcare system will have to accept risk. Providers and product suppliers, including pharmaceutical companies, will have to learn to become successful risk-bearing organizations.

They will also have to demonstrate the real value of their products, show how they can contribute to managing both cost and outcomes for complex patients and how they can help keep those with less acute conditions healthy and out of high-cost treatment settings. Supporting a value-based purchasing strategy will allow more of their products to be integrated into benefit packages provided on exchanges so that providers can use those products as core components of their population-based delivery model strategies.

(Editor's Note: For more information on ACA and data, please see the January issue of PharmaVOICE. To contact Mr. Frohlich directly, please email: jfrohlich@manatt.com.)

Advancing Clinical Innovation

inVentiv Health Clinical combines state-of-the-art clinics and bioanalytical labs, leading therapeutic expertise in Phase II-IV, and customizable strategic resourcing approaches to provide a full range of clinical development services to accelerate drug development.

- Global Footprint: A top 5 CRO operating in more than 70 countries
- Therapeutic Excellence: Leading therapeutic expertise aligned to all stages of development
- Patient Recruitment and Retention: Data-driven and research-informed communication strategies to maximize effective patient recruitment and retention
- Late Stage Expertise: Effectively generating and persuasively communicating evidence of real-world safety and value
- Strategic Resourcing: Adaptive, cost effective solutions from contingent staffing to functional models and staff lift-outs

inVentiv Health clinical

inVentivHealthclinical.com