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## Health Information

### **Health IT: An Essential Ingredient in the New Health Reform Recipe**



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#### **Introduction and Background**

**T**he Patient Protection and Affordable Care Act,<sup>1</sup> the sweeping health reform legislation enacted in March 2010, mandates the development of innovative models of health care delivery and payment that will align incentives between and among key industry stakeholders to achieve coordination and accountability across the full care continuum, improve quality and outcomes, and control the health care cost curve.

<sup>1</sup> Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by the Health Care and Education Reconciliation Act of 2010, P.L. 111-152, 124 Stat. 1029-1084 (collectively, PPACA).

Of course, these goals are not entirely new. A quest for alignment was also a strong driving force behind the care delivery and payment integration initiatives of the 1990s, such as acquisition of physician practices and subsequent employment of the practices' physicians; the creation of physician-hospital organizations, independent practice associations, and management service organizations; joint managed care contracting and contractual risk sharing; joint operating agreements; and formal corporate affiliations and mergers and acquisitions. The less than widespread success of such models in the 1990s is causing both health reform skeptics and supporters to question whether they can be used effectively to create accountable care organizations (ACOs) and to respond to other PPACA mandates, if so whether they need to be re-focused and re-shaped, and what new and different approaches may be needed. Indeed, the PPACA does not dictate the use of any one or all of the models prevalent in the 1990s.

What is new, however, is PPACA's clear and consistent emphasis on an electronic health information technology (HIT) infrastructure as a key ingredient in its recipe for health reform. Alignment failures of the 1990s can be attributed in part to the lack of available information for measuring quality and performance in an effective and reliable way. PPACA leaves little doubt that successful implementation of any alignment strategy for achieving its health reform goals and rewards without a solid HIT infrastructure is not only unlikely, but impossible. Moreover, it will also be a valuable resource for conducting streamlined biomedical research and, ultimately, for adapting to the slow and steady movement towards the delivery of personalized medicine.

Accordingly, all stakeholders should move swiftly and deliberately to build a solid HIT foundation for responding to PPACA, either on their own or through public and private collaborations. Those who do so without delay will not only assure their survival, they will position themselves as leaders in the transformation of both health care delivery and payment and biomedical research.

This article provides an overview of (1) pre-PPACA developments and components of the PPACA for which the rapid development and implementation of a robust electronic HIT infrastructure will be critical, (2) the HIT infrastructure development and implementation continuum, and (3) key feasibility considerations that must be addressed at the earliest stages of any HIT infrastructure development continuum.

## Pre-PPACA Developments Calling for HIT Infrastructure

PPACA's health reform program carries forward several notable initiatives that began during the five-year period preceding its enactment and that telegraphed the future role to be played by HIT.

### *Federal Government's EHR Vision and Related Funding*

In January 2006, President George W. Bush announced a plan designed to ensure that most Americans have electronic health records (EHRs) within 10 years.<sup>2</sup> The plan called for the adoption of health information standards, increased funding for HIT demonstration

<sup>2</sup> Exec. Order No. 13,410, 71 Fed. Reg. 51,089 (Aug. 22, 2006).

projects, and use of the federal government's purchasing clout to create incentives for health care providers to adopt health information technology. The HIT envisioned included electronic medical records, computerized prescribing and ordering of diagnostic tests, clinical decision support tools, and the technology that will enable the interoperability needed to achieve the secure exchange of electronic health information among providers, payers and others.

The Office of the National Coordinator for Health Information Technology (ONC of the Department of Health and Human Services (HHS), to which the Bush administration assigned responsibility for providing the leadership and coordination for implementation of this HIT vision, articulated four important and interrelated goals: (1) to inform clinical practice with the use of EHRs; (2) to interconnect clinicians so that they can exchange health information using advanced and secure electronic communications; (3) to personalize care with consumer-based health records and better information for consumers; and (4) to improve public health through advanced biosurveillance methods and streamlined collection of data for quality measurement and research.<sup>3</sup> Together, these goals capture the various dimensions of the current and rapidly growing demand for an electronic health information exchange that will support uses extending well beyond traditional clinical care delivery, operations and research, such as more robust quality and patient safety measurements, pay-for-performance incentive programs, and leading edge genomic and translational research that explores individualized disease states and treatments and ultimately supports the delivery of personalized medicine.<sup>4</sup>

The Health Information Technology for Economic and Clinical Health Act (HITECH Act), which was enacted as part of President Obama's 2009 economic recovery legislation,<sup>5</sup> converted President Bush's HIT vision into a funded mandate. The HITECH Act committed approximately \$20 billion in federal support for the establishment of a nationwide health information network, including significant Medicare and Medicaid reimbursement incentives for physicians and hospitals who move quickly to achieve "meaningful use" of EHR technology.<sup>6</sup> It also codifies the ONC under the HHS to

<sup>3</sup> U.S. Dep't of Health & Human Servs., Health Information Technology: Summary of Strategic Framework, <http://www.hhs.gov/healthit/framework.html> (last visited June 10, 2010).

<sup>4</sup> Personalized medicine or personalized health care is an explicit health reform goal that HHS has addressed in detail in two recent reports. U.S. Dep't of Health & Human Servs., Personalized Health Care: Opportunities, Pathways, Resources, <http://www.hhs.gov/myhealthcare/news/presonalized-healthcare-9-2007.html> (last visited Jan. 10, 2009); U.S. Dep't of Health & Human Servs., Personalized Health Care: Pioneers, Partnerships, Progress, <http://www.hhs.gov/myhealthcare/news/presonalized-healthcare-2008.html>. See also *HHS Secretary Releases Second Report From Initiative on Personalized Healthcare*, 2 LIFE SCI. LAW & INDUSTRY REPORT 1004, BNA (2008); Michael O. Leavitt and Raju Kucherlapati, *The Great Promise of Personalized Medicine*, boston.com (Dec. 26, 2008).

<sup>5</sup> Health Information Technology for Economic and Clinical Health Act § 13101 et seq., Pub. L. No. 111-5, 123 Stat. 115 (2009) (to be codified at 42 U.S.C. § 3001(b)).

<sup>6</sup> Economic Stimulus Package: Policy Implications of the Financial Incentives to Promote Health IT and New Privacy, McDermott Will & Emery White Paper (February 20, 2009), *avail-*

coordinate the development and administration of HIT policy and standards to support the prudent and effective use of federal funds. The HITECH Act funding and incentive provisions tied to meaningful use of EHR technology were an early and concrete manifestation of the federal government's emphasis on HIT as an essential tool for health reform, and they are aligned with ONC's previously stated goals.<sup>7</sup>

#### *Widespread Emphasis on Measurement of Quality, Safety and Effectiveness*

*Patient Safety and Quality Improvement Act.* The Patient Safety and Quality Improvement Act (PSQIA) was enacted in 2005 in response to growing concern about patient safety in the United States and the 1999 Institute of Medicine's (IOM) report, *To Err is Human: Building a Safer Health System* (the 1999 IOM report) to improve patient safety by encouraging voluntary and confidential reporting of events that adversely affect patients. The PSQIA created patient safety organizations (PSOs) to collect, aggregate, and analyze confidential information reported by health care providers. Historically, patient safety improvement efforts have been hampered by the fear of discovery of peer deliberations, resulting in under-reporting of events and an inability to aggregate sufficient patient safety event data for analysis. By analyzing patient safety event information, PSOs would be structured to identify patterns of failures and propose measures to eliminate patient safety risks and hazards. Finally, the PSQIA called for the establishment of a network of patient safety databases (NPSDs) to provide an interactive, evidence-based management resource for providers, PSOs, and other entities. NPSDs were designed to analyze national and regional statistics, including trends and patterns of patient safety events. The NPSDs employ common formats (definitions, data elements, and so on) to promote interoperability among reporting systems.<sup>8</sup>

*Physician Pay For Performance Programs.* Pay-for-performance (P4P) programs emerged in part as an outgrowth of the 1999 IOM report's recommendation that payers reexamine their payment policies to remove bar-

riers to, and to create stronger incentives for, quality improvement. These programs call the establishment of performance goals and measurement of achievement of the goals in areas such as patient safety, clinical effectiveness, utilization and cost management measures, and patient satisfaction. Some also incorporate infrastructure goals such as investment in EHR systems and other technology such as computerized physician order entry.

