

## How ACA Could Transform the U.S. Pharmaceutical Marketplace

By Jerry Gacciotti  
and Mark Mozeson

The day after the passage of the Affordable Care Act (ACA) felt like a victory lap for pharma. In previous health reform initiatives pharma industry executives had been largely excluded from shaping legislation. This time they were deeply involved. In exchange for industry user fees, extended Medicaid rebates, and a closing of the doughnut hole, pharma received access to a larger market: ACA decreases the ranks of the uninsured, increases government subsidies, improves access to healthcare, and offers favorable treatment of exclusivity for biologics. As the political dust settled, the general feeling was that the industry had escaped relatively unscathed. The net impact of the provisions specifically directed at pharma was expected to amount to 2 to 3 percent of U.S. revenues for most companies—a small price to pay for a larger insured market.

But as we consider ACA's long-term effect on healthcare, it appears that the feeling of victory was premature. Factor in the full range of reform-related changes, and the impact on the typical pharma company looks significantly higher—as much as 20 percent of U.S. revenue. That's \$2 billion at risk for every \$10 billion in U.S. sales. While there is still significant uncertainty about how reform will be altered by rulemaking and further legislation, a transformation of the healthcare system is now inevitable. The industry faces a fundamental imperative: healthcare costs in the United States are growing at an unsustainable rate. If changes driven by ACA don't succeed in "bending medical trend" over the next decade, the whole

care system—pharma along with payers and providers—will face draconian measures to control costs. Pharma has no choice but to ready itself.

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In a sense, ACA is both a platform for changing healthcare’s economic model and a reflection of a broader process of change—one that already has significant momentum. The system will not and cannot change overnight; it will take several years just for ACA’s full impact to be realized. But as reform touches different parts of the market, we believe it will transform them. Specifically, as we observe the dynamics created by reform, we see five game-changing transformations:

1. The shift to value and the greater risk providers will assume
2. Diminished economic viability among payers
3. The shift of health insurance to a retail marketplace
4. Increasing state influence (Medicaid and exchanges)
5. Dramatically enhanced liquidity of health information

These transformations will reshape how healthcare is bought, sold, and delivered in the United States. How and why will they affect treatment and expenditure? And, most important, how should pharma companies adjust their strategies now and over time to position for maximum advantage? These are the central issues that pharma needs to address to mitigate risk and create opportunity in the post-reform world.

#### **Reform Timeline: 2010**

- *Expansion of Medicaid rebate*
- *Reduction of Medicare Retiree Drug Subsidy*
- *PCORI established*

## 1. The Shift to Value and the Increasing Role of Providers

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**What's happening:** Over the last two decades, payers have made many attempts to contain costs within the fee-for-service model. Their efforts have produced few results, for two principal reasons: (1) physicians have retained substantial power to determine what treatment is delivered and how, and (2) they have had little direct incentive to choose treatment pathways that drive better health value. In some settings, fee-for-service incentives push them in exactly the opposite direction: to provide more care to those covered by insurance and to use higher-cost procedures when cheaper ones would suffice.

ACA recognizes providers' central role in driving (or containing) costs. It provides specific incentives for providers to form coordinated care entities called Accountable Care Organizations (ACOs) in a bid to force the system to deliver better value. ACOs will contract with health plans to cover the treatment needs of specific patient populations at a fixed reimbursement rate reflecting historical costs and adjusted for population-specific risk. If an ACO is able to deliver care for less than the target rate, a portion of the savings generated will drop to its bottom line. Provider organizations will now have the greatest exposure to cost risk, but also the most to gain through more rational allocation of healthcare dollars.

While it is not easy to make the transition to a value-based system (also known as fee-for-value), many provider organizations find it attractive, for several reasons:

### Reform Timeline: 2011

- *Coverage for preventative and in-home services*
- *Significant rebates to close the doughnut hole begin*

- Under fee-for-service, payers have tried to control cost without fundamentally changing the way care is administered, putting increasing pressure on provider margins.
- Although providers bear a greater portion of clinical risk under the new model, they are better positioned than payers to make “high value” clinical decisions and appropriate tradeoffs.
- Providers will for the first time have the opportunity to profit from more cost effective health outcomes.

