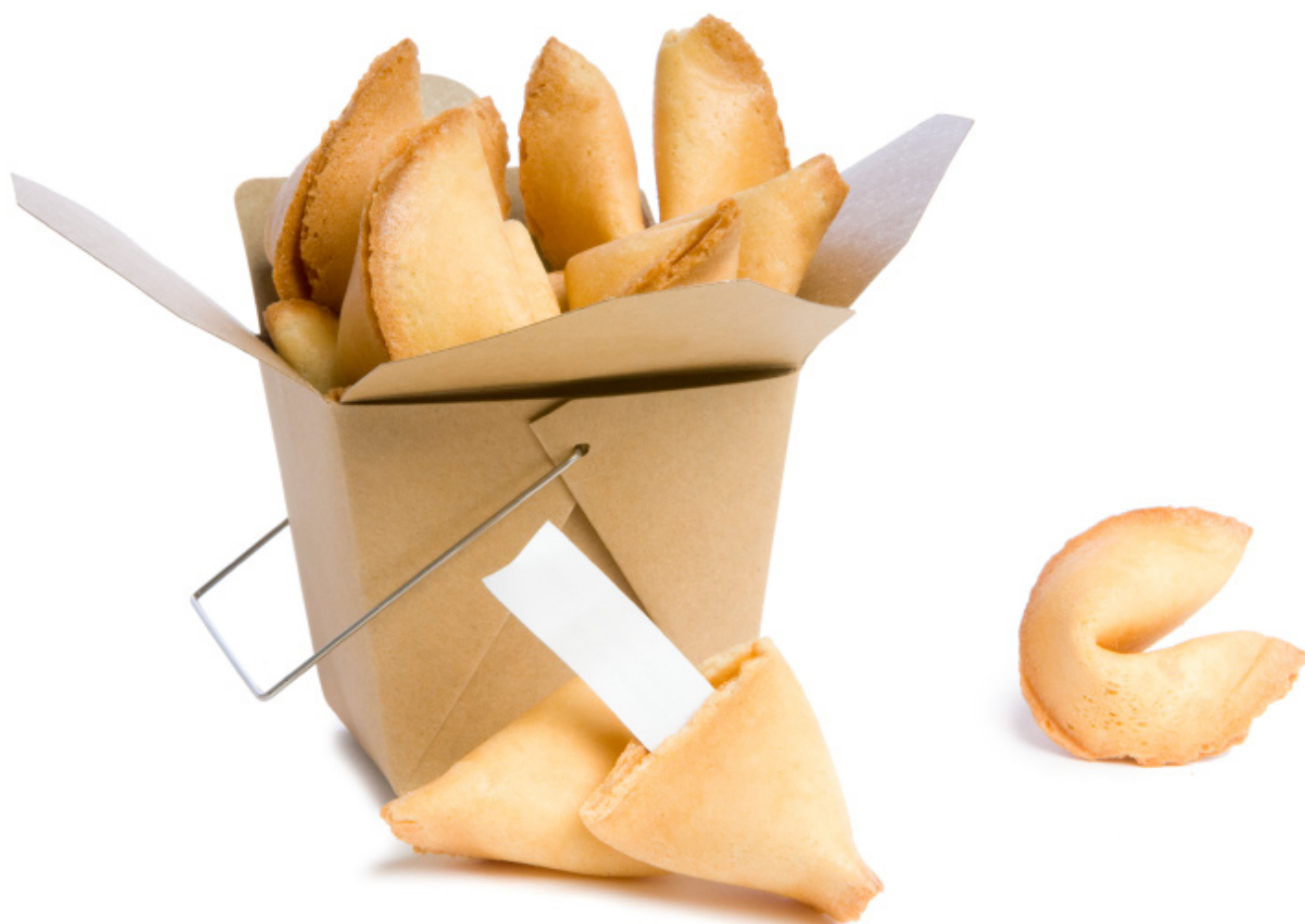


## 2009 Industry Outlook: Health Sciences Challenging Times, Emerging Opportunities





# Health Sciences: Health Care Providers, Health Plans, Life Sciences



Two equivalent forces – internal and external – are expected to generate both challenges and opportunities for the Health Sciences industry in 2009. From an internal perspective, escalating health care costs will continue to be problematic for employers and individuals: Health debt is responsible for half of involuntary bankruptcies and 1.5 million individuals are added to the ranks of the uninsured annually as employers drop health coverage.<sup>1</sup> External drivers will be evidenced by continued economic distress, government policy changes emanating from the 2008 elections, increased demands for transparency, and the integration of non-traditional players into the health care ecosystem. Now, more than ever, stakeholders in the industry's three major sub-sectors – health care providers, health plans, and life sciences companies – must balance

short-term needs to control costs, fill product pipelines and connect with consumers with the longer-term imperative to radically transform expensive, cumbersome and inefficient systems that threaten the sustainability of their organizations.

Among the major challenges that all three health sciences sub-sectors must monitor, evaluate and address in the coming year include:

**Continued economic distress** – The United States' economic woes are expected to extend well into 2009. For health care providers, this means the continuation of a worsening capital situation: higher interest and debt costs, lower endowments and investment returns and lower contributions. Expect to see increasing bad debt and charity in the provider space, which could strain organizations' compliance with debt covenants and generate tense discussions with bond rating agencies. In addition, tight credit markets could squeeze hospital construction and information technology projects. Merger and acquisition plans will either go on the back burner or be sought out of a need for survival.

Health plans are similarly stressed: The average premium increase for 2009 is projected to be just five percent – all the market will bear – and enrollment growth is anticipated to be zero, as increasing numbers of people lose their jobs and employers are challenged to provide more competitive health care benefits, and Medicaid benefit reductions mirror state budget cuts. This obviously will create tension in contract negotiations between the two sectors, both of which are under significant financial stress. While most health plans' balance sheets are in fairly good shape, some companies have written down investments by hundreds of millions of dollars and others face capital market risks in the form of debt refinancing which is coming due.