Both the private sector<sup>9</sup> and the government have initiated P4P programs. For example, the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 authorized the Physician Group Practice Demonstration Program (PGP program)<sup>10</sup> to create incentives for primary group practices to reduce utilization for Medicare fee-for-service patients. The primary data sources used for analysis of savings under the PGP program, which was ultimately launched by CMS in 2005, were Medicare enrollment files and the national claims history. The utility of P4P programs for federal payment programs was reinforced by a March 2005 report of the Medicare Payment Advisory Commission (MedPAC), which concluded that physicians should be rewarded for implementing systematic processes to improve care management and that payment should be based on the physician's ability to produce information related to quality rather than solely on the purchase of an information technology system. The MedPAC report recommended that Medicare adopt a strategy. On the other hand, a 2008 General Accounting Office report concluded that wider use of the P4P payment approach may be hampered by difficulties group practices of under 200 physicians may have in absorbing the costs of EHR systems needed to achieve cost savings.<sup>11</sup> As discussed further below, federal health reform-focused legislation passed in 2009 and 2010 both call for payment reform initiatives that build upon the P4P program concept and address the GAO's HIT infrastructure concern in various significant respects.

*Quality Improvements Through Evidence-Based Medicine.* Evidence-based medicine seeks to apply evidence gained from scientific methods such as randomized controlled trials to certain parts of medical practice to predict outcomes as well as to assess the quality of evidence relevant to the risks and benefits of treatments (including lack of treatment).<sup>12</sup> The Centers for Medicare and Medicaid Services (CMS) has been engaged in

able at [http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object\\_id/ea996ed0-ba3b-480a-988a-135230c441d6.cfm](http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/ea996ed0-ba3b-480a-988a-135230c441d6.cfm) (last visited June 14, 2010); HHS Establishes the Initial Pathway for Qualifying for HITECH Act Incentive Dollars for Meaningful Use of Certified Electronic Health Record Technology, McDermott Will & Emery White Paper (Feb. 4, 2010), available at [http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object\\_id/0c356337-b1ab-47fc-bf1b-a452db2ae132.cfm](http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/0c356337-b1ab-47fc-bf1b-a452db2ae132.cfm) (last visited June 14, 2010).

<sup>7</sup> The HITECH Act restates ONC's goals as follows: (a) ensuring that each patient's health information is secure and protected; (b) improving health care quality, reducing medical errors, reducing health disparities and advancing the delivery of patient-centered medical care; (c) reducing health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care and incomplete information; and (d) facilitating health and clinical research and health care quality. Health Information Technology for Economic and Clinical Health Act § 13101, Pub. L. No. 111-5, 123 Stat. 115 (2009) (to be codified at 42 U.S.C. § 3001(b)).

<sup>8</sup> Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41 (July 29, 2005). For a brief explanation of the achievements of the act, see Agency for Healthcare Research and Quality, Patient Safety and Quality Improvement Act of 2005, <http://www.ahrq.gov/qual/psoact.htm> (last visited June 10, 2010).

<sup>9</sup> See, e.g., Bridges to Excellence, Francois S. Brantes and B. Guy D'Andrea, "Physicians Respond to Pay-for-Performance Incentives: Larger Incentives Yield Greater Participation," *The American Journal of Managed Care*, Vol. 15, No. 5 (May 2009), available at [http://www.ajmc.com/media/pdf/AJMC\\_09May\\_deBrantes305to310.pdf](http://www.ajmc.com/media/pdf/AJMC_09May_deBrantes305to310.pdf) (last visited June 27, 2010); UnitedHealth Premium designation program, described at [https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/News/2009/UHPD\\_Updates\\_120909.pdf](https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/News/2009/UHPD_Updates_120909.pdf) (last visited June 27, 2010).

<sup>10</sup> 106 P.L. 554 (2000). See also, Secretary of Health and Human Services, Report to Congress: Physician Group Practice Demonstration First Evaluation Report, [http://www.cms.gov/DemoProjectsEvalRpts/downloads/PGP\\_Final\\_Congress.pdf](http://www.cms.gov/DemoProjectsEvalRpts/downloads/PGP_Final_Congress.pdf).

<sup>11</sup> Report to congressional committees, Medicare Physician Payment, <http://www.gao.gov/new.items/d0865.pdf>.

<sup>12</sup> Wikipedia, Evidence Based Medicine, [http://en.wikipedia.org/wiki/Evidence-Based\\_Medicine](http://en.wikipedia.org/wiki/Evidence-Based_Medicine) (last visited June 10, 2010) defines "evidence-based medicine" as the "con-

the use of data registries in recent years to collect outcomes information as evidence of whether the effectiveness of certain treatments and products where clinical information is limited but promising is sufficient to support Medicare reimbursement coverage for such treatments and products. The concept is known as “coverage with evidence development.”<sup>13</sup>

*Expanded FDA Post-Market Authority and Requirements.* The Food and Drug Administration Amendments Act of 2007 (FDAAA)<sup>14</sup> made significant changes to the Food, Drug, and Cosmetic Act that expand the statutory “post-market surveillance” authority of the Food and Drug Administration (FDA). With regard to drug safety, these amendments (a) require the FDA to establish a system for post-market drug safety surveillance, (b) grant the FDA the power to require post-market studies, and (c) authorize the FDA to require drug manufacturers to include in their application for FDA approval to market their products a risk evaluation and mitigation strategies (REMS) for ensuring that the benefits of the drug or biologics outweigh the risks. In particular, Section 905 of the FDAAA requires the FDA to develop methods to obtain access to different data sources (including, public, private and academic entities, many of which are likely to be hospitals, health system and some of which will be HIEs) and validated methods to link and analyze safety data of at least 25 million patients by 2010 and 100 million patients by July 2012.<sup>15</sup> These methods would then be used to establish procedures for a post-market risk identification and analysis system.

*ARRA’s Funding for Comparative Effectiveness Research.* Comparative Effectiveness Research (CER) involves the “rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients.”<sup>16</sup> Traditional health care research which focuses on whether an item or service is effective and safe in ideal rather than “real world” settings is difficult to apply to a given patient or population. In contrast, CER takes a retrospective look at health information from particular patient populations or subpopulations to compare similar products (e.g., competing drugs) or diagnosis or treatment approaches (e.g., surgery versus drug therapy).

Both the public and private sectors have been involved in advancing CER for the last couple of years.<sup>17</sup>

scientific, explicit and judicious use of current best evidence in making decisions about the care of individual patients.”

<sup>13</sup> For a description of the concept, see Ctrs. for Medicare & Medicaid Serv., National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development, [http://www.cms.hhs.gov/mcd/ncpc\\_view\\_document.asp?id=8](http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=8) (last visited June 10, 2010).

<sup>14</sup> Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007), amending 21 U.S.C. §§ 301, *et seq.*

<sup>15</sup> FDAAA § 905(a), adding § 505(k) to the Federal Food, Drug and Cosmetic Act, amending 21 U.S.C. § 355.

<sup>16</sup> Cong. Budget Office, Research on the Comparative Effectiveness of Medical Treatments (December 2007), available at <http://www.cbo.gov/ftpdocs/88xx/doc8891/12-18-ComparativeEffectiveness.pdf>.

<sup>17</sup> See, e.g., Alliance for Health Reform, Comparative Effectiveness: Better Value for the Money (August 2008), [http://www.allhealth.org/Publications/Quality\\_of\\_care/Comparative\\_Effectiveness\\_Better\\_Value\\_for\\_the\\_Money\\_84.pdf](http://www.allhealth.org/Publications/Quality_of_care/Comparative_Effectiveness_Better_Value_for_the_Money_84.pdf).

In addition to the funding ARRA provided to support and encourage meaningful use of EHR technology, it provided \$1.1 billion in funding to support CER, created a Federal Coordinating Council to oversee use of the funds, and commissioned reports on CER by the council and the IOM. Both reports were issued in June 2009.<sup>18</sup> The council’s report in particular identifies four categories of investment and activity as part of its strategic framework for CER, two of which are the development of a data infrastructure consisting of distributed practice-based data networks and longitudinally-linked administrative or EHR databases or patient registries.

#### *Antitrust Review of Clinical Integration Programs*

One of the primary considerations applied by the Federal Trade Commission (FTC) in assessing the legitimacy under federal antitrust laws of a clinical integration program formed for the purpose of undertaking joint managed care contracting is the extent to which the program will seek to modify its participants’ clinical practice behavior through true clinical integration that will create significant efficiencies and improve the quality and cost-effectiveness of care. In a report issued in 2004, the FTC and the Department of Justice (DOJ) stated that two of the four primary *indicia* of clinical integration are the use of common information technology for the exchange of patient data, and the development and adoption of clinical protocols.<sup>19</sup> Between 2002 and 2009, the FTC issued three favorable and one unfavorable advisory opinions concerning whether it would seek to challenge the legitimacy of clinical integration programs.<sup>20</sup> Each of the three programs receiving favorable opinions included establishment and implementation of an HIT infrastructure to support the program (e.g., a web-based clinical data records system that would enable program participants to share clinical information related to common patients, order prescriptions and lab tests electronically, and access patient information from hospitals and ancillary providers throughout the community).