As ACOs and other integrated models take hold, we anticipate a fundamental shift in how risk is managed in healthcare delivery. Payers will retain substantial selection risk—relating to the health status of specific covered populations. For their part, providers will increasingly bear clinical risk—relating to decisions about what care is delivered and how. Overall, we expect that up to \$500 billion in

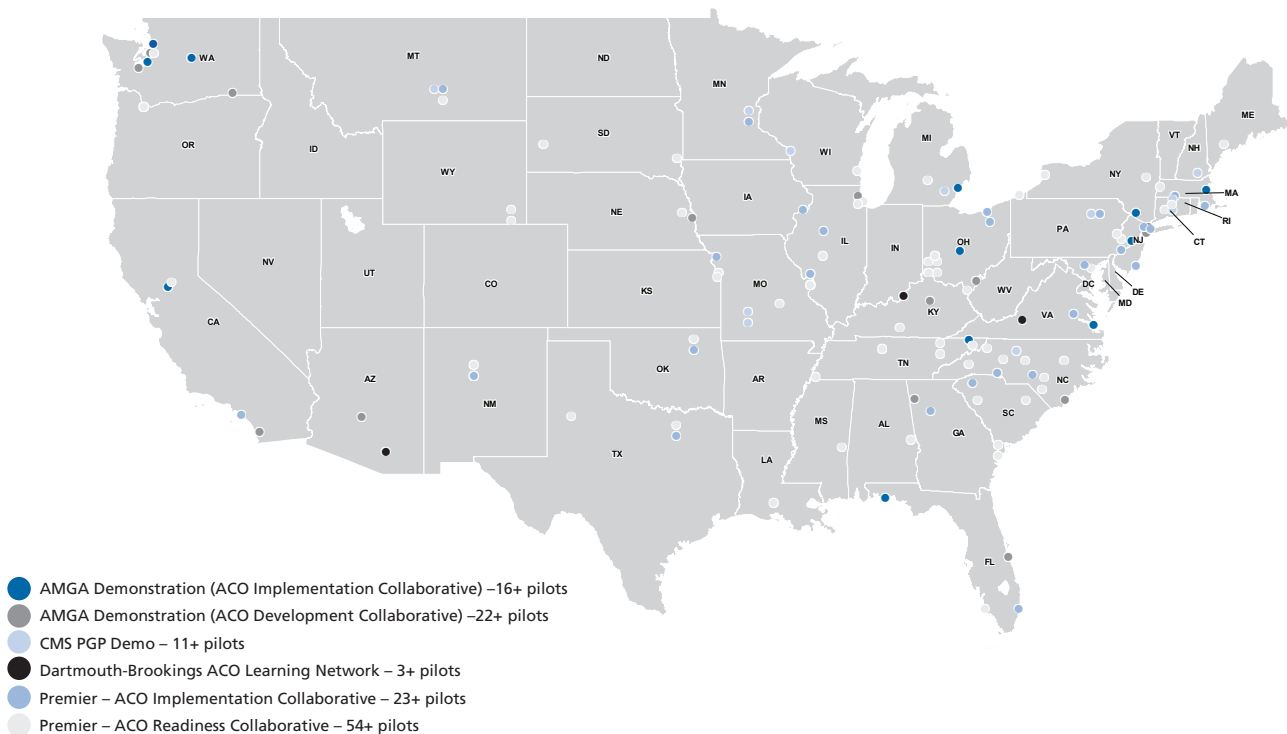
clinical risk will shift from payers to providers over the next five years—roughly 20 percent of the costs currently managed in the U.S. system.

**ACOs are just one approach to value—albeit one backed by significant incentives—and additional models will likely emerge.**

Given the poor track record of prior efforts, there is no shortage of skeptics who doubt that ACOs—or any value-based provider model—can create real savings. But we believe they are overlooking a fundamental change that makes this attempt different from the rest: the alignment of payers, providers, and the government around cost saving. Already, more than 125 ACO pilots have formed in anticipation of the January 1, 2012 launch of the Medicare Shared Savings Program (see Exhibit 1). Some ACOs are focusing on specific high-cost disease categories such as cardiovascular disease. Others concentrate on high-cost episodic procedures, such as knee and hip replacements. Still others are working with high-cost patient populations, such as frail elders with multiple comorbid conditions. ACOs are just one approach to value—albeit one backed by significant incentives—and additional models will likely emerge. One way or another, we believe the shift to value is unavoidable.