The life sciences sub-sectors – biotechnology, pharmaceuticals, medical devices – face similar, although unique, challenges because their markets are global. The economic downturn is certain to restrict access to capital for start-ups and early-stage ventures. Combinations via

<sup>1</sup> Paul Keckley, Executive Director, Deloitte Center for Health Solutions, December 2008

mergers and acquisitions are accelerating as a result of the tepid market for innovators and entrepreneurs seeking access to markets. Large-cap companies with established users are already seeing volume reduction as providers seek protection of thinning margins to access capital for more clinical programs and services. And the global economic meltdown is impacting the largest markets for drugs, devices and biotech, as Europe and Japan are both rocked by currency volatility and near deflation. Not surprisingly, R&D budgets are being cut and marketing programs curtailed to ride out the storm. Life sciences companies may be reining in 2009 performance expectations a bit and could find private capital harder to come by; however, when viewed against the typical 10 to 15 years it takes to develop a pharmaceutical product or medical device, life sciences companies can more easily absorb an economic "bump in the road."

**Government policy changes** – Health care reform will be a key agenda item for President Barack Obama and the 111th Congress in 2009. Election results suggest an appetite for change in the health care system that extends beyond providing health insurance for America's 47 million uninsured (16 percent of the population). The public wants more oversight of the system, and the policymakers and reformers now in power are expected to leverage this sentiment to shift dollars and focus. While the majority of legislative activity will take place at the federal level, it is important to note that state governors and legislators in 2009 also will need to address budget shortfalls in Medicaid, State Children's Health Insurance Program (SCHIP) and state employee health benefits – a particularly challenging situation since their constitutional spending power and revenue base are limited.