#### *The Rapid Movement Toward Translational Research and Personalized Medicine*

*The National Cancer Biomedical Informatics Grid (caBIG).* caBIG is the national cancer biomedical informatics grid initiative launched by the National Insti-

<sup>18</sup> U.S. Dep’t of Health & Human Servs., Federal Coordinating Council for Comparative Effectiveness Research Report to the president and Congress (June 2009), <http://www.hhs.gov/recovery/programs/ce/ceannualrpt.pdf>; Inst. of Med., Initial National Priorities for Comparative Effectiveness Research (June 2009), <http://www.iom.edu/Reports/2009/ComparativeEffectivenessResearchPriorities.aspx>.

<sup>19</sup> “Improving Health Care: A Dose of Competition” (July 2004) (FTC 2004 report), available at <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf> (last visited June 14, 2010).

<sup>20</sup> In re TriState Health Partners Inc. (April 2009), available at <http://ftc.gov/os/closings/staff/090413tristateoletter.pdf> (last visited June 14, 2010); FTC staff letter regarding Greater Rochester Independent Practice Association Inc. (Sept. 17, 2007), available at <http://www.ftc.gov/bc/adops/gripa.pdf> (last visited June 14, 2010); FTC staff letter regarding MedSouth Inc. (Feb. 19, 2002), available at <http://www.ftc.gov/bc/adops/medsouth.shtm> (last visited June 14, 2010); FTC letter regarding MedSouth Inc. (June 18, 2007), available at <http://www.ftc.gov/bc/adops/070618medsouth.pdf> (last visited June 14, 2010).

tutes of Health (NIH) in March 2008 to establish an information network enabling all constituencies in the cancer community—researchers, physicians, and patients—to share data and knowledge so as to accelerate the discovery of new approaches for the detection, diagnosis, treatment, and prevention of cancer, ultimately improving patient outcomes. The specific goals of caBIG are to connect scientists and practitioners through a shareable and interoperable infrastructure, develop standard rules and a common language to more easily share information, and build or adapt tools for collecting, analyzing, integrating, and disseminating information associated with cancer research and care.

*NIH Clinical and Translational Science Awards.* Translational research involves three areas of translation that generate an on-going, circular flow of input from bench-to bedside. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation applies the results of clinical trials into changes in clinical practice—the translation of research into real therapies for real patients. The third feeds actual clinical care findings back into the research dimensions.<sup>21</sup>

In October 2006, NIH launched the Clinical and Translational Science Awards (CTSA) program to fund the creation of a national consortium of medical research institutions that would work together and share a common vision to improve the way biomedical research is conducted across the country, reduce the time it takes for laboratory discoveries to become treatments for patients, engage communities in clinical research efforts, and train the next generation of clinical and translational researchers.<sup>22</sup> The CTSA program is led by NIH's National Center for Research Resources (NCRR) and has as one of its principal goals the development of the infrastructure needed to support translational research, including improved bioinformatics and centralized databases.

*Personalized Medicine.* In simple, personalized medicine refers to medical practices that use genetic tests and family history information to develop preventive, diagnostic, and therapeutic interventions that are tailored to individuals on the basis of their specific genetic code. The goal of personalized medicine is to improve health outcomes and quality of life. HHS has issued two extensive reports on personalized medicine in the last several years, in which it expresses its view of personalized medicine as a goal of health reform and a catalyst for a relationship shift between and among, providers, patients, drug manufacturers, drug development regulators and researchers.<sup>23</sup> Together, HHS' two re-

ports emphasize four essential building blocks of the personalized health care movement: (a) the development of gene-based knowledge involving an understanding of human biology at the molecular and genetic levels; (b) a transformation of health information technology that will provide data standardization and the infrastructure for robust, interoperable electronic information databases and networks that will facilitate the sharing of vast amounts of clinical care and research information about medical history, genetic variability and patient preferences between and among all industry sectors and the patient; (c) collaboration across the private and public sectors and across many disciplines and stakeholders; and (d) public trust.

*Medical Informatics.* A rapid evolution of medical informatics has been occurring on a parallel track with these other significant developments. Health or medical informatics is the intersection of information science, medicine, and health care, which deals with the resources, devices, and methods required to optimize the acquisition, storage, indexing, retrieval, and use of information in health and biomedicine. Health informatics tools, which will be essential to the implementation of most if not all strategies involved in the transformation of care delivery and biomedical research, include not only computers but also clinical guidelines, formal medical terminologies, and information and communication systems.

## HIT Infrastructure as a Recurring Theme in PPACA

PPACA's emphasis on HIT infrastructure carries forward and builds solidly upon the trend started by the PSQIA, ARRA, the HITECH Act and other prior developments discussed above. Following is an overview of PPACA provisions that either implicitly or explicitly reflect the health reform legislation's emphasis and reliance on HIT.

### *Quality Measurement and Tracking*

Few concepts are as integral to PPACA as quality of care measurement, tracking and payment. The PPACA contemplates the establishment and ongoing maintenance of quality-related initiatives and metrics in almost every aspect of health care, and requires health plans and insurers, insurance exchanges, Medicaid and Medicare programs, hospitals and other health care facilities, and physicians to compile, report and receive payment adjustments related to quality metrics. Meeting these demands will be impossible without the ability to measure, track and reported achievements electronically.

*Reporting by Health Plans and Insurers.* Health plans and insurers will be required to participate in quality reporting based on requirements that focus on improvement of health outcomes; implementation of activities to prevent hospital readmissions, improve patient safety and reduce medical errors; and implementation of wellness and health promotion activities. Insurers must also report the percentage of total premium revenue expended to pay for activities that improve health care quality.<sup>24</sup>

Medicine," boston.com (Dec. 26, 2008) at [http://www.boston.com/news/health/articles/2008/12/26/the\\_great\\_promise\\_of\\_personalized\\_medicine/](http://www.boston.com/news/health/articles/2008/12/26/the_great_promise_of_personalized_medicine/) (Dec. 26, 2008).

<sup>24</sup> PPACA, *supra* note 1, §§ 2717-2718.

<sup>21</sup> See Wikipedia, Translational Medicine, [http://en.wikipedia.org/wiki/Translational\\_medicine](http://en.wikipedia.org/wiki/Translational_medicine).

<sup>22</sup> NCRR Fact Sheet, Clinical and Translational Science Awards, available at [http://www.ncrr.nih.gov/publications/pdf/ctsa\\_factsheet.pdf](http://www.ncrr.nih.gov/publications/pdf/ctsa_factsheet.pdf) (last visited June 14, 2010).

<sup>23</sup> "Personalized Health Care: Opportunities, Pathways, Resources," available at <http://www.hhs.gov/myhealthcare/news/phc-report.pdf> (last visited June 18, 2010); "Personalized Health Care: Pioneers, Partnerships, Progress," available at <http://www.hhs.gov/myhealthcare/news/personalized-healthcare-2008.html> (last visited June 18, 2010). See also, "HHS Secretary Releases Second Report From Initiative on Personalized Healthcare," *Life Sciences Law & Industry Report*, 2 LSLR 1004, BNA (November 2008); Michael O. Leavitt and Raju Kucherlapati, "The Great Promise of Personalized

*Physicians and Physician Group Reporting.* Existing physician quality reporting initiatives are to be expanded under the PPACA to affect payment rates for physician providers, with incentive payments related to electronic prescribing and meaningful use of electronic health records.<sup>25</sup>

*Insurance Exchange Quality Performance Reporting.* Insurance exchanges have the potential to receive market-based incentives linked to quality performance and improved health outcomes related to the implementation of quality reporting, effective case management, care coordination, chronic disease management, and medical and care compliance initiatives. Relationships with patient safety evaluation systems as part of quality improvement efforts are encouraged.<sup>26</sup>

*Medicaid Quality Measures.* Core health quality measures for adults and children covered by Medicaid are included in the PPACA. Additional state-specific measures may also be implemented (§ 2701). Medicaid payment adjustments would also be implemented based on quality measures, including health-care-acquired infections.<sup>27</sup>

