Paul Keckley

The executive director of the Deloitte Center for Healthcare Solutions discusses how the changing policy and reimbursement environment is likely to affect the biotech and pharmaceutical sectors.

A veteran in health services research with experience in both the private sector and academic medicine, Paul Keckley has a unique vantage point on how US legislative and political changes are affecting healthcare delivery. Here he highlights some of the most important developments in healthcare reform and policy and how they are likely to affect the industry.

How will US healthcare reform affect the drug industry?

Paul Keckley: I would say healthcare reform is challenging the industry in four major areas. One would be the new tax applied to drug companies, which started this January—a $2.5-billion-plus increase that provides rebates to states for Medicaid prescription drugs and over ten years will close the so-called doughnut hole in Medicare Part D [the coverage gap between the initial coverage limit and the catastrophic coverage threshold]. In effect, the drug industry is contributing about $80 billion toward health reform. Of course, the trade-off was that if large numbers of people were newly insured, you'd get back what you pay because more revenue is flowing into the system. But the question of how well those mandates and how well the numbers of previously uninsured enter the industry is still an unknown.

The second component in the law is the role of comparative effectiveness and the Patient-Centered Outcomes Research Institute, which has a broad scope to both evaluate the evidence around diagnostics and therapeutics and, on an annual basis by April of each year, go to Congress and say, here's how we see the strength of evidence for comparable therapies for comparable patient populations. Because there are so many variables in looking at efficacy and it's difficult to predict how the worlds of policy and public opinion might influence this, I think this could present challenges to drug development.

A third problem is the law basically says that the delivery system, meaning doctors, hospitals and long-term care providers, is to consolidate into risk-bearing, clinically integrated entities. The law talks about accountable-care organizations, bundled payments, medical homes and value-based purchasing. If you look at all of those, it's essentially saying that incentives for high quality and cost need to be shifted from volume-based payments to results. This puts a lot of pressure on the cost structure and the delivery system.

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So we should expect doctors and hospitals to become much more aggressive in their contracting and direct negotiations with the drug industry in the supply chain.

And then, lastly, there's a substantial amount of change in the insurance industry, which has to reengineer itself and operate very differently through health exchanges. They have to take on a lot of additional cost to be in compliance with the law, so the negotiations between the health insurance industry and the drug industry are going to become much more challenging.

What factors might affect the prescription drug market following reform?

PK: There are four major unknowns in the health reform legislation. The first is the individual mandate and whether that successfully convinces the 32 million people who are currently uninsured to become insured. Is the penalty stiff enough? Will the market swell with people who are already sick and high cost, or will it be younger or healthy people? That's one big bet. The second is the employer pay-or-play mandate. Does the building up of these health exchanges and these insurance industry changes, coupled with the employer pay-or-play provision of the law, mean that large numbers of employers will stop providing health insurance to employees and individuals buy insurance through these exchanges? In other words, do you see employers exiting health benefits? Third, each US state bears a substantial financial responsibility to implement the law, and yet last year they had [a] $126 billion deficit. So can the states do everything that's expected, given their shortfalls? And then, lastly, the changes proposed in the healthcare delivery system, from more siloed medicine to a more consolidated model, does that have the result of improving care or does it add cost?

What about prescription drug user fees?

PK: We will see dramatic increases. Much more so than the past because, given the US economic situation and Congress's appetite to curb spending, the Food and Drug Administration's [FDA] budget will face big cuts. The only place the FDA can go is to industry and raise its industry fees. So companies should expect substantial spikes in industry fees.

What do you see as the most profound changes to healthcare going forward?

PK: One would be applying evidence to care—the alignment of the evidence with the process of delivering care—because we have a substantial gap between the evidence and the care we deliver. Second is resource allocation. We have finite resources. We can't do everything, so where do you focus? Third would be, I think, public support. I think what is problematic in many markets is that consumers really don't think about the health system. They react anecdotally to their own experiences with doctors, hospitals, drugs and insurance, but they don't have a systemic view. They don't step back and say maybe of the two treatment options where the evidence is equally strong, the cheaper of the two is the one I should pursue. They're more inclined to basically default to the doctor's judgment and go with whatever recommendation they're given. I think we've got a gap in consumer engagement in the system. We've got a fundamental limit on resources forcing us to make tough decisions, and the alignment of the evidence with practice is maybe the biggest hurdle of all.