### Exhibit 1: Where the ACO action is

As of April 30, 2011 there were approximately 125 pilot programs for accountable organizations in the United States



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And there are already models in the market where fee-for-value is producing results: Integrated systems like Kaiser, Geisinger, and Intermountain Health achieve better health value per dollar spent in many disease categories and present themselves as “already ACOs.” Major insurers—WellPoint, Blue Cross Blue Shield of California, and Blue Cross Blue Shield of Massachusetts—have established working ACO pilots and initiated applications to form Patient Centered Medical Homes and to establish bundled payments for conditions such as orthopedic care. In addition, WellPoint recently spent \$800 million to buy CareMore, a seniors-focused healthcare delivery system based in California. As we describe in the insert (“Why It’s Different This Round”), the financial pressure in the system, coupled with the real possibility of cost savings via more coordinated care, will drive future provider models toward value. By the end of the decade, health outcomes—specific measures of the cost and quality of care—will replace utilization as the driver of revenue and profits in our healthcare system.

**Why it matters:** The emergence of value-based providers gives pharma an entirely new customer segment. Over the next five years, we expect as much as 20 percent of healthcare spend to flow through ACOs or other integrated delivery systems. To serve this segment, pharma companies will need to develop new capabilities, shift marketing resources from other segments toward value-based providers, and develop a stronger value proposition to demonstrate the real-world cost-effectiveness of their therapies. They will need to embrace new models for sharing risk and value with tomorrow’s provider organizations—organizations equipped with new transparency on costs, and increased, direct incentives to manage them.

#### Reform Timeline: 2012

- *MLRs take effect*
- *ACO shared savings with CMS*
- *Reduced rebates for Medicare Advantage plans*
- *Form W-2 reporting for health coverage*
- *Benefits summaries distributed to employees*
- *Industry fees start for pharma*
- *Hospital reimbursement tied to quality measures*

Adding to the challenge is the rapidly shifting ACO landscape: New organizations are forming rapidly and have yet to define a preferred model for engaging with pharma. Will ACOs leverage PBMs to manage spend, as payers have done, or will they directly engage pharma manufacturers? Will ACOs provide pharma with new opportunities for collaboration via outcome-based pricing or risk sharing arrangements? Will they become “enlightened” partners, driving adherence to therapy and ensuring appropriate use of medicines, or will they simply treat pharmacy spend as another cost to be managed down? In the short run, pharma companies need to decide whether to try to drive the engagement model in a particular direction or wait to see what emerges.

It might be tempting for pharma to cling to fee-for-service, but we see that as a losing proposition. We believe the industry should experiment proactively with ACOs and other integrated, value-

focused models. In the short run, every company should identify the areas in its portfolio most likely to shift toward fee-for-value. For example, segments such as respiratory and cardiology will move faster toward fee-for-value than areas where the overall cost exposure to payers and providers is low—anti-infectives, chronic pain, and even rare diseases (for which payers largely reinsure). In most cases, the list will focus on:

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- High-total-cost disease areas such as diabetes, congestive heart failure, and neurodegeneration
- Chronic conditions that generate significant per-patient cost, particularly for treatment failures
- Disease categories in which drugs account for a significant percentage of payer spend, with the possible exception of oncology, where political sensitivity may slow this shift
- Highly competitive disease markets, which may provide opportunities to leverage personalized medicine, improved adherence, and prevention and wellness services

To gain advantage in a fee-for-value-based market, pharma needs to focus on how its customers define value. Value-based providers will give top priority to reducing the total cost of managing disease, providing earlier interventions to improve patient outcomes, and measuring the impact of different treatment modalities on long-term outcomes. To create a strong health value proposition, pharma companies will need to go beyond post-marketing observational studies and comparator trials. They must provide a hard economic rationale for using novel drugs, a direct cost-effectiveness comparison to other real-world therapy options (including generics), and a clear understanding of which patients will benefit most. That means they will need to think about providers and payers as key customers during the development process, just as they think about regulators today. New evidence requirements represent a challenge for clinical and commercial organizations that all must face and few have even begun to address. For many companies, appropriate movements on these dimensions will amount to a fundamentally different business model.