*“Value-Based” Purchasing of Health Care Services.* Hospitals (and eventually other types of health care facilities) will see payments tied to value-based purchasing programs under which facilities will receive payments based on the achievement of particular performance standards on a year-to-year basis. Beginning Oct. 1, 2012, Medicare will implement a value-based purchasing program, which will award incentive payments for meeting certain quality performance standards and, beginning in 2014, certain efficiency measures. Performance results will be publicly reported. Implementation of the program will involve the development of measures to be used to assess achievement of the standards.<sup>28</sup>

*National Quality “Strategy.”* The PPACA directs the Secretary to establish a national quality strategy on or before Jan. 1, 2011 to improve the delivery of health care services, patient health outcomes and population health. Specific goals include enhancement of the use of data to improve quality, efficiency, transparency and outcomes and the improvement of research and dissemination of best practices to improve patient safety and reduce medical errors, preventable readmissions and health care-associated infections. The data-driven strategy would also identify “gaps” in quality and report strategic plans for health care quality improvement on a health care quality website accessible to the public. Working group activities to align efforts in this regard are expected to begin reporting to Congress by Dec. 31, 2010.<sup>29</sup>

#### *New Patient Care Delivery and Payment Models*

PPACA calls for the formation of a Center for Medicare and Medicaid Innovation (CMI) to test innovative payment and service delivery models with the goal of reducing program expenditures while preserving or enhancing the quality of care furnished to Medicare and

Medicaid beneficiaries. The criteria and considerations PPACA provides for CMI’s use in testing and assessing new care delivery models include, among others, use of a health information technology-enabled provider network to support care coordination for chronically ill individuals at high risk of hospitalization and the use of technology such as EHR and patient-based remote monitoring systems to coordinate care over time and across settings.<sup>30</sup>

PPACA directs the secretary of HHS to develop a shared savings program specifically relating to ACOs that will promote accountability for a patient population and coordination of items and services under Medicare Parts A and B, as well as encourage investment in infrastructure and redesigned care processes for high-quality and efficient service delivery.<sup>31</sup> ACOs will be required to submit data on measures to be prescribed by the secretary (e.g. care transition—discharge planning and follow-up—across health settings) in a form and manner as the secretary deems necessary to allow the proper evaluation of the quality of care they deliver. In light of the PPACA’s recurring emphasis on having an EHR and other HIT infrastructure, submission in electronic form is likely to be required.<sup>32</sup> In addition, PPACA permits the secretary to include electronic prescribing and EHRs in the metrics used to assess quality of care.

In addition to the ACO shared savings program, PPACA empowers the secretary to establish a pilot “bundled-payment” program for integrated care during an episode of care provided to an applicable beneficiary around a hospitalization designed to improve the coordination, quality and efficiency of health care services.<sup>33</sup> The payment methodology will include payments for the furnishing of health care and related services, such as care coordination, medication reconciliation, discharge planning, transitional care services and other patient-centered activities as determined appropriate by the secretary. As required of ACOs, entities that participate in the pilot program will be expected to improve the quality of care provided according to quality measures to be established by the secretary. To the extent practicable, the data relating to these measures is to be submitted through the use of qualified EHRs.

The PPACA also anticipates the development of a Center for Quality Improvement and Patient Safety of the Agency for Healthcare Research and Quality (AHRQ) to use research from a variety of disciplines to help establish best practices for quality improvement in the delivery of health care services; propose changes to the processes of care and redesign of systems to improve patient safety and reduce medical errors; identify high-performing providers across the health care spectrum; and create strategies for quality improvement through tools, methodologies and interventions.<sup>34</sup> Given the significant role AHRQ has played in administration of federal funding for private sector HIT infrastructure initiatives, it will undoubtedly emphasize the HIT support needed to implement these quality improvement-focused responsibilities.

<sup>25</sup> *Id.* § 3002.

<sup>26</sup> *Id.* § 1311.

<sup>27</sup> *Id.* § 2702.

<sup>28</sup> *Id.* § 3001. Section 10301 directs the secretary to submit a report on the development of a similar program for skilled nursing facilities and home health agencies.

<sup>29</sup> *Id.* §§ 3011-3012.

<sup>30</sup> *Id.* § 3051.

<sup>31</sup> *Id.* § 3021.

<sup>32</sup> *Id.*

<sup>33</sup> *Id.* § 3023.

<sup>34</sup> *Id.* § 3501.

### *Patient-Centered Outcome Research Institute and Comparative Clinical Effectiveness Research*

Building on ARRA's financial and administrative support for CER, PPACA establishes a nonprofit Patient-Centered Outcomes Research Institute in order to "assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of [certain] medical treatments, services, and items."<sup>35</sup>

The Institute, which is neither an agency nor an establishment of the federal government, will be focused on identifying opportunities for, and carrying out, "comparative clinical effectiveness research" defined as research to "evaluate and compare health outcomes and the clinical effectiveness, risks, and benefits of 2 or more of [certain] medical treatments, services and items." Its efforts will be funded through a trust fund and supported through data that is either provided by the HHS secretary from data collected by CMS, derived from data networks developed by the Public Health Service Act, or data the institute may request and obtain from federal, state, or private entities, including data from clinical databases and registries. This provision also appears to contemplate the conduct of both primary and secondary research under the Institute's auspices.

### *Community Health Teams to Support Medical Homes*

Community health teams created under PPACA must (1) collect and report data that permits the evaluation of the success of the collaborative effort on patient outcomes (including collection of data on patient experience and areas for improvement) and quality measures; and (2) demonstrate the capacity to implement and maintain certified EHR technology to facilitate coordination among members of the care team and affiliated primary care practices.<sup>36</sup>

### **HIT Development Continuum for Key Stakeholders**

The ability to access robust, reliable electronic health information exchange (HIE) networks and repositories will be a key element in all industry stakeholders' strategies for responding to the health reform legislation's emphasis on care coordination, quality and outcomes measurement and reporting, comparative effectiveness research and evidence-based medicine. For academic medical centers, universities and research institutes, in particular, such networks and repositories will also be essential to qualify for future federal research funding. Pharmaceutical and device manufacturers need them now to support expanded regulatory requirements for mandated post-market surveillance and inclusion of REMS in product approval applications submitted to the FDA and, in the near future, to adapt product reimbursement and development strategies to respond to the CER and personalized medicine movements. Clinical research support organizations are rapidly realizing

how such HIT resources can diversify and enhance the scope and quality of their services. And, even governmental agencies such as the FDA will need massive electronic data repositories that are built, in part, using EHRs and HIEs.

The design of the HIT infrastructure underlying such networks and repositories will vary, as will the participants involved in and the pathways followed in the development process. For illustration purposes, the diagram below depicts just one possible, hypothetical development continuum, which begins with a single provider's conversion from paper medical records to an EHR system, the provider's collaboration with other providers (directly or through public or private, regional or state-wide health information exchanges) to achieve meaningful use of interoperable EHR systems, its implementation of a clinical trial management system and integration of that system with the EHR system, and ultimately, collaboration between and among the provider and other stakeholders such as universities, payers, manufacturers, research institutes or research support organizations, and governmental entities for the creation and use of a robust, multi-disciplinary electronic information repository.<sup>37</sup>

A discussion of financial, technological, strategic, and operational considerations involved in the design and development of an HIE or robust electronic data repository is outside the scope of this article.<sup>38</sup> Key HIT infrastructure design considerations are likely to include, among others: (1) with which other stakeholders will information be exchanged (e.g., provider-to-provider within a health care system or with unaffiliated providers in the community, only between and among employed and affiliated physician practices and physicians or with unaffiliated physicians in the community, between providers and payers, between one health information exchange and another within a community and between an exchange in one community and an exchange in another); (2) what data and technical standards will be needed to support harmonization of different information systems, networks, software applications, interoperability infrastructures and vocabularies; (3) when and how can interoperability be achieved; (4) will EHR data from various provider participants be aggregated into a single integrated health record; (5) will EHR data be integrated with electronic clinical trial information of one or more network participants; (6) will information in an EHR network be aggregated into a non-EHR data warehouse for secondary uses such as health care operations and research; (7)

