



## Prescriptions for Excellence in Health Care Newsletter Supplement

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# Prescriptions for Excellence in HEALTH CARE

A COLLABORATION BETWEEN JEFFERSON SCHOOL OF POPULATION HEALTH AND LILLY USA, LLC

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## TABLE OF CONTENTS

**A Message from Lilly: The Opportunity to Create Policy Insights via the Implementation of the Patient Protection and Affordable Care Act (ACA)**  
By *Karen L. Friss, BS, MBA*..... 2

**Accountable Care: Will it Transform Health Care Delivery?**  
By *Allan B. Goldstein, MD, MPH*..... 3

**Health Care Payment Reform: A Look Ahead**  
By *Cary Sennett, MD, PhD*..... 6

**Rethinking Health Information Technology on the Journey to Personalized Medicine**  
By *Brett J. Davis* ..... 9

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## Editorial

### Population Health and Health Reform - Inseparable Concepts

By *David B. Nash, MD, MBA*  
*Editor-in-Chief*

As dean of one of the nation's leading schools of population health, I would be remiss if I didn't devote special attention to this critically important concept.

With 45% of us suffering from at least 1 chronic condition<sup>1</sup> and more than 49 million of us lacking health insurance,<sup>2</sup> the need for a population health approach in the United States has never been more urgent. Without exaggeration, the scope of today's population health challenge is unprecedented, particularly when it is coupled with the unrelenting upward spiral of health care costs and the declining health status of the general population (as compared with previous generations).

Whatever shape it may take eventually, population health will be essential to the success of health care reform. Why? Because it takes aim at the some of the very basic shortcomings in our traditional health care delivery system: namely, enhancing health and wellness through prevention and lifestyle changes, reducing or eliminating waste and error, eradicating disparities, improving transparency and accountability, and improving care coordination – a goal shared with health care reform.

Population health looks beyond public health at “the distribution of health outcomes within a population, the health determinants that influence distribution, and the policies and interventions that impact those determinants.”<sup>3,4</sup> It spans wellness and health promotion, chronic disease management, care of the frail and elderly, and palliative and end-of-life care. In essence, broad population health approaches are designed to preserve wellness and minimize the physical and financial impact of illness.

How does the Patient Protection and Affordable Care Act (ACA) incorporate the principles of population health? First and foremost, it creates a new framework for health care delivery in the United States by adopting a comprehensive national strategy for quality improvement, the focus of which is clinically integrated

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systems-based practice. This should result in care that is coordinated across all diseases, providers, and care settings over time. Importantly, hospitals and health systems will be required to extend their quality oversight processes as they pursue collaborative relationships with physicians and other entities.

The Accountable Care Organization (ACO) program, a prominent feature of the ACA, will have a major influence on extending quality oversight processes to outpatient settings,<sup>5</sup> which is where Americans receive the overwhelming majority of their health care services. A shared savings model, the ACO will require participating providers to use the tools of population-based care to achieve the cost savings necessary for success.

The patient-centered medical home and ACO models that feature prominently in health reform contain aspects of care delivery that fall under the umbrella of population health. These efforts and related new payment models are an attempt to identify and eliminate waste and inefficiencies in the system. Today, much of the emphasis of health reform is on these new payment models that seek to improve quality and cost-effectiveness in the system. However, for true success in this environment, explicit

new methods for delivering care must be part of the overall plan. Rather than simply following the rules of reform, health care leaders must fully understand and follow the intricately related tenets of population-based care as these will have a major influence.

At this point, I'll segue to a brief overview of the articles featured in this issue of our series on how various provisions of the ACA have begun to affect health care quality and population health. This issue delves into 3 important areas:

*"Accountable Care: Will it Transform Health Care Delivery?"* takes us through the concepts, competencies, regulatory constraints, and challenges associated with the deployment of ACOs. The author observes that it won't be a cakewalk, but there are opportunities for success.

*"Health Care Payment Reform: A Look Ahead"* takes a hard look at the issues related to, and the likely impact of, new payment models for health care delivery.

The final article, *"Rethinking Health Information Technology on the Journey to Personalized Medicine,"* reflects on how secondary use of existing

health information can hasten the development of more individualized care - an exciting prospect!

I hope that this issue will serve to enlighten and provoke discussion around the linked concepts of health reform and population health. As always, I welcome questions and comments from our readers. I can be reached at: david.nash@jefferson.edu.

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## A Message from Lilly

### The Opportunity to Create Policy Insights via the Implementation of the Patient Protection and Affordable Care Act (ACA)

By Karen L. Friss, BS, MBA

By now the public may know the Supreme Court ruling on key aspects of the ACA: the individual mandate, severability of the mandate from some or the entire 2700-page law, and Medicaid expansion.

The individual mandate requires that all citizens (not currently enrolled in a public health program) purchase health insurance. Various models have been created to forecast the impact of a court decision

invalidating the individual mandate while maintaining the other components of the ACA. These forecasts range from an exponential increase to a significant reduction in persons seeking insurance.

If the entire law is struck down, Congress may act quickly to reinstate some of the provisions that generate revenue or are valued by the public, or gridlock may continue. This debate will play out alongside presidential and congressional elections in November. Everything could look completely different politically in 2013.