The current fiscal crisis will be a higher priority for the Obama administration in the coming year than health care system reform, so incremental but substantive redirection is likely rather than a major system overhaul. The biggest campaign promise to which Obama must respond in his first term is increased access to coverage for the under- and uninsured; fortunately, it is anticipated that Congress will afford Senator Ted Kennedy major support for legislation to extend coverage to the uninsured as his legacy. Demonstrating its commitment, the Obama health

team – headed by ex-Senate Majority Leader Tom Daschle as Secretary of Health – will work closely to accommodate provisions beyond children's care.

Lacking a filibuster-proof majority in the Senate, moderates in the Senate and House will have substantial influences on health care program changes and strategies. The framework of the Health American Act (Wyden-Bennett) will be considered a starting point for administration-moderate reconciliation discussions and lay the pipeline for major changes to support a health care industry transformation. These changes are likely to include:

- setting the stage for a comparative effectiveness platform to reduce inappropriate variation and costs for surgery, diagnostics and prescription drugs;
- increasing the use of health care information technology (HCIT) and facilitating the widespread adoption of electronic medical records (EMRs) and personal health records (PHRs) to insure safety and quality, reduce redundancy and inefficiency, and to support e-prescribing;
- expanding the medical home model of delivering health care services, which will require hospitals to strengthen their relationships with primary care providers (PCPs); and
- shifting from episode-based payment for providers to reward coordination of care and avoidance of complications.

It is anticipated that the Obama administration could make more changes to the nation's health care system than have occurred since the 1960s. Of course, the government will face associated issues such as access to revenues from employers and/or taxpayers to fund increased health care spending; rationalization of care for the newly insured in expanded government insurance programs; potential expansion of health care regulatory agency roles; and integration and coordination of state and federal policies for health & human services programs, oversight and management.

Similarly, health care industry stakeholders could expect to see numerous issues arising from new government programs; they would be well-advised to monitor and participate in the legislative process as early and fully as possible. Potential issues include:

**Providers:** Medicare cuts; impact of comparative effectiveness and episode-based payment on physician credentialing, revenues for surgery and diagnostics; access to capital for clinical IT; likely integration of physicians and hospitals, prompting redeployment of capital; demonstration of community benefits and protection of tax-exempt status; capacity for newly insured enrollees in primary care.

**Health Plans:** Elimination of pre-existing condition provisions for denials; impact of insurance exchange/connector model; transparency of P&T, denial and eligibility decisions; transparency of quality, service and enrollee satisfaction; reduction of Part D premiums; expansion of regulatory oversight.

**Life Sciences:** Protection of direct relationships with providers versus increased government formulary influence; rationalization of R&D risk as a government leverage on pricing increases; impact of Medicare reforms on access to therapeutics; impact of comparative effectiveness to drug utilization; funding for personalized therapeutics and diagnostics; protection of IP in global markets; legislative action regarding biologic generics.

**Increased demands for transparency** – The growth of health care consumerism is generating a corresponding increase in demands for access to provider price and quality data that can assist consumers in making health care purchase decisions. To date, employers and health plans have taken the lead in advancing transparency efforts. Some providers are voluntarily starting to post prices and quality scores; all need to be prepared to address potential government mandates to do so. Also, the call for increased transparency is not confined to providers: Senators Chuck Grassley and Arlen Specter last year introduced legislation that would require medical device manufacturers, as a condition of receiving direct or indirect payments under Medicare, Medicaid and CHIP, to submit to the Secretary of Health and Human Services (HHS) on a quarterly basis data on average and median sales prices for all implantable medical devices used in inpatient and outpatient procedures. Driven by changes and federal and state policy, health sciences industry transparency requirements are expected to increase in the coming years; stakeholders should stay alert to evolving legislative policies.