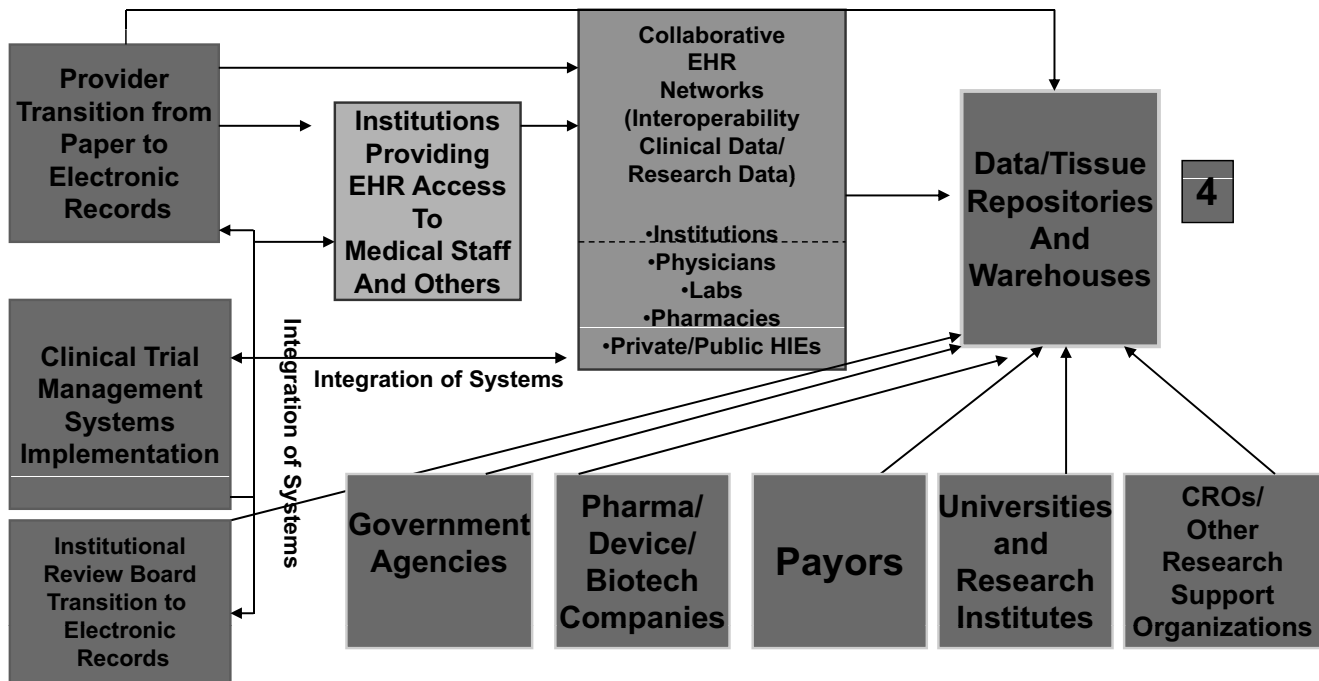
<sup>37</sup> The 2007 HHS report on Personalized Medicine emphasized the collaboration across all stakeholders in both the public and private sectors as being "at the heart of the project." U.S. Dep't of Health & Human Servs., *Personalized Health Care: Opportunities, Pathways, Resources*, *supra* note 4. The 2008 report includes informative descriptions of case studies of collaboration initiations that have emerged since the first report. U.S. Dep't of Health & Human Servs., *Personalized Health Care: Pioneers, Partnerships, Progress*, *supra* note 4. See also Moffitt, Merck join forces: One of the world's largest drugmakers forms a research venture with the Tampa institute to adapt cancer treatments to individuals, *ST. PETERSBURG TIMES* (Dec. 19, 2006), available at [http://www.sptimes.com/2006/12/19/Tampabay/Moffitt\\_Merck\\_join\\_f.shtml](http://www.sptimes.com/2006/12/19/Tampabay/Moffitt_Merck_join_f.shtml).

<sup>38</sup> A useful resource for additional information concerning HIEs in particular is the eHealth Initiative website at [www.ehealthinitiative.org](http://www.ehealthinitiative.org). See also,

<sup>35</sup> *Id.* § 6301.

<sup>36</sup> *Id.* § 3502.

# EHR/HIE Development Continuum



will the network or repository be made available to other than those who contribute information to it; and (8) will the infrastructure or support of third parties (e.g., the services and infrastructure of application service providers (ASPs) offering a complete turnkey arrangement or just certain infrastructure such as cloud computing<sup>39</sup> or other server capability that will facilitate the exchange of information without the need for myriad source-to-source interfaces) be needed on a short-term or long-term basis.

## Key Legal and Regulatory Planning Considerations

An EHR, HIE, and robust health data repository each can be a powerful resource for achieving reform in health care delivery and research and a valuable asset in its own right if critical legal and regulatory compliance requirements are addressed early in the planning and development process. Conversely, a lack of careful upfront compliance planning can result in an EHR system, HIE or repository that cannot be used without serious compliance risk and a corresponding loss of the substantial time, effort and financial resources devoted to the development effort.

Following is a brief overview of key legal and regulatory planning considerations that should be addressed at the outset of any EHR, HIE, and repository initiative.

<sup>39</sup> [http://en.wikipedia.org/wiki/Cloud\\_computing](http://en.wikipedia.org/wiki/Cloud_computing) (last visited June 27, 2010).

## Federal and State Privacy Laws

Various domestic and international laws governing the privacy and security of personal health information will apply to the exchange of information by, and between and among participants in an HIE or electronic data repository of any size and scope. Any strategy for addressing these laws should address the extent to which compliance steps are required both for the initial inclusion of data in the HIE or repository and for each subsequent exchange or use of the data.<sup>40</sup>

*HIPAA Privacy and Security.* As outlined above, both the HITECH Act and PPACA incentivize investment in HITECH infrastructure that will support widespread electronic exchange and analysis of health care information. Recognizing that this health reform policy also elevates the privacy and security risks regulated by the Health Insurance Portability and Accountability Act of 1993 and accompanying regulations<sup>41</sup> (HIPAA), however, the HITECH Act strengthened existing HIPAA privacy and security requirements in several significant respects. In particular, the act extended the applicability of the HIPAA security standards and penalties for security and privacy violations directly to business associ-

<sup>40</sup> For example, HIPAA and the Common Rule will treat as two separate research studies needed appropriate authorization or informed consent (or corresponding exceptions to or waivers from the authorization and informed consent requirement), and both the creation of a data repository that is intended to be used for research regulated by the Common Rule and a subsequent research study conducted using the data in the repository.

<sup>41</sup> 45 C.F.R. §§ 160, 162 and 164.

ates; established rigorous data security breach notification requirements; extended the accounting for disclosures requirement to treatment, payment and health care operations; imposed an express prohibition on the “sale of data” other than in limited circumstances; and significantly modified the categories of HIPAA violations, the range of civil money penalty amounts and the available defenses to a HIPAA action. The new federal data security breach notification requirements apply in addition to those recently adopted in various states for the breach of either personal health information or personal information of any kind.<sup>42</sup> Increased and more aggressive HIPAA privacy and security compliance enforcement is expected.<sup>43</sup>

Whether and to what extent HIPAA will permit providers to share protected health information (PHI) (as defined by HIPAA)<sup>44</sup> from their EHR systems with each other and with nonproviders will be driven by various considerations, including: (1) whether the providers sharing the network are participants in the same organized health care arrangement (OHCA);<sup>45</sup> (2) the nature and extent of the information in the EHR to which they are permitted access (e.g., their own patient information only, information of patients of the hospital or other physicians); (3) who will have access and the purpose of the access and use (e.g., treatment, payment, health care operations<sup>46</sup> (including those of an OHCA that engages in joint quality assurance and utilization review or joint managed care contracting involving financial risk), and research); (4) whether the information is in individually identifiable or in de-identified form,<sup>47</sup> or part of a limited data set,<sup>48</sup> and (5) whether the network includes HIPAA’s administrative, physical, technical and organizational security safeguards.

Worth noting here is that studies undertaken using an electronic network or repository for purposes of cost, quality and safety studies may be considered “health care operations” rather than “research” under HIPAA and that use for such health care operations purposes are not subject to the HIPAA authorization requirement. Careful consideration must nonetheless be

given to whether the study is research under the Common Rule.<sup>49</sup> Drawing the lines is not always easy.

Any electronic sharing of PHI, other than sharing by providers in connection with treatment or payment matters for common patients, should be carefully analyzed to verify compliance with HIPAA privacy requirements such as (1) the need for patient authorizations and eligibility for exceptions to or waivers of the authorization requirement; (2) establishing access controls to meet minimum necessary standards and comply with the provisions of authorizations, authorization exceptions and authorization waivers; (3) patient record access and amendment rights provisions; (4) patient rights to accounting of disclosures; (5) the criteria and contracting requirements for engaging business associates; (6) the criteria and contracting requirements relating to creation and use of de-identified data and limited data sets; and (7) the new prohibition against the sale or data. Typically, the strategy for meeting these requirements will involve a combination of the HIT infrastructure design elements, policies and procedures, and associated training.