So, although the future of health care for the current uninsured is uncertain, it is a fact that ACA implementation is under way. This is evident on many levels:

- Over 2.5 million young adults have enrolled in their parents' insurance plans.
- 129 million Americans have gained coverage as a result of the elimination of preexisting condition restrictions.
- Demonstration projects have been initiated to improve care and reduce costs in Medicare and Medicaid.
- The federal government has received revenue from the private sector in various ways.

Significantly, many states have already begun to evaluate and

prepare to implement state-based insurance exchanges – a more organized and competitive market for buying health insurance. As of March 2012, thirteen states plus the District of Columbia had legislatively established state-based exchanges while 3 more states have announced their intent to create these entities.<sup>1</sup> For those states that move forward with exchange implementation (regardless of the Supreme Court decision), the health policy field will benefit from very public case studies.

The exchanges will be organized at the state level while incorporating a federally defined basic level of care (the Essential Health Benefits). Per the ACA, the state exchanges must address 10 service categories<sup>2</sup> but their average standard of care is driven by local standards (based on small and large employer plans, Medicaid plans, and the federal employee health benefits program). And, the insurance providers in each state will have to propose plans that relate actuarially to that average standard of care. More information is available online at: <http://cciio.cms.gov/resources/regulations/index.html#hie>.

Watching these state implementations raises interesting policy questions that today's scholars might want to

consider. Here are a few and I suspect you can think of more:

- Can the states tailor care standards to their specific populations and achieve better outcomes because of variability between state plans?
- What state model of basic services provides the best outcomes for the overall population as well as specific patient populations?
- Do exchanges work without federal subsidies (if the Court strikes down the ACA) or can state-level oversight drive improvements in quality and reductions in cost more rapidly and effectively than the federal government (if the Court upholds the ACA)?

*Karen L. Friss, BS, MBA is Senior Director, Global Public Policy at Eli Lilly and Company.*

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## Accountable Care: Will it Transform Health Care Delivery?

By Allan B. Goldstein, MD, MPH

### What is an Accountable Care Organization?

The Patient Protection and Affordable Care Act describes an Accountable Care Organization (ACO) as a group

of providers of services and suppliers “willing to become accountable for the quality, cost, and overall care of the Medicare beneficiaries assigned to it.”

Additional characteristics of the ACO include a formal legal structure with shared governance; appropriate

*(continued on page 4)*

leadership and management structure; processes to promote evidence-based medicine, patient engagement, and care coordination; mechanisms to report on quality, patient experience, and cost measures; and creation of an environment of patient-centeredness.<sup>1</sup>

Although other ACO definitions and descriptions have been formulated, the common denominator is that *provider groups* working together will be *accountable* for a *defined population* and employ *measurable outcomes* as criteria.<sup>2</sup> The accountable care model takes many of the disparate threads of health care reform and weaves them into an integrated fabric. From another perspective, accountable care may be viewed as a health care delivery model that optimally employs standardized processes and tools, measurement, and information-driven improvement to achieve its goals. Because a broad range of delivery systems meet these requirements, the ACO structure allows for both flexibility and diversity in delivery system design as we learn more about this model and refine it based on experience.

### Key Organizational Competencies

Organizations may need a tool to help them understand what it means to be an ACO, as well as to evaluate the status of their current operational capabilities and to identify the gaps they must fill to qualify as an ACO. One such benchmarking tool, developed by Premier Inc., has established 6 key organizational competencies required to perform the functions of an ACO (Premier Accountable Care Organization Capabilities Framework Assessment Tool, unpublished data, 2011). These core competencies are shown in Figure 1.

Each component is divided into *Capabilities* and subdivided into

*Operating Activities*, each of which constitutes a discrete core competency the organization must develop to become an ACO. With more than 150 operating activities (Premier Accountable Care Organization Capabilities Framework Assessment Tool, unpublished data, 2011), the task of organizational transformation to an ACO will be a prodigious undertaking.

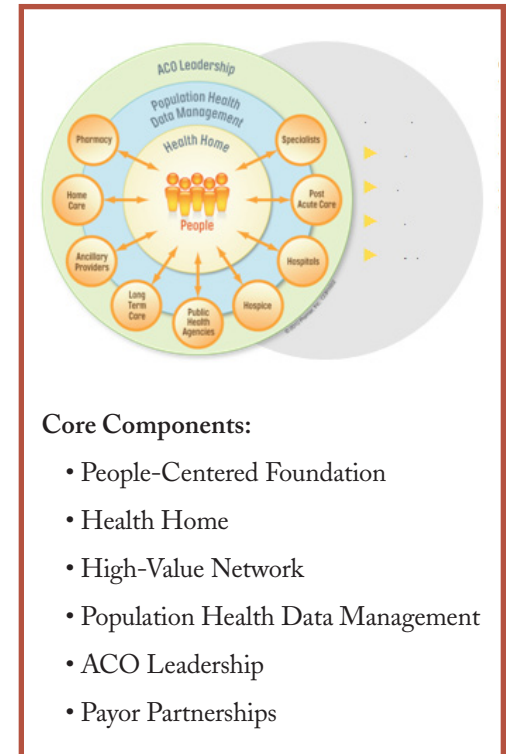
Figure 1 provides a visual representation of the relationships among these key components as interpreted by Premier's Accountable Care Collaborative.