**Reform Timeline: 2013**

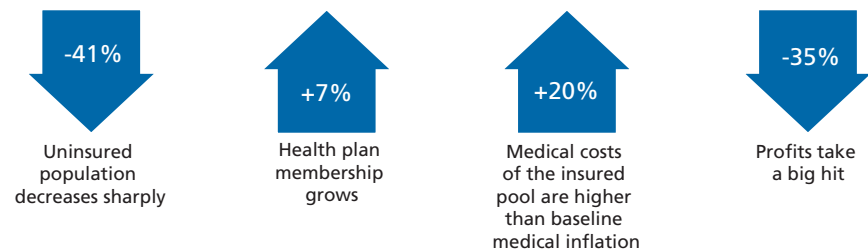
- *Higher Medicare tax on high income individuals*
- *Expansion of Medicare bundled payments*

## 2. Diminished Economic Viability for Payers

**What's happening:** One issue is emerging from reform with particular clarity: payers are under significant and increasing financial pressure. Oliver Wyman analysis suggests that when both direct and indirect consequences are considered, ACA could lead to the evaporation of more than one-third of payers' current margins (see Exhibit 3). Perhaps the most direct impact will come from ACA's provisions on Medical Loss Ratios (MLRs), which require plans to direct 85 percent of premium revenue in the employer market (80 percent in the individual market) toward medical costs. Other changes—such as the relatively weak mandate for individual coverage and requirements to cover preexisting conditions—will make it difficult for plans to select risk and raise the importance of appropriately managing that risk. In addition, reimbursement for Medicare Advantage and Managed Medicaid is expected to drop. With reduced pricing power and rising costs, payers will have a much smaller slice of revenues available to cover administrative costs and generate operating profit.

### Exhibit 2: Health plan margins are facing unprecedented pressure

The years following the implementation of healthcare reform will be marked by increasing membership—but also by rising costs and plummeting profits.



#### Reform Timeline: 2014

- Health insurance exchanges
- Rating rules implemented
- Individual coverage mandate; subsidies begin
- Medicaid expands
- Health insurance industry fees begin

What is not yet clear is how payers will respond and when. Most payers have not yet embraced drugs as a tool to advance the fee-for-value world, and we do not anticipate a major shift in the near term. The formulary, the tier, and the rebate will not suddenly vanish. But as integrated delivery systems start to view full-cycle disease cost more holistically, the most progressive will be open to the idea of drugs as a positive lever against cost. This “value-sensitive” segment of payers will insist on compelling evidence and will raise the bar on what “compelling” means. Pharma’s case for a role in the fee-for-value world will require credible evidence, tailored to the real-world health economic needs of individual payers’ businesses.

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**The high road—and the only win-win option—is to help payers move toward fee-for-value.**

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**Why it matters:** In the face of greater than 35 percent margin compression, payers will have no choice but to act more aggressively on all elements of cost in the system, including what they spend on pharmaceuticals.

The question for pharma is: Who has the leverage in a particular disease category? In areas where drugs achieve significant differentiation, or in areas of high unmet need where any therapeutic benefit is meaningful, pharma still has significant pricing power. Novel therapies in oncology, neurology, and immunology command prices of tens of thousands of dollars per year. For example, until recently there were no oral therapies for multiple sclerosis, and injectable therapies entailed significant cost and clinical risk. Newly launched Gilenya, the first oral therapy in the area, costs close to \$50,000 per year, about 30 percent more expensive than injectable therapies. We don't see this pattern changing dramatically under reform.

In many areas, though, pharma's pricing power has eroded significantly. Where there are many therapy options, particularly cheap, safe generics, payers increasingly have the leverage—and use it. Already we see payers looking to extend Medicaid rebate levels across the board. Pharma can't win in this game. The high road—and the only win-win option—is to help payers move toward fee-for-value—to create compelling evidence that drugs, used appropriately, can be a positive lever on cost and outcomes—and to share some of the risk and upside of medicine therapy with payers and providers.

We recognize that partnering with payers to move toward value is easier said than done. Twenty years of attempts have yielded scant results. The payers' traditional economic model—which treats in-patient care, outpatient services, and drugs as independent cost elements—has made it difficult to demonstrate the economic value of medicines. Other barriers have been membership churn and the lack of a watertight evidence to support the use of advanced, expensive therapies.

More promising results have been seen in Europe. Single-payer systems—with a more unified, long-term view of health value—do a better job of aligning incentives and ensuring appropriate use of evidence-based medical practices, including drugs. In these settings, we have seen the emergence of creative arrangements involving performance guarantees and outcomes-based pricing. Most often, the driver in creating these arrangements has been the government-as-single-payer, with the pharma company playing a cooperative partner.