*Other Federal Privacy Laws and State Laws Protecting the Confidentiality of Sensitive Health Information.* Certain other federal laws protect particular categories of information that may be included in the electronic information exchange. Principal among them is the federal law protecting the confidentiality of alcohol and drug abuse patient records.<sup>50</sup> Similarly, the laws of most if not all states prohibit or restrict uses and disclosures of information relating to mental health, developmental disabilities, AIDS and other sexually transmitted diseases, and genetic testing and counseling information, and some states have laws protecting the confidentiality of health information generally.<sup>51</sup> Further, use of information from the exchange for clinical research may also trigger applicability of (a) the protections afforded human subjects in research by the federal regulations that protect human subjects who participate in federally funded research (i.e., the Common Rule),<sup>52</sup> (b) the FDA regulations applicable to research conducted in support of an application for FDA approval of the marketing of a new product,<sup>53</sup> and the Ge-

<sup>42</sup> See, e.g., M.G.L.A. 93H § 1 *et seq.*; Cal. Health & Safety Code § 1280.15.

<sup>43</sup> See, Economic Stimulus Package: Policy Implications of the Financial Incentives to Promote Health IT and New Privacy, McDermott Will & Emery White Paper (Feb. 20, 2009), available at [http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object\\_id/ea996ed0-ba3b-480a-988a-135230c441d6.cfm](http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/ea996ed0-ba3b-480a-988a-135230c441d6.cfm) (last visited June 14, 2010); HHS Issues Interim Final Rule Conforming HIPAA Civil Money Penalties to HITECH Act, McDermott Will & Emery White Paper (November 12, 2009), available at [http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object\\_id/ae68626d-301b-4aa7-9a20-911cbe1b1f4a.cfm](http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/ae68626d-301b-4aa7-9a20-911cbe1b1f4a.cfm) (last visited June 20, 2010); Regulatory Update: HITECH’s Security Breach Notification Requirements, McDermott Will & Emery White Paper (April 22, 2009), available at <http://www.mwe.com/info/news/wp0409e.pdf> (last visited June 20, 2010); Regulatory Update: HITECH’s HHS and FTC Security Breach Notification Requirements, McDermott Will & Emery White Paper (Aug. 27, 2009) available at [http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object\\_id/8e9bbcf4-afe4-4992-a277-6c3ce953a249.cfm](http://www.mwe.com/index.cfm/fuseaction/publications.nldetail/object_id/8e9bbcf4-afe4-4992-a277-6c3ce953a249.cfm) (last visited June 20, 2010).

<sup>44</sup> 45 C.F.R. § 160.103.

<sup>45</sup> *Id.*

<sup>46</sup> 45 C.F.R. § 164.501

<sup>47</sup> 45 C.F.R. §§ 164.514(b)(1) and (2)(i).

<sup>48</sup> 45 C.F.R. §§ 164.514(2)(i) and (e)(2).

<sup>49</sup> In December 2008, an official of OHRP publicly addressed the need to carefully draw lines between these two activities. “OHRP Official Recommends Drawing Lines To Determine Which Activities are Research,” *BNA Medical Research Law and Policy Report*, 7 MRLR 761 (Dec. 3, 2008).

<sup>50</sup> 42 U.S.C. § 290dd-2 and 42 C.F.R. Part 2. See also “The Confidentiality of Alcohol and Drug Abuse Patient Records Regulation and the HIPAA Privacy Rule: Implications for Alcohol and Substance Abuse Programs” (June 2004), available at <http://www.samhsa.gov/HealthPrivacy/docs/SAMHSAPart2-HIPAAComparison2004.pdf> (last visited June 20, 2010), and “Frequently Asked Questions, Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE),” (June 16, 2010) available at <http://www.samhsa.gov/HealthPrivacy/docs/EHR-FAQs.pdf> (last visited June 20, 2010).

<sup>51</sup> A comprehensive review of state sensitive information confidentiality laws is outside the scope of this article. Examples of such state laws include the following: IND. CODE ANN. § 16-18-2-226 (mental health information); MASS. GEN. LAWS. ch. 111, § 70F; ARIZ. REV. STAT. 12-2802; 74 ILCS 110/ (mental health information); 410 ILCS 305/ (HIV/AIDS information); 410 ILCS 513/ (genetic information); 410 ILCS 50/ (medical information generally).

<sup>52</sup> 45 C.F.R. § 46(A)-(D).

<sup>53</sup> 21 C.F.R. § 50.1.

netic Information Nondiscrimination Act of 2008 (GINA) which addresses the use of genetic information by group health plans, health insurers in group and individual markets, and issuers of Medigap policies in connection with certain insurance business functions.<sup>54</sup>

In certain respects, these other federal and state privacy and confidentiality laws are more restrictive than, and thus preemptive of, HIPAA. In particular, they may require a written patient consent for both *uses and disclosures* for which HIPAA would not require an authorization, even at times when the information is being used internally by a covered entity or being exchanged only between or among treatment providers or with a business associate who has been hired to convert the information to a limited data set or fully de-identified form. Obtaining consent to use of data collected over several years and from a large number of patients prior to the creation of the electronic network or repository can be particularly challenging. Other challenges arising from a consent requirement include (b) developing ways to track and firewall all information from a patient who refuses to give consent or who withdraws consent, and (b) attempting to segregate sensitive from non-sensitive information contained in a single patient record of a non-consenting individual (particularly in the context of mental health information where the lines between the two can be extremely gray).

*EU and Other Foreign Data Protection Laws.* Electronic information exchanges and repositories that contain identifiable health information of a foreign national may be subject to privacy requirements under myriad privacy laws of foreign countries, including those of the 27 countries comprising the European Union (EU). The cornerstone of privacy protection in the EU in the EU Data Privacy Directive.<sup>55</sup> The EU adopted the Data Privacy Directive to establish a minimum level of protection among the member states and to prevent diverse national laws from becoming an obstacle to the integration of a single European market. While it provides some level of harmonization, it does not establish uniformity among the various national laws of the member states. Countries outside the EU also have privacy laws needing to be addressed.

#### *Federal Laws Regulating the Donation of EHR Technology by Hospitals to Physicians*

The health reform related HIT strategy of many hospitals and health systems is likely to include the donation of EHR technology to physicians to expedite their adoption of EHR. Such donations raise implications under federal health care fraud and abuse laws as well as tax-exemption laws.

Prior to the adoption of the HITECH Act's financial incentives for meaningful use of Certified EHR Technology, the federal government implemented some relief from the fraud and abuse concerns that were impeding EHR initiatives. Specifically, in August 2006, the Centers for Medicare & Medicaid Services (CMS) pub-

lished final regulations setting forth an exception to the Stark law for the provision of EHR items and services by hospitals to physicians (EHR exception)<sup>56</sup> and the Office of the Inspector General (OIG) published final regulations setting forth a corresponding safe harbor under the anti-kickback statute<sup>57</sup> (EHR safe harbor and, collectively, with the EHR exception, the "federal EHR regulations"). The EHR regulations provide a roadmap for structuring permissible donations of EHR technology by hospitals to physicians. The structural considerations and conditions relate to (i) which individuals and entities are permitted to be donors; (ii) which individuals and entities are permitted to be recipients; (iii) what items and services may be donated; (iv) what agreements must be in place to document the donation; (v) what requirements exist for cost sharing; and (vi) certain other conditions that must be satisfied in order to assure that the arrangement avoids improper inducements to make referrals for Medicare and Medicaid-covered items and services and that the hospital makes prudent use of the resources it has available to invest in a donation program.<sup>58</sup> A summary of some of the key requirements follows.

The Internal Revenue Service (IRS) subsequently issued a directive concerning the tax-exemption implications of the EHR donations contemplated by the federal EHR regulations under the private inurement and more than incidental private benefit prohibitions of Section 501(c)(3) of the Internal Revenue Code (code) (the IRS EHR directive).<sup>59</sup> The IRS EHR directive states that the IRS will not treat the corresponding benefits a hospital provides to its medical staff physicians as an impermissible private benefit or inurement if the hospital meets several requirements: (a) the hospital and the participating physicians comply with the requirements of the federal EHR regulations on a continuing basis; (b) to the extent permitted by law, the hospital may access all of the electronic medical records created by a physician using the donated items or services; (c) the hospital ensures that the donated items and services are available to all of its medical staff physicians; and (d) the hospital provides the same level of subsidy to all of its medical staff physicians or varies the level of subsidy by applying criteria related to meeting the health care needs of the community.<sup>60</sup> The IRS subsequently clarified that for any entity that is not able to meet all of these requirements, it would utilize a facts and circumstances analysis to determine whether the arrangement poses

<sup>56</sup> 42 C.F.R. § 411.357(w).