### Regulatory Constraints

On March 31, 2011, the Centers for Medicare and Medicaid Services (CMS) published proposed rules for Medicare contracting with ACOs.<sup>3</sup> Following receipt of extensive feedback from a broad range of stakeholders regarding the regulatory constraints imposed by the proposed rules, CMS published final rules governing the implementation of the Medicare Shared Savings Program (MSSP) on November 2, 2011.<sup>4</sup> Four requirements in the final rules represent significant obstacles to provider entities that are considering creating ACOs to serve the Medicare population.

First, CMS acknowledged that provisions of the Physician Self-Referral Law, the Federal antikickback statute, and the civil monetary penalties law “may impede development of some of the innovative integrated-care models envisioned by the” MSSP.<sup>5</sup> In conjunction with the Office of the Inspector General, CMS established 5 unique waiver requirements covering a variety of arrangements that ACOs might need to undertake in order to be successful at carrying out the MSSP.<sup>6</sup>

**Figure 1. The Accountable Care Organization: Conceptual Architecture**



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The Internal Revenue Service has provided guidance for 501(c)(3) not-for-profit corporations that participate in the MSSP through an ACO, enumerating those circumstances under which the not-for-profit entity could avoid impermissible inurement or private benefit that would adversely impact its status.<sup>7</sup> Organizations forming ACOs also must satisfy state anticompetitive rules. Creating a legal and governance structure that conforms to all the regulatory requirements will be a challenging early step for prospective ACOs.

Second, beneficiary assignment for the MSSP will be retrospective based on the “plurality of their primary care services during the performance year.”<sup>8</sup> CMS acknowledges the challenges this creates for the prospective ACO that must develop and implement a

population management strategy for a population that is defined after the fact.

Third, in response to extensive comments and criticism of the proposed quality reporting requirements, the final rule requires ACOs to report on 33 quality measures (instead of 65) spanning 4 quality domains (patient/caregiver experience of care, care coordination/patient safety, preventive health, and at-risk populations).<sup>8</sup> Although this reduction in the number of reportable quality measures (and employment of nationally endorsed measures already in use) mitigates the magnitude of the data collection and reporting requirement for ACOs, 33 measures represent a significant administrative burden for most organizations. In addition, there is concern that ACOs will manage to the metrics rather than focusing on other meaningful process improvements that may not impact the metrics.

Fourth, ACO receipt of shared savings is subject to meeting quality performance targets and exceeding a minimum savings rate of 2.0%-3.9% below the applicable benchmark. The ACO will be eligible for a maximum shared savings rate of 50% (1-sided model) or 60% (2-sided model). Calculation of benchmarks and actual payments from CMS will be subject to a variety of adjustments that may make cash flow projections difficult.<sup>9</sup>

Organizations will be required to make substantial up-front investments to create the requisite ACO infrastructure. However, it may be several years before the ACO generates savings and it remains unclear if the savings realized will be adequate to repay the initial investment, motivate behavior change by providers, or create a sustainable business model.

### **Critical Challenges to Accountable Care Deployment**

In many localities, the hospital is the only care delivery entity with the organizational and financial resources to develop an ACO. Hospitals have been acquiring primary care and select specialty practices at an accelerated rate over the last several years. Collaborations between hospitals and physicians have a troubled history marked by mistrust and competition for lucrative services.<sup>10</sup> Converting physicians to hospital/health system employees does not obviate the need to align physicians' goals with those of their new employers and to make necessary attitudinal and behavioral changes. Many physicians may fear their loss of autonomy, and resist efforts to standardize care delivery processes and measure performance against objective metrics. Overcoming such resistance will be essential to ACO success.

Establishing the infrastructure necessary to support an accountable care delivery system will require considerable capital investment. CMS has estimated the initial ACO development investment at \$1.8 million, but the American Hospital Association estimates that \$5.3 to \$12.0 million will be needed, depending on system size and complexity.<sup>11</sup> These figures do not include the ongoing cost of ACO operations, which is estimated at \$6.3 to \$14.1 million annually. These costs will be incurred regardless of the ACO's success or its ability to earn shared savings. Despite such substantial investment, organizations have no guarantee that there will be a return on investment or that accountable care represents a sustainable, long-term business model.

Accountable care will challenge the basic tenets of today's health care system. Although providers are currently paid

on a piecework basis, they can expect numerous efforts to foster alternative payment mechanisms. Long viewed as a major revenue generator for the delivery system, the hospital will become a cost center, as will all other care delivery settings. Hospitals will become the focus of intense efforts to eliminate waste and duplication with the goal of maximizing system efficiency and value.

Transforming to an accountable delivery system will not occur at a fixed point in time. Rather, it will occur over an as yet undetermined span of time. During this transition phase, providers will be operating in a care delivery environment with a split personality. Managing through that transition will be one of the most difficult challenges for future ACOs.