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In drawing this comparison, we acknowledge that in the U.S., pharma is constrained in the kind of value-sharing structures it can use. The Robinson/Patman Act requires pharma companies to give identical treatment to all payers in a customer class. Anti-kickback provisions stipulate that any services wrapped into the delivery of value to a payer must be priced and factored into AMP, which in turn affects Medicaid best-price considerations. While these and other provisions stifle potentially value-creating arrangements, the implementation of reform offers an opportunity—and a motivation—to reconsider them.

Pressures on payer profitability should be a call to action for pharma. The health delivery system is entering a period of entrepreneurial activity and value-focused experimentation. Legislative and rule-making bodies are showing unprecedented openness to new models. Pharma as a whole needs to address its constraints and advocate rule changes to enable more productive engagement with payers. But real innovation won't come out of conversations between managed markets teams and pharmacy directors. Pharma CEOs and other executives need to engage directly with CEOs and CMOs of health plans on how they can work jointly to enhance outcomes and clinical value.

### 3. Health Insurance Goes Retail

**What's happening:** One of the most transformative aspects of ACA is the provision requiring states to create exchanges where uninsured individuals can purchase coverage. Oliver Wyman research suggests that, just as most employers abandoned defined-benefit pensions in favor of defined-contribution retirement savings plans two decades ago, over time many small and large employers will use the exchanges to limit their exposure to healthcare costs. Many will subsidize their employees' health insurance with vouchers, while some will exit the health-benefits game altogether. We predict that many small employers will shift their employees to the exchanges after they are allowed to do so in 2014, and a significant number of large employers will do so after 2017. As the post-reform market stabilizes in 2017-2018, we estimate that between 80 and 120 million people will purchase insurance through an exchange, a vast increase from the 17 million who purchase individual policies today.

To prepare for this shift, major insurance plans are already designing products tailored to early exchange participants. This "exchange-likely" population will come from insurance market segments that generate 60 percent of current profits and companies are developing benefit designs to meet the preferences and needs of millions of individuals.

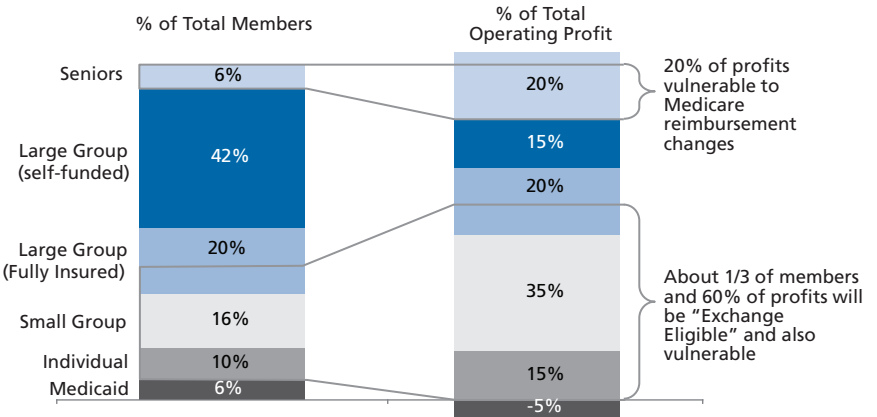
#### Reform Timeline: 2015

- *Physician reimbursement based on quality*

### Exhibit 3: Where ACA makes a difference for payers

In a typical health plan, about one-third of members, most of them in the small-group and individual markets, will be eligible to buy on the exchanges. But these members represent about 60 percent of profits—which will be threatened by the rules and the price competition of the new market.

The number of consumers potentially affected is staggering, and the window for action will not remain open for long.



**Why it matters:** As healthcare moves to more retail formats—on and off exchanges—product choice will be driven by consumers—not employers. Payers and providers alike will have to realign their business models to address consumer preferences and cost-benefit tradeoffs. This is a far cry from today’s market, where most healthcare is purchased wholesale, much of it with government mediation. The change is disruptive for payers and providers, and it will have an impact on how pharma companies market to consumers. Will there be an opportunity to create pull for medicines by targeting messages to consumers? Can pharma partner with plans to create “consumer-noticeable” benefits addressing areas of high need or preference? How should pharma leverage or adapt direct-to-consumer marketing strategies? While exchanges are still several years away, this is an area pharma should monitor closely: the number of consumers potentially affected is staggering, and the window for action will not remain open for long.