<sup>57</sup> 42 C.F.R. § 1001.952(y).

<sup>58</sup> For a more detailed discussion of the criteria and conditions, see the Federal EHR Regulations themselves *supra* at Notes 66 and 67 and McDermott Will & Emery White Paper "Donating Health Information Technology: Final Regulations Compete with HR 4157 for Public Policy Control," available at <http://www.mwe.com/info/news/wp1006a.pdf> (last visited June 24, 2010).

<sup>59</sup> IRS Memorandum, "Hospitals Providing Financial Assistance to Staff Physicians Involving Electronic Health Records" (May 11, 2007).

<sup>60</sup> IRS Circular 230 Disclosure: To comply with requirements imposed by the IRS, we inform you that any U.S. federal tax advice contained herein, unless specifically stated otherwise, is not intended or written to be used, and cannot be used, for the purposes of: (1) avoiding penalties under the Internal Revenue Code or (ii) promoting, marketing or recommending to another party any transaction or matter herein.

<sup>54</sup> The Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, § 1(a) (May 21, 2008). See also, 45 C.F.R. § 144.103.

<sup>55</sup> Directive 95/46/EC of the European Parliament and of the council of 24 October 1995 on the protection of individuals with regard to the processing personal data and on the free movement of such data. Official Journal of the European Communities, Nov. 23, 1995, No. L. 281/31.

any tax concerns. The directive thus amount essentially to a “safe harbor” that can be varied from as necessary so long as alternative facts and circumstances exist to provide a defensible position.

#### *State Laws on Medical Records Form, Content, and Retention*

A lack of uniformity among current state laws governing the form, content, and retention of medical records impedes the standardization of electronic health records and retention and destruction practices.<sup>61</sup> Further, the development of necessary changes to these laws is unlikely to keep pace with the rapidly accelerating exchange and integration of EHR databases. Challenging medical records issues that will likely arise in an effort to apply these state laws include: (1) what is the medical record and what information comprises it (e.g., pop-ups, alerts, and reminders, video files (e.g., videos of office visits, procedures, and telemedicine consultations), information stored in audio files (for example, recorded patient telephone conversations, physician dictations, data from multiple electronic source systems));<sup>62</sup> (2) who owns the information and the record containing the information; (3) who controls the record; and (4) who has the obligation to maintain it for purposes of applicable legal requirements. As patients create their own personal health records as part of integrated, community-wide health data networks and personalized health care delivery, an organization must also determine whether and to what extent these personal health records should be incorporated into its legal health record.

#### *Antitrust*

Inclusion of fee and non-fee related information in a health information network that integrates the data of multiple providers, other than those that are under common ownership or control or part of an integrated economic risk sharing arrangement,<sup>63</sup> creates risk under federal antitrust laws that seek to promote competition and restrict anti-competitive behavior.<sup>64</sup> In August 1996, the FTC and the DOJ issued joint statements on health care antitrust issues that established two safety zones for the exchange of information between providers and payers. These safety zones remain in effect today and are instructive for purposes of managing antitrust risk in the formation of HIEs.<sup>65</sup>

<sup>61</sup> See William H. Roach, Jr., Robert G. Hoban, Bernadette M. Broccolo, Andrew B. Roth, Timothy P. Blanchard, *Medical Records and the Law*, 4th ed. Jones and Bartlett, MA (2006), pp. 31-50.

<sup>62</sup> The electronic health record has been defined by the Health Information and Management Systems Society; by the American Health Information Management Association (AHIMA), “Update: Guidelines for Defining the Legal Health Record for Disclosure Purposes,” *Journal of AHIMA* (September 2005): 64A; and by the federal EHR regulations *supra* at Notes 66 and 67.

<sup>63</sup> See FTC 2004 report *supra* at Note 17 and discussion *supra* at Note 18.

<sup>64</sup> e.g., Section 1 of the Sherman Act, 15 U.S.C. §§ 1-7. See also *United States v. Burgstiner*, 1991-1 Trade Cas. (CCH) Par. 69422 (S.D. Ga. 1991), and discussion *supra* at note 16.

<sup>65</sup> Federal Trade Commission and Department of Justice Statement of Antitrust Enforcement in Healthcare (August 1996), 4 Trade Reg. Rep. ¶¶ 20,809-11 (FTC 1996 Statements) available at <http://www.ftc.gov/reports/hlth3s.pdf> (last visited June 22, 2010).

The first of the two applies to the exchange of non-fee-related information such as medical data (e.g., outcomes data for a particular medical procedure collected by a medical society from its members) that may help to conduct activities that address issues related to the mode, quality or efficiency of treatment such as the development of practice parameters (i.e., standards for patient management developed to assist providers in clinical decision-making) or clinical protocols.<sup>66</sup>

The second one applies to the exchange of fee-related information and sets forth three qualifying criteria for qualifying for “safety zone” for use of an integrated data network to share financial information among nonintegrated competing providers: (a) the collection of financial data must be managed by a third party (e.g., a purchase, government agency, consultant, academic institution or trade association); (b) even if current fee-related information is provided to purchasers, any information shared among or available to competing providers furnishing data must be more than three months old; and (c) if information is available to providers furnishing data, the information disseminated must be sufficiently aggregated that it would not allow recipients to identify the prices charged by any one provider (there must be at least five providers reporting data upon which each disseminated statistic is based and no individual provider’s data may represent more than 25 percent of that statistic on a weighted basis).<sup>67</sup> For surveys of price or cost (e.g., surveys of employee compensation), there is an additional requirement that the data collected must be more than three months old.<sup>68</sup> Information exchanges outside of the safety zone are analyzed under the rule of reason.<sup>69</sup>

In April 2010, the DOJ announced that it will not challenge a proposal by the Hospital Value Initiative (HVI) to establish an information exchange program that will provide data on the relative costs and resource efficiency of more than 300 hospitals in California because the proposed information exchange may reduce health care costs by improving competition among hundreds of hospitals in California and facilitating more informed purchasing decisions by group purchasers of health care services. Consistent with the above safety zone requirements, the DOJ concluded that a low risk of anticompetitive effect existed in part because the exchange would involve data that is at least 10 months old and the program would not disclose disaggregated data or any hospitals’ actual services fees.<sup>70</sup>

In mid-June 2010, the FTC announced its plan to hold a public workshop on health care competition policy, payment reform, and new models for delivering health care that seek to incentivize high-quality, cost-effective care, including ACOs, and to create a workshop website that will contain the program agenda, list of speakers,

<sup>66</sup> *Id.* At p. 41.

<sup>67</sup> *Id.* at pp. 43-48.

<sup>68</sup> *Id.*

<sup>69</sup> *Id.*

<sup>70</sup> “Department of Justice Will Not Challenge Hospital Cost Information Exchange Program in California, PR Newswire (April 26, 2010), available at <http://www.prnewswire.com/news-releases/department-of-justice-will-not-challenge-hospital-cost-information-exchange-program-in-california-92101269.html> (last visited June 22, 2010).

materials, etc. as these are developed.<sup>71</sup> These efforts of the FTC and any corresponding efforts of the Department of Justice should be watched closely for policy and enforcement guidance concerning the antitrust implications of implementing the HIT infrastructure incentivized by ARRA and PPACA, including any changes to the two 1996 safety zones applicable to such exchanges.

### *Standard of Care for Malpractice Liability*

Widespread proliferation of electronic health record networks and repositories may ultimately elevate the standard of care for negligence purposes, at least in certain communities or regions. The question which has been asked in other contexts that may well be asked in this one is whether a physician is negligent or provides substandard care if he or she does not utilize information that is available for making medical decisions.<sup>72</sup>

Also, maintaining the integrity and reliability of health information used to exercise medical judgment will be increasingly challenging as information is aggregated and exchanged electronically between and among key stakeholders in the public and private sectors. Failure to do so clearly carries professional liability risk.

An important consideration is the risk that the secondary use of an individual's health information will create an implicit obligation to notify an individual of observations made when using the data that may relate to the individual's health or propensity for certain diseases or conditions. Necessary consents and authorizations should be carefully drafted with this risk in mind.

Finally, the availability of electronic health information networks will also likely fuel the growing trend toward e-discovery litigation. Important considerations relevant to the use of and defense against the use of e-discovery include: (a) what portion of the electronic health record constitutes the medical record (clinical care information, administrative information, laboratory test results, etc.) (discussed further below); (b) will the electronic health record meet the standards for admissibility, particularly in light of the challenges of authentication; (c) how to manage the increased risk of inadvertent "destruction of evidence" under electronic record and retention practices; (d) what will be the cost of electronic discovery and who should bear it; and (e) the ease of searching and the persistence/ indestructibility of electronic health information.