### **Opportunities for Early Success**

The Health Home represents a major innovative advance in primary care and is a foundational prerequisite for a successful ACO. Despite significant energy and resources currently dedicated to Health Home deployment, these transformed practices still represent a small fraction of the primary care delivery system. ACO deployment can facilitate and support the rapid expansion and adoption of Health Homes, resulting in higher quality, patient-centered care. Embedding case management services within the Health Home and concentrating efforts on the sickest patients will improve coordination of patient services and reduce costs.<sup>12</sup> In addition, coordinating care transitions can dramatically reduce hospital readmissions.

A corollary to ACO implementation is the commitment to make clinical quality improvement part of the organization's core business strategy. Reduction of unwanted variation in physicians' practices is an excellent place to begin these efforts. By selecting high-volume, high-cost

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treatments and focusing on care delivery processes, the organization can embed evidence-based clinical practice guidelines into the flow of clinical activities. With 20 years of experience using this model, Intermountain Healthcare estimates that it can reduce clinical costs by 6%-10% while improving clinical outcomes.<sup>13</sup> Once physicians are provided with relevant, actionable information and see the impact of process improvement activities, they will drive most of the changes themselves. Process improvement has been shown to reduce the frequency of adverse events and avoidable deaths in the hospital.<sup>14</sup>

### Potential Downstream Consequences of Adopting Accountable Care

Many changes will occur in the health care landscape over the next 10 years. The adoption of ACOs is expected to accelerate the pace at which these changes take place.

In the future, US health care will be dominated by competing, vertically integrated delivery systems comprising a diverse group of provider stakeholders and, potentially, insurers. The integrated delivery system will be a risk-taking entity accountable for a defined population of patients. Customer service will be a foundational element of the delivery system and critical to its success. System performance will be measured using broadly accepted cost, quality, and patient experience metrics.

The Health Home will be the system point of entry and the center for care delivery and coordination. Disease and case management services will emanate from the Health Home. Primary care practices will be larger and linked into self-managing networks. Non-affiliated solo and small group practices will not be financially viable business options. An increasing percentage of patient encounters will be provided by e-visits, group visits, and in the home setting.

Reimbursement systems that align incentives and reward performance will predominate. Fee-for-service reimbursement will be the exception rather than the norm.

Medical schools and hospitals will recalibrate projected manpower needs (both the number and type of practitioners), training, and deployment. Inpatient facilities will have fewer beds, a higher proportion of which will provide intensive care.

Those insurance companies that have not partnered or merged with an integrated delivery system will focus on core competencies of marketing and claims processing. Some will become vendors for other services such as disease and case management or actuarial services.

Currently, accountable care is the vehicle driving these changes. However,

if ACOs fail to meet the challenge, other economic, demographic, and governmental forces will step in. In any event, transformation of the American health care delivery system is inevitable.

*Allan B. Goldstein, MD, MPH, is the Founder and Principal, Goldstein Health Care Consulting, LLC. He can be reached at: allanbg626@gmail.com.*

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## Health Care Payment Reform: A Look Ahead

By Cary Sennett, MD, PhD

The public debate about raising the federal debt limit—and Standard and Poor's downgrading the rating of federal bonds—have contributed to a growing consensus that controlling federal spending should be an urgent national

priority. Controlling federal spending on health care must be a central part of that.

Figure 1 lays out the issue visually: the Congressional Budget Office projections for federal spending (as a percentage of

gross domestic product) show inexorable growth to levels that are clearly unacceptable. But, when the spending is broken down into its components, we see that the projected growth is driven entirely by outlays for health

care; specifically Medicare, Medicaid, the state Children's Health Insurance Program, and projected subsidies for the Health Insurance Exchanges created by the Affordable Care Act (ACA). The problem of rising health care costs is not merely a threat to health care; it is a very real threat to the sustainability of the American economy.

Long-term control of health care costs—or, more desirably, long-term improvements in the value of health care—will require fundamental reform of our health care system and, in particular, fundamental change in the organization and operation of health care delivery systems across the country. Given the indispensable role of physicians in delivering health care and shaping the processes through which it is delivered, it is inconceivable that necessary changes can take place without the active and willing participation of those who practice medicine. And therein lies the concern; many physicians are neither active nor willing partners in effecting the process changes that must accompany health care reform.

Health care reform is seen by some as a threat to physician income. The new law is, after all, the Patient Protection and *Affordable Care Act*, and *affordability* can translate into pressure on the incomes of all health care providers. More often though, health care reform is equated with *accountability*; indeed, many people think that “ACA” stands for the *Accountable Care Act*. For physicians, accountability has come to mean public reporting, compliance, and the considerable costs associated with them. It should come as no surprise that, as they are understood by physicians, *affordability* and *accountability* offer little to make health care reform an appealing and attractive proposition.

#### Solving the Problem: The Central Role of Payment Reform

Although improving the value of health care will require movement on several fronts, new ways of paying for care are likely to be central to efforts. Clearly, delivery system reconfiguration is the “end game” but, as Donald M. Berwick, MD put it, “Every system is perfectly designed to achieve exactly the results it gets.”<sup>1</sup> Fee-for-service (FFS) payment for

health care services drives service volume and intensity. If we want a delivery system that drives value, we must change the way we pay for health care.

