DRIVEN TO TIERS

While healthcare reform presents issues and challenges for pharma, not to worry: reform also brings with it numerous opportunities to increase sales and market share. Components of the law align with the value proposition of brands and foster adherence. **Shaun Urban** lays out the risks and rewards

Since the Patient Protection and Affordable Care Act (PPACA) was signed into law and amended by the Health Care and Education Reconciliation Act (HCERA) nearly a year ago, there has been much talk—within the lay, healthcare and business communities alike—about various elements and aspects and its likely impact on our country.

Although many components of the legislation do not take effect until 2012-2014 and many areas must be more clearly defined by the Department of Health and Human Services, fundamentally the law is designed to address three primary national needs: unsustainably rising healthcare spending; incomplete or inadequate insurance coverage; and inconsistent quality of care. While many stakeholders in our healthcare system, from patients to purchasers, will be impacted both positively and negatively as a result of these changes, how did pharma make out in the context of these developments?

Well, clearly, the biggest wins for the industry came when Congress compromised on its desires for a single-payer system and for drug price controls. However, there are many other opportunities, issues and challenges that reform will create

The profit impact

Although price controls were avoided, drug profitability will still be impacted as a result of increases in mandated Medicaid rebates