<sup>71</sup> See the full text of the chairman's speech available at <http://www.ftc.gov/speeches/leibowitz/100614amaspeech.pdf> (last visited June 14, 2010).

<sup>72</sup> Jacobsen, P.D., *Medical Liability and the Culture of Technology*, Project on Medical Liability in PA, 7/2004, <http://mediabilitypa.org>. See also *Das v. Thani*, 2002 N.J. Lexis 548, 171 N.J. 518 (N.J., 2002) (fetal monitoring case in which physician did not use ultrasound available in his office in favor of "1960s-style" maternal fetal monitoring; expert testimony went both ways); *Suniga v. Eyre*, 2004 Tex. App. Lexis 486 (unpublished) (regarding whether the standard of care included the duty to consult past medical records); *Susnis v. Radfar*, 2000 Ill. App. Lexis 859, 739 N.E. 2d 960 (Ill. App. 2000) (involving allegations that the standard of care included the duty to consult past medical records); *Primus v. Galgano*, 2003 U.S. App. Lexis 9803, 329 F. 3rd 236 (1st Cir., 2003) (failure to obtain past medical records is a departure from the standard of care).

### *Ownership of Repositories and their Contents*

Widespread disagreement currently exists regarding who owns repositories of biological tissue and data and the intellectual property rights associated with and derived from them. This ownership question is critical both to use of such repositories for future research and to commercialization of products based on such use. Recent case law<sup>73</sup> and state laws governing tissue donation will all have implications for the approach that should be taken in individuals' informed consents and in agreements between and among the parties involved in an electronic information exchange or repository to establish ownership of data and to the products derived from such data. The law in this regard remains somewhat unsettled. As the debate continues and key legal and ethical questions are addressed, the participants should take steps to confirm that intellectual property ownership and access rights and expectations are clearly articulated and understood.

### **Vendor Contracting Considerations**

The evaluation of the HIT needed to establish and operate an EHR, HIE, or repository and the vendor contracting to acquire the systems must be carefully undertaken with the legal, financial, and strategic considerations in mind. Following is an overview of key considerations to be addressed.<sup>74</sup>

*Whether the system will provide the necessary features, functions, and tools to implement the intended strategy and to comply with applicable legal and regulatory requirements, both as they exist at the time of the contract and as they are likely to evolve and change during the life of the contract.* Examples of strategic considerations include whether the system's plan for interoperability and data integration will accommodate the short and long-term nature and extent of contemplated information exchange. Key compliance considerations for a provider or payer include (a) whether the technology qualifies as certified EHR technology that can achieve interoperability and meaningful use on an ongoing basis, and (b) whether the system can establish and manage access rights according to role and purpose of access (e.g., treatment, billing and payment, utilization review and quality assurance, research); limit access to certain records or types of data (e.g., records of patients who have refused or withdrawn consent, categories of information given special protection under federal and state laws), monitor and audit access, and maintain compliance with other federal and state privacy and security requirements; accommodate the centralized administration of the HIPAA patient rights provisions (i.e., the right to request additional restrictions on disclosure of their PHI, the right to access their records, the right to accounting of certain disclosures, and the right to amend records); and enable implementation of a joint notice system for an OHCA. An important related contracting consideration is the extent of the vendor's commitment to update and modify the system as regulatory changes occur (e.g., EHR certification and meaningful use standards) and the financial terms corresponding to that commitment.

<sup>73</sup> See, e.g., *Washington Univ. v. Catalona*, 552 U.S. 1166 (2008).

<sup>74</sup> This discussion is not intended as legal advice and should not be considered exhaustive of the full scope of issues needing to be addressed in the contracting process.

*Crafting the Scope of License Rights to Accommodate the Universe of Intended Uses and Users.* The scope should be consistent with the short term and long-term business plan. For example, an EHR system agreement should contemplate both an initial roll-out to a hospital's medical staff physicians and a subsequent roll-out to other community physicians, laboratories and other ancillary providers, pharmacies, etc. Similarly, an agreement for technology to support an HIE should contemplate exchange of information initially among entities within a health system and ultimately with unaffiliated providers, vendors, and other HIEs. Affordability and predictability of license, implementation, and support fees will be important to the short-term and long-term feasibility of the HIT initiative, particularly in achieving an EHR strategy that will be economically palatable to physicians, financially sustainable, and consistent with legal and regulatory requirements for donating EHR technology to physicians and other compliance standards. Rights to expand the scope of permitted use and users over the license of the agreement and associated fees should be addressed in the negotiation of the vendor agreement at the front end.

*Allocating Responsibility for Data Accuracy, Integrity and Completeness.* Of course, the accuracy, integrity, and completeness of the data in an EHR, HIE, and health information repository, at all time, is essential. Maintaining that may become more challenging as the scope of the participants expands. The agreement should expressly articulate the relative responsibility of the participants and the vendor in this regard—the participants for including only accurate and complete information and technical and administrative security protections in their facilities and operations, and the vendor for providing and maintaining technology that is free from defects and meets functional and performance expectations. As a related matter, vendor disclaimers of malpractice liability arising from the use of data in the exercise of medical judgment is acceptable in most cases other than to the extent the liability arose from the vendor's failure to perform from defects in the system.

*Defining Vendor Rights to Access and Use Data.* Vendors themselves can have an interest in having accessing and using data in an EHR or HIE for secondary purposes (e.g., future product development, testing, and marketing). Including a provision that clearly establishes the exclusive data ownership rights of the hospital, physicians, and other participants and appropriate limits on the vendor's ability to use the data for other than providing services is advisable.

*Assuring Cross-Vendor Accountability and Cooperation.* The establishment and ongoing operation of the EHR, HIE, or repository agreement will likely involve the technology and services of various vendors. An agreement with each vendor that contains a clear and complete description of the technology and services the vendor is providing will enhance the basis for effective overall management of the endeavor and minimize the risk of "finger-pointing" among the vendors that can produce project disruption, delays and failures. Also, including an affirmative commitment by each vendor to cooperate with other vendors is advisable.

*Narrowing Liability Limitations and Disclaimers.* Vendors generally typically impose caps on direct dam-

ages and disclaimers of all liability for consequential, incidental and special damages. Harm resulting from violations of federal and state privacy, confidentiality laws and data breach notification laws (e.g., injury to patients, penalties and fines, and internal costs incurred to meet notification requirements and implement other remediation steps) will likely fall into one or more of the categories of disclaimed harm and thus should be expressly carved out of any vendor damage limitations and disclaimers.

*Anticipating Changing Relationships.* Exceptions to common restrictions on assignments will be needed to accommodate structural and relationship changes that are likely to occur as an organization's HIT strategy evolves over time.

## Collaborations

As discussed above, an EHR network, HIE, and robust health information repository can emanate from any one stakeholder's HIT initiatives and evolve into subsequent collaborations and relationships of various types among two or more industry stakeholders, such as an institutional provider, university, research institute, governmental body, other HIEs, or product manufacturers. Whether the collaboration exists solely by contractual agreement or creation of a new entity, a detailed written agreement is essential. The agreement should clearly articulate the purpose, scope, and goals of the collaboration as contemplated over its anticipated life, the nature and extent of the HIT infrastructure being created through the implementation of new systems and the integration of existing systems, and current or future plans to create a new entity to assume all or part of the responsibility for operation of the network. It should also specify the relative rights and responsibilities of the participants with regard to the following: (1) governance and management of the network, HIE, or repository; (2) funding, both initial and future; (3) ownership of, and rights to access and use, the systems and data; (4) extension of access to nonparticipants; (5) responding to electronic discovery requests; (6) liability and compliance risk and indemnification and insurance; (7) development and management of a legal and regulatory compliance plan; (8) strategic planning and budgeting; (9) communications and relationships among the participants and with external constituencies (e.g., government, HIT vendors); (10) long-term sustainability of the repository; and (11) termination and withdrawal of the relationship by one or more participants.

## Next Steps for Stakeholders

The interoperable EHR technology contemplated by the ONC's goals and funded by HITECH Act stimulus funds will be the cornerstone in the HIT foundation upon which any health reform strategy must be built. Waiting for further implementation of key components of PPACA before aggressively pursuing relationship alignment strategies indeed may be a wise approach. Aggressively developing and implementing an HIT strategy, however, need not and should be delayed. All stakeholders should begin now to assess where they are in implementation of EHRs and other key components of the HIT infrastructure development continuum and to design a strategy for swiftly but steadily moving themselves forward.