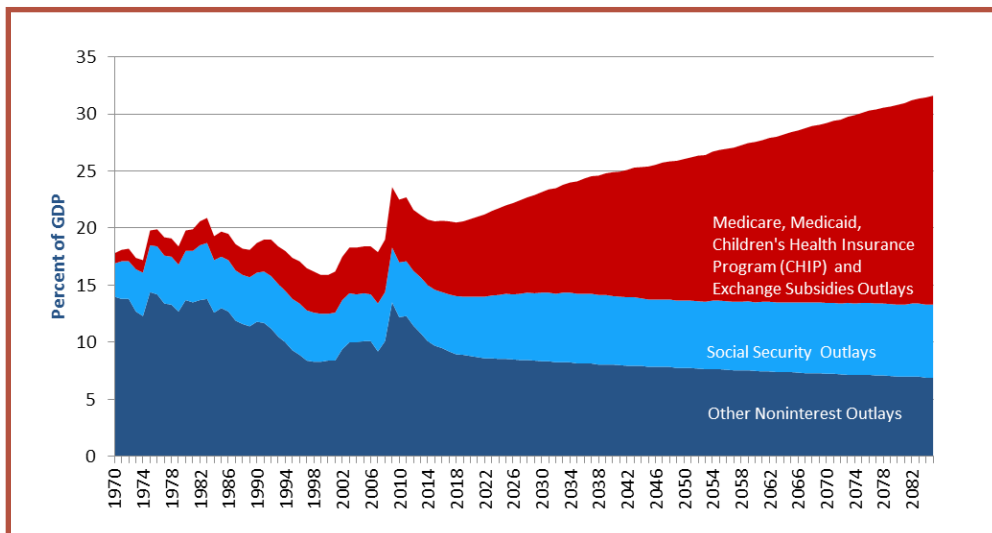
If there is any good news, it is that the political will to take on the issue of payment reform appears to have reached a tipping point. On one hand, the budgetary issues that have driven federal debt have intensified pressure to act. On the other hand, there is growing acceptance of the premise that the current formula for Medicare adjustments to physician payments—the “Sustainable Growth Rate”—is not “fixable” and that some other methodology must replace it. In fact, the Medicare Payment Advisory Commission has issued recommendations to move away “from the Sustainable Growth Rate System,” to “shift Medicare payment policies away from FFS,” and to “make FFS less attractive.”<sup>2</sup>

There are several alternatives that could “shift Medicare payment policies away from FFS”—alternatives that vary substantially with respect to the performance risk they create for providers. At one end of the risk spectrum is “salary.” Salaried physicians have income predictability, but very little upside (and virtually no downside) risk to that income. At the other end of the spectrum are “bundled” or “episode-based” payments, and global or “population-based” payments. Under these systems, physician income may have considerable upside potential but there often is considerable downside risk. Figure 2 is a brief, high-level summary of alternative payment strategies plotted along a risk continuum. Of course, variation is possible in each of these payment themes and the strategies for combining them.

Which strategy/strategies are “best” for achieving the optimal results? The

*(continued on page 8)*

**Figure 1. Actual and projected federal outlays as a percentage of Gross Domestic Product (GDP).**



Source: CBO's 2011 Long-Term Budget Outlook. Washington, DC: Congressional Budget Office; June 22, 2011. CBO=Congressional Budget Office, CHIP=Children's Health Insurance Program



evidence is still accumulating. It seems likely, though, that almost any strategy can work in some settings—and that almost none can work in all settings. So, the challenge will be to understand what type of payment model works best in a particular context or setting.

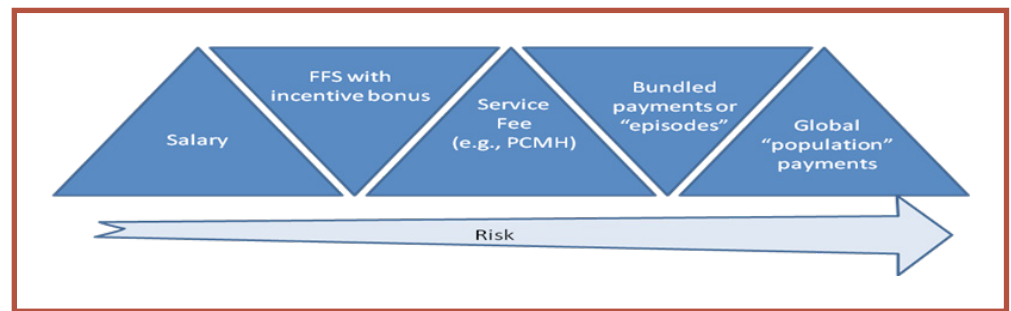
### Physicians and Financial Risk

Given the importance of risk as a motivator of change—and the variation in risk implicit in different payment models—it is necessary to consider how physicians respond to risk. Historically, physicians have not managed risk well, and many have been inclined to avoid it to the extent possible. At the limit, avoiding risk is best achieved through salaried employment, and we have seen more and more physicians embracing that model. But there are strategies to mitigate risk as opposed to avoiding it completely.

One such strategy is affiliating with an entity that is better prepared to accept and to manage risk. Physicians and medical groups are motivated to affiliate with larger, better capitalized (hence more risk-tolerant) organizations such as integrated delivery systems, physician-hospital organizations, and larger medical groups or Independent Practice Associations, which function as large, virtual medical groups. As part of these larger entities, physicians are insulated from some of the risk that attends more advanced payment models.