**Integration of non-traditional players** – Some big names outside of the health care system – including Google, Intel, Microsoft, Verizon, and others – view its inefficiencies and high costs as opportunities to introduce disruptive innovations and capture market share. (Microsoft's Amalga, a Unified Intelligence System which provides clinical staff members with real-time, consolidated views of comprehensive patient information, is one example.) These non-traditional players share common characteristics that are found lacking in many established health care organizations: They are driven by innovation; have a global vision and operations; are technology-savvy; and stress strategic flexibility in planning, development and implementation. All three health sciences sub-sectors need to better understand these outside forces and their potential impact as industry game-changers. Lessons learned from other industries that have proceeded along a semi-manufacturing operating model clearly show that if someone comes along with a newer, better, cheaper product, they will take substantial market share from the established players. Health care is not immune to the disruptive forces that other industries face.

Beyond these shared issues, health care providers, health plans and life sciences companies will need to address numerous sector-specific challenges in 2009:

#### **Providers**

The news for health care providers in 2009 is more bad than good. If the economy continues to have problems, all industries will be negatively impacted, hospitals included. Also, Medicare cuts of 1-2 percent are programmed for July 2009, with implementation scheduled for October. Yet, even in the current environment there are still pockets within health care where providers can make money, particularly service lines such as orthopedics, cardiology, and some areas of oncology.

As they look ahead to the coming year, health care providers first and foremost must make sure they are financially stable. The typical provider is not an overly wealthy organization. Although hospitals and health systems generally manage expenses to revenues, and have been able to achieve thin, positive operating margins in recent years, the financial picture for 2009 looks murkier. Credit-worthiness will be tougher to achieve,



with anticipated near-term downgrades three to one over upgrades. Bad debt will increase as cash-squeezed consumers have difficulty paying their medical bills. In response, providers will need to focus on maximizing cash flow and revenues, minimizing expenses, and implementing operational improvement activities. They also may need to consider delaying certain planned investments, acquisitions or capital projects.

Provider supply chain, revenue cycle and health care information technology (HIT) initiatives in 2009 will need to be laser-focused to protect margins and access to capital. Also, hospitals and health systems are very labor-intensive – two-thirds of their operating costs typically are labor-related – so expect to see continued executive focus on identifying cost-saving opportunities in this area. These efforts could be complicated, however, by the sector’s continued talent shortage, especially among nurses, and the high (and increasing) level of unionization in provider facilities.

As mentioned earlier, calls for increased price and quality transparency will require provider attention in 2009, as will the growth of medical tourism – both inbound and outbound. Yet these issues pale in comparison with providers’ need to reduce costs, maintain margins and identify sources of capital to fund mission-critical programs and opportunistic acquisitions.

### Health Plans

Health plans in 2009 should focus on blocking and tackling as a way to navigate through the struggling economy. This means being extremely efficient, challenging cost structures, managing and allocating capital with an eye

toward liquidity and debt structure, and looking at all aspects of the way information flows throughout their organizations.

For many health plans, provider negotiations could be quite challenging in 2009. Providers are experiencing increased bad debt and ever-tightening margins, which can heighten tensions in contract discussions with health plans. Both sub-sectors’ financials are stretched, so health plans will have to be very effective in their contract negotiations. Strengthening relationships with plan enrollees can help health plans control costs and maintain revenue flow. For example, health plans can encourage members to use lower-cost, alternative care sites such as retail clinics and to participate in wellness and chronic care management programs, which offer both short- and long-term health and cost benefits. Health plans also should strive to enhance communication channels and support services for members to help build brand loyalty: All health plans will be eyeing possible avenues for growth in this challenging environment, and that includes luring away competitors’ members.

Concurrent with member service and retention efforts, health plans need to strengthen relationships with employers at the highest levels, particularly if they hope to slow the growth of independent wellness and care management companies. By working closely with senior management, health plans can demonstrate how a company can achieve lower costs and better outcomes by offering health-plan-provided wellness and care management services that are bundled with core health care plans for employees.

It is important to note that the ability to develop strong relationships with members and employers depends, in large measure, on understanding their needs and providing the products and services to meet them. Health plan executives can gain important customer and market insights by mining the wealth of data contained in their company’s information technology systems. As they look to maximize their IT investments in the coming year, executives should ask, “Do we have a thorough understanding of our customers and their needs? Do we know how our products compare to competitors’, particularly in emerging areas such as the individual

market? Can we provide exceptional, multi-channel customer service? Do we have the necessary information systems infrastructure to connect the dots?”