### 4) Increasing State Influence

**What’s happening:** It’s old hat for pharma companies to monitor state legislative activity, but ACA has given them considerable reason to raise their game. States are concerned about the expansion of Medicaid, the extension of consumer protection in healthcare, and the “budget buster” ACA. Officials are considering every possible option to rein in costs. Some governors are doing more than lamenting reform—they are going to court to fight it.

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Legal battles aside, early moves to implement ACA are raising vital questions:

- Will open-formulary states implement new restrictions on drug choice?
- Will cost pressures tip the balance of usage further toward generics?
- As state exchanges emerge, how will drug formularies be structured, and what options will consumers have?
- How will newly insured populations behave in the system? How can pharma most directly and expeditiously access pools of the newly insured?

**Why it matters:** The winners and losers in reform will be determined at the state level. Over the next few years, every pharma company will need to participate in legislative and rule-making processes in 50 states. That means they need to:

- Understand which states offer the greatest risks and opportunities.
- Tailor strategies to each state's specific economic and legislative climate—and the relative position of their own portfolios there.
- Use influence, advocacy, or other means to guarantee that their key branded products are included in drug formularies advanced through the exchanges and state Medicaid programs.

Each company will need to ensure that it has sufficient influence with the political entities shaping the implementation of reform. Defining and advancing a local influence agenda will require ongoing diligence, now and throughout the full legislation timeframe.

#### Reform Timeline: 2017

- *Large Employers exchange eligible (... and how many enter?)*

## 5) Health Information Liquidity

**What's happening:** Even before the passage of ACA, the healthcare information landscape was in flux, driven by billions of dollars in federal stimulus spending and private investment. The American Recovery and Reinvestment Act (ARRA) provided \$30 billion in incentives for Electronic Health Records deployment. HHS invested \$375 million in State Health Information Exchanges to enhance data sharing. ACA has accelerated the pace of change, by providing new investment in comparative effectiveness reviews, health IT backbone, and programs to measure and advance quality care. It will take time before the impact of these investments is realized, but the objective is clear: providing IT platforms to link payers, providers, patients, and other healthcare stakeholders, with the goal of increasing efficiency through the electronic exchange of patient information.

All of this means that an immense mass of traditional health information—recorded and stored on paper, transmitted by fax and on foot—is being digitized and made easy to communicate. The adoption of electronically mediated, evidence-based standards at the point of care will be an essential element of business models to standardize practice patterns, manage cost, and improve value for patients.

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**Why it matters:** As information becomes more liquid, new information sources and “health quality” stakeholders will emerge, bringing with them new standards for determining how treatment decisions are made at the point of care. Pharma needs to collaborate proactively with these new entities, working to generate value-based evidence that complies with emerging standards and seamlessly integrates into point-of-care systems—systems that will define quality and efficiency in a fee-for-value world. Companies need to ensure that information about their branded products is readily available everywhere. They need to go on the offensive against “expert” sources or studies that may arbitrarily refer to generics as the low-cost, high-quality option. Further out, innovations in the infrastructure and interoperability of clinical information systems will generate new transparency about cost and outcomes. As this happens, the next generation of medicines will need to be supported with compelling, real-world health economic claims that are readily available across a vastly more complex and vastly transformed information infrastructure.

## Summarizing the Impact and the Actions

Our clients often express surprise at the level of impact we predict. During the 2010 victory lap, most analysts estimated the impact of reform at no more than 3 to 5 percent of revenues—important, certainly, but less significant than a major launch, generic entry, or advance in a key pipeline product.

In our view, these analyses focused too narrowly on ACA’s direct impacts and its pharma-specific provisions. As we consider these five transformations, we see a much greater risk or potential upside to pharma company portfolios. Our nominal assessment puts the value at risk at 20 percent of current revenues, but impacts for some companies could be much larger. With this much at risk, pharma can’t afford to put its head in the sand.

Beyond the specific provisions and marketplace changes, it is critical for leaders in pharma to embrace the macro shift toward fee-for-value. To the extent that any constituent clings to the fee-for-service model, they only intensify pressures already acute in the system.

### Reform Timeline: 2018

- *Excise tax on high cost plan*

If this round of change doesn't make real progress on slowing the growth of healthcare spending, the market-driven system in the U.S. will be at risk. Accelerating the shift toward fee-for-value affords all players a meaningful compromise: acceptance of new rules of engagement to preserve the private system that fosters innovation and high standards of care.