At the other end of the spectrum, some physicians and medical groups have prepared (or are preparing) themselves to understand and accept financial risk, and are seeking to be paid in ways that offer significant upside opportunity. To manage risk, these groups had to acquire new actuarial and care management skills and invest in the information, knowledge, and care management infrastructure required to understand and respond to clinical risk. These

Figure 2. Payment Strategies as a function of Provider Risk



FFS=fee for service, PCMH=patient-centered medical home

investments require size and scale as well as considerable capital.

### Where Are We Headed?

We are in the early stages of a period of rapid change. The specific shape of that change is difficult to predict and, almost certainly, the course will be one marked by frequent correction. That said, I believe that there are certain givens or, at the very least, likely outcomes:

*- There will be progressive expansion of the number and intensity of risk-based payment options*

We are already seeing some experimentation, and I expect that promising models for replacing FFS will be scaled rapidly. Much of the experimentation is occurring in the private sector where pressure for change is intense, but regulatory constraints on innovation may be less binding. It is very important to note that the Center for Medicare and Medicaid Innovation (“the Innovation Center” at the Centers for Medicare and Medicaid Services [CMS]) has recently announced a Bundled Payment for Care Improvement initiative,<sup>3</sup> which complements CMS’s Acute Care Episode demonstration.<sup>4</sup> Together, and with the construction of a Medicare-specific Episode Grouper (Section 3003 of the ACA requires that the Secretary develop a Medicare-specific episode grouper by January 1, 2012),<sup>5</sup> these

strategies suggest that Medicare may be able – and inclined – to introduce bundled payments into the mainstream of Medicare in the foreseeable future.

*- Vertical integration in health care will continue...*

Although the response to the Medicare Shared Savings Program (MSSP) may be limited, the marketplace clearly understands the inevitability of “accountable care,” and is responding in a variety of ways to create entities that are better able to coordinate care and manage risk. Although these responses are quite pleomorphic, many appear to be steps on a path toward structural integration: in particular, “clinical integration” achieved through the acquisition of physician practices by hospitals.

*...but there will be more and more virtual integration*

Structural integration is a vehicle to accomplish the coordination of care necessary to achieve better clinical and financial outcomes; however, it is only one way in which hospitals, physicians, and other providers can achieve those ends. Although they offer certain advantages, it is important to note that truly integrated systems (eg, Geisinger) are not built quickly and more nimble, virtual structures are likely to continue to emerge. Some of the models being developed in

the private sector<sup>6</sup> may be in response to the MSSP, and to the Innovation Center's Bundled Payment Initiative.

*- There will be many bumps in the road*

Although there is a path forward, the direction is clearer than the topography. At a time when there is intense pressure to respond, there will be some missteps. "Nimbleness" will be a critical success factor.

One of the central challenges that will need to be addressed—and one that can be anticipated and managed affirmatively—is potential resistance among practicing physicians. Physician resistance to change in payment and delivery system organization will, at a minimum, create inertia and friction. At the limit, they could cause gridlock.

Physician resistance is not inevitable but, for the reasons outlined earlier, is probable. In general, health care reform represents a threat to physicians who may perceive the cornerstones of reform—"affordability" and "accountability"—as forces that exert pressure on their income and autonomy. A recent survey

by the Massachusetts Medical Society suggests that the majority of physicians, for example, would not participate in a voluntary bundled payment program, and only about half would participate in a voluntary Accountable Care Organization.<sup>7</sup> At the same time, many physicians are dissatisfied with the current health care system, and many would welcome change if that change would allow them to practice medicine as the professionals they are.

So, among the critical requirements for making the necessary changes in the payment and delivery systems are:

1. An understanding of what physicians perceive as a better way to deliver care, and
2. Recognition that the tools and additional supports needed by physicians to reconfigure their practices must be made available in parallel with – or in advance of – the policy changes that will force the reconfiguration.

Transforming health care means changing the way physicians practice.

For success under the new set of rules that will guide the transformation, we must ensure that physicians are equipped with the knowledge and tools they need.

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## Rethinking Health Information Technology on the Journey to Personalized Medicine

*By Brett J. Davis*

Health care and life sciences organizations have long recognized the potential for a convergence of their 2 disciplines, envisioning a bidirectional information pipeline between bench and bedside that would facilitate the development of more personalized and effective treatments. For several years, the health care community has struggled to make progress on this front in the face of multiple challenges that

range from institutional objections to change, to security/privacy concerns, to inadequate funding, to technology limitations.

With global health systems under unprecedented strain, the realization of personalized medicine has never been more imperative – and, in the wake of breakthroughs in our understanding of biology at the molecular level, it has never been more possible.

Although the health care industry is poised for progress, a significant hurdle remains: Building the right information technology (IT) infrastructure to support the new data management challenges of this paradigm. Many IT systems being adopted across research and care domains today were not designed to permit the secondary data uses that are necessary for research and personalized care. To a great extent, these existing transactional systems

*(continued on page 10)*

support individual silos across the health science ecosystem that impede - and in many cases prevent - the integrated view of data that is essential for collaborative research activities including management of genotypic and phenotypic data, analytical secondary uses of health data, and the ultimate realization of personalized medicine.