The health plan industry goes through cycles – whether it is due to the economy or federal deficits, every 15 years or so the industry sees a downturn. Fortunately, health plans have been very prudent in the past few years in building financial reserves. Some companies will perform well in 2009 but it will be harder to deliver results commensurate with previous years. Those health plans that differentiate themselves through product offerings and exceptional customer service will ultimately reap the rewards available in a tight economy. Where there is change, there is opportunity.

### Life Sciences

2009 is expected to be a guardedly positive year for pharmaceutical companies, biotechnology firms, and diagnostics and medical device manufacturers, as the life sciences sector focuses on transforming itself into the type of industry it needs to be going forward. Company strategies likely will include restructuring and moving to more efficient cost structures; investing in more effective and efficient processes for research and development (R&D), manufacturing, sales and marketing, and distribution; and increasing the emphasis on globalization. All of these actions are designed to improve the flexibility, agility and reach of life sciences companies as the industry transitions to a “niche-buster” versus “blockbuster” product development model.

Mergers and acquisitions (M&A), licensing and divestiture activity should move forward in 2009 as life sciences companies rethink what businesses they want to be in and how they want to evolve to compete in the future. Also, an increase in cross-border M&A, licensing and partnering could help to fuel U.S. companies’ aggressive entry into emerging markets such as India. As part of this expansion, however, companies will need to remain alert to potential supply chain and product integrity issues.

Innovation will be an important theme in the coming year; expect to see an increased level of technology applied to the industry, especially as the convergence between medical devices and diagnostics continues. In

addition, given the slowed innovation in new products and the ever-present need to fill the pipeline, the life sciences sector could see more companies incorporating generic and over-the-counter (OTC) drugs in their product portfolio strategies. Many are now working aggressively to capitalize on opportunities in the generics market. For example, a company that acquires a therapeutic near the end of its patented life can capitalize on existing channels and relationships to enter large markets via a genericized version of the product.

The economic dimension of filling the pipeline also remains an issue. How will life sciences companies be rewarded/incited for innovation when the government, consumers and health plans are trying to drive down the cost of therapeutics? Greater public scrutiny and more regulatory oversight around product pricing can work against innovation in the industry. In response, companies will have to become more efficient at keeping costs down. This includes behaving differently regarding R&D; for example, identifying new sources of innovation for basic research, increasing relationship-building with investigators funded by National Institute of Health (NIH) grants, using overseas resources for production, and moving to a variable versus fixed cost structure in an effort to only incur costs when they have associated revenues.

Finally, life sciences companies are facing growing challenges around their traditional, physician-focused sales and marketing model. Sales and marketing are all about creating demand. As the industry becomes more consumer-oriented, life sciences companies need to rethink the steps they take around demand creation. The markets of the future will be less physician-centric; other stakeholders will be involved in the product evaluation and purchase process and companies need to understand how to engage them. This will be particularly challenging in light of increasing regulatory constraints around patient education and information. In addition, the nature of the physician/manufacturer relationship is changing. The traditional reach-and-frequency models that worked for decades are being abandoned for lower-cost, more efficient, closed-loop, physician- and institution-defined relationships. Life sciences companies will have to work harder to confirm that their messages reach their intended consumer and provider audiences.

# Contributors

## Health Sciences

### **John Bigalke**

U.S. Health Sciences & Government Industry Leader

U.S. Health Plans Sector Leader

Deloitte LLP

### **Russ Rudish**

U.S. Health Care Providers Sector Leader

Deloitte LLP

### **Terry Hisey**

U.S. Life Sciences Sector Leader

Deloitte LLP

### **Paul Keckley**

Executive Director, Center for Health Solutions

Deloitte LLP

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