**It is critical for leaders in pharma to embrace the macro shift toward fee-for-value.**

As we look at what pharma needs to do and what is at stake, it is important for leaders in each pharma company to develop a clear set of priorities vis-à-vis reform. In Exhibit 4 we highlight the issues that require immediate action and there those where monitoring is appropriate, as key uncertainties play out over time. Our assumptions on impact are conservative. They assume no major economic upheaval, and they reflect our optimism that, with such potential for innovation, key stakeholders will in fact find ways to deliver better outcomes at a lower cost. If those assumptions do not hold, the prospect of direct public control of healthcare looms larger. The impacts to pharma under that scenario will likely be more dramatic and more draconian.

**Exhibit 4: Key reform issues for Pharma—estimated potential steady state financial impact**

Issue	Drivers	% of Revenue Impact
1. Shift to Value/ Increasing Role of Providers	<ul style="list-style-type: none"> <li>■ 20% of payments flowing through channel</li> <li>■ 50% of those at risk with no response</li> </ul>	10%
2. Diminished Economic Viability for Payers	<ul style="list-style-type: none"> <li>■ Potential of 8% rebates increase in private market (non-provider – 40%)</li> </ul>	3%
3. Health Insurance Goes Retail	<ul style="list-style-type: none"> <li>■ Risk of non-response to exclusions from formulary</li> </ul>	2% – 3%
4. States/Exchanges	<ul style="list-style-type: none"> <li>■ Accelerated use of generics, exclusion from coverage</li> </ul>	2% – 3%
5. Health Information Liquidity	<ul style="list-style-type: none"> <li>■ Allowing others to disseminate information about generic use with no response</li> </ul>	1% – 2%
<b>Total</b>		<b>18% – 21%</b>

In many ways, ACA was a solid accomplishment for pharma, and a testament to power of coordinated, proactive engagement in major legislative processes. But it certainly does not merit a victory lap. ACA put in motion or accelerated a number of dynamic changes that will transform the U.S. healthcare market. Resting on our laurels and ignoring the substantial upheavals to payers and providers is a high-risk strategy. Leaders that take action now to reorient their businesses toward the value of medicines will realize more opportunity than risk in the post-reform world.

## Why It's Different This Time Around

Many longtime observers of pharma are asking the obvious question: "Is this round of change different from the many others that have come and gone in years past?" Pharma survived the prospect of "Hillarycare" in the 90s. Despite tales of doom, managed care and disease management approaches never really had a meaningful impact on drug spending. In recent years, Medicare Part D has, if anything, provided a modest boost to drug sales, and productive engagement in the Reform debate produced real legislative victories. Moreover, recent public dialogue and rule-making in the wake of ACA suggest that—at a minimum—implementation of ACA is more complicated and will take longer than anticipated. In all likelihood, progress will slow in the face of election-year politics, but 2012 is just around the corner, and the momentum towards system-wide change is irreversible given the magnitude of stress on the system.

### 1. The U.S. system is expensive – unsustainably so

- \$8,000 per capita cost
- 40 percent higher than every other country in the world
- Cost growth 3 times GDP
- Lots of old, sick baby boomers coming
- Without change, the system will go bankrupt

### 2. ACA actually increases cost pressures

- Expansion of coverage
- MLR floors
- Fewer levers to drive selection of lower-cost members

### 3. Private sector experiments are working

- Investments in HIT are driven by incentives supported by government
- Integrated systems—Kaiser, Intermountain, Geisinger—have shown traction on getting better quality for less cost the system will go bankrupt

### 4. The largest payers in the system—the state and federal governments—are out of money

- Protracted economic slowdown, draining state and federal coffers
- Public sentiment is more hostile; large public indebtedness system will go bankrupt

**Imperative for Reducing  
U.S. Healthcare Spend**

If this round of public-market driven change does not succeed, in all likelihood we will see more blunt and draconian public-driven changes to the system.



## About Oliver Wyman

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## About the authors

**Jerry Cacciotti** is a Partner in Oliver Wyman's Health and Life Sciences practice. He is trusted advisor to senior executives across the pharmaceutical and biotechnology industries.

**Mark Mozeson** is a Partner in Oliver Wyman's Health and Life Sciences practice in New York. He has 24 years of experience consulting to the pharmaceutical and biotech industry.

They can be reached at:

[jerry.cacciotti@oliverwyman.com](mailto:jerry.cacciotti@oliverwyman.com)

[mark.mozeson@oliverwyman.com](mailto:mark.mozeson@oliverwyman.com)