To move forward, health sciences organizations must take a different approach to their health care IT infrastructures – an approach that enables large-scale reuse of the vast volume of health care information that is locked in today’s transactional systems. New platforms will be required to enable health care information exchange among organizations. New analytic solutions will be necessary to answer the most difficult questions in health care: What works, for whom, why, in what context, and at what cost? The next generation of health care IT systems has the potential to be truly transformational and usher in a new era of health care delivery but a critical first step is recognizing that today’s systems were not designed to get us there.

### **Industry at a Crossroad**

Over the past 25 years, the world has seen an unprecedented expansion of scientific knowledge as a result of breakthroughs in imaging, genomics, proteomics, diagnostics, and other disciplines. These breakthroughs promise to deliver precision medicine for some of the most complex and debilitating diseases (eg, cancer, Alzheimer’s disease, Parkinson’s disease) as well as prevalent chronic conditions such as diabetes.

At the same time, global health systems are nearing their breaking points. Like other developed nations, the United States is struggling with skyrocketing costs associated with aging populations and the management of increasingly expensive chronic conditions. The

United States also must address the serious issues of inconsistent quality and outcomes that are not commensurate with the dollars expended.

Even after accounting for variations in wealth, the Organization for Economic Cooperation and Development estimates that approximately 31% of total US health care expenditures are “excess” in comparison with other member nations.<sup>1</sup> In the United States alone, estimates of the tab for unwarranted care range from \$250 billion to \$325 billion annually.<sup>2</sup> Another example of “wasted” care is that many major classes of drugs do not work for a large percent of the population who take them each year. For example, 38% of patients with depression, 50% of patients with arthritis, 40% of patients with asthma, and 43% of patients with diabetes will not respond to initial treatment.<sup>3</sup>

Personalized medicine represents a potential way forward. It can help address cost and quality challenges by promoting targeted therapies and interventions for the patient populations most likely to benefit from them. If built using a data driven approach, it can sustain and accelerate new discoveries and innovations that advance prevention or improve outcomes.

### **A Perfect Climate for Change**

At a time when it is most needed, the health care industry is experiencing a convergence of developments that present an opportunity to achieve substantial progress on the path to personalized medicine. Each of these developments requires new information management platforms beyond today’s clinical systems.

First, scientific advances in the last decade are providing valuable insight into the reasons why some patients may be more susceptible to particular conditions and/or respond differently to specific treatments. With the completion

of the Human Genome Project, we have entered an exciting new era that is yielding a broader understanding of health and disease at a molecular level. We are realizing important benefits, such as the ability to assess genetic risk for certain types of cancer or to predict which individuals may react positively or negatively to a particular treatment. Most experts expect the rapid pace of advancement in scientific understanding to continue for many years to come.

The second important trend is a fundamental shift in the approach to health care reimbursement. For example, the United States has begun a transition from its traditional fee-for-service model to a pay-for-value approach that rewards outcomes. The Patient Protection and Affordable Care Act of 2010 (ACA) will expand a number of programs that were piloted by the Centers for Medicare and Medicaid Services in the last decade. Specifically, Medicare’s launch of the Hospital Value-based Purchasing Program in October 2012 will mark the beginning of a fundamental shift in how Medicare pays health care providers and facilities. Under the new program, US hospitals will be paid for inpatient acute care services based on care *quality* - not just the *quantity* of the services they provide. Many private insurers are also experimenting with new reimbursement strategies that reward value and outcomes.

Finally, comparative effectiveness research (CER) initiatives also factor into the mix of activities that are likely to reshape how health care organizations treat patients. The ACA authorizes the creation of a nonprofit corporation known as the Patient-Centered Outcomes Research Institute, the purpose of which is to assist patients, clinicians, purchasers, and policy makers to make informed health decisions through CER. The Institute supplants the Federal Coordinating Council for

Comparative Effectiveness Research, established under the American Recovery and Reinvestment Act of 2009, which allocated \$1.1 billion for CER.

### A Fractured Frame

With the necessary scientific and policy components in place to advance personalized medicine, the industry now must address the technological barriers. To be effective, health care organizations must reconfigure their information infrastructures to enable large-scale secondary use of the health care data that is locked in their existing transactional systems (Figure 1).

Secondary use of data captured in transactional systems across the health care ecosystem (eg, electronic health records, claims/billing systems, clinical trial management systems, research databases, clinical and laboratory systems) is essential to enable and accelerate the new paradigm of personalized health care. The information-based transformation of health care to a more personalized health care paradigm is conceptualized in the “learning health care framework” first introduced in a 2007 Institute of Medicine Study.

A majority of today’s health care IT systems were created to automate specific workflows (eg, research, back office, direct care); hence, they are fragmented from a data perspective. The secondary use of data captured in core transactional systems is required for analysis that affords insight. In order to support a rapid-learning, value-based, personalized health care paradigm, data from these source systems must be “freed” and aggregated for secondary data usage.

For example, there are many financial, supply chain, claims, and billing systems that can determine costs within a health care organization; however, these systems

cannot correlate these data with the actual cost of treating a patient for a specific condition or calculate the outcome of that treatment. The initial goal of capturing the data was to track a set of procedures in order to bill a payer and/or patient for the services rendered. In a value-based reimbursement system, organizations must be able to access, aggregate, and analyze these data to correlate costs and outcomes across patient populations.

The IT implications for this new paradigm are significant, particularly with respect to the need for secure exchange of data between systems and the analytics necessary to glean insights from the secondary use of the data in these systems.

Recognizing this need, the industry has begun to make the investments necessary to create interoperability between transactional systems and analytics platforms for the analysis of that data. As stated previously, most transactional IT systems adopted across the research and care domains today were purpose built (ie, not designed, developed, or implemented with the requirements of value-based personalized medicine in mind). These systems fall short on multiple fronts; most importantly, their failure to collect the necessary information in the right context and their inability to provide the necessary linkage between financial, operational, research, and clinical data and processes.

### Building a New Foundation

Value-based personalized medicine requires the ability to manage, integrate, analyze, and leverage clinical, financial, claims, and other biomedical information from across the health care enterprise and from external sources.

Two fundamental technologies will drive the transformation. The first is an interoperable health information

**Figure 1. Multiple Applications of Secondary Use of Health Care Data**

#### Health Care Providers

- Clinical quality initiatives and reporting
- Operational efficiencies
- Financial performance management
- Pay-for-performance initiatives

#### Pharmaceutical / Biotechs

- Comparative effectiveness
- Adaptive trials to support personalized medicine
- Consumer and physician engagement and decision support

#### Academic Medical Centers

- Translational, clinical, and comparative effectiveness research
- Collaborative and extra-enterprise research

#### Public Health

- Disease surveillance
- Comparative effectiveness and clinical utility studies

Adapted from *Transforming Healthcare Through Secondary Use of Health Data*. PricewaterhouseCoopers (PCW); 2009.

exchange that will aggregate and normalize data from core transactional systems and enable health care providers and researchers to act on it. In today’s multi-vendor environments, integration standards and repeatable processes are critical to providing adequate data management capabilities. Building the right infrastructure to support data collection, integration, and transformation is essential to enabling new insights.

The second essential IT component, enterprise analytics, will drive more productive use of secondary health data on a wide scale. In the business bestseller, *Competing on Analytics*, authors Tom Davenport and Jeanne Harris make important distinctions between capabilities that enable access and reporting and those that provide true analytical insights. Much of the business intelligence industry has focused on capabilities that enable reporting, structured or ad hoc queries, and

*(continued on page 12)*

alerts that make delivery of surfacing information to decision makers more efficient. Davenport and Harris point out that the next level of value will be through more predictive and optimization-oriented solutions and practices.<sup>4</sup> Their careful analysis of high-performing companies across multiple industries found a substantial correlation between the extensive use of analytics among high performers versus low performers.<sup>4</sup>

The same approach applies to the business and delivery of health care as well. Health care organizations require retrospective and predictive analytics that span enterprise data. Only then will they acquire the necessary insight to predict the likely outcome of a specific course of treatment for a specific patient in real time. With these tools, providers also may be able to gain a better understanding of the true cost of care and more accurately predict important outcomes such as the likelihood for readmission, the precise treatment for an individual's genotype and phenotype, or the risk of adverse events.

In the short term, the industry is deploying various stopgap measures. End users' need to glean some insights from existing transactional systems is driving investment in expensive, limited, one-off data marts and analytics environments. This, in turn, is generating more silos and complexity in health systems' IT environments. Without exaggeration, this is a very complex and thus expensive way to approach analytics.

As health care organizations come to realize the importance of analytics

systems, they are beginning to invest in enterprise-class, interoperable analytics platforms. This is true for biopharmaceutical companies, payers, and providers as well as academic medical centers. Health care organizations should think about these investments in the context of their trading partners. By investing in more robust information management architecture, organizations extend their ability to share data with other partners. In addition to leading to greater innovation, such investments can create new opportunities for collaboration.

### **A Platform Approach Accelerates Change**

Historically, the process of creating and implementing a data model, building an enterprise data warehouse, and creating customized analytical applications has been a very expensive and lengthy undertaking - one that is beyond the resources of all but the largest of health care organizations. In essence, this approach requires health care organizations to be software development shops. An alternative to this expensive, complex approach is a platform-based approach to analytics solutions. The move toward a "productized" platform enables enterprise analytical applications and reduces costs and implementation timelines, thereby making the technology more accessible for health sciences organizations of all sizes.

### **Conclusion**

Secondary use of electronic health care data can answer the hard questions in health care: What works for whom, why, in what context, and at what cost? To enable secondary use of health data and drive the advancement of

personalized medicine, health sciences organizations require an integrated view across disparate transactional systems. This calls for a robust enterprise model that is optimized for analytics versus transactions. Once such a model is in place, the use of well-defined and well-integrated analytics throughout the health care value chain can be transformative. Given the immense size of the data challenge, the distinctness and geographic spread of many health care-related activities, and the fact that so many health care activities are conducted by different companies and organizations that must interact with each other, there is really no other way to provide the tools necessary to enable and deliver personalized medicine and to control spiraling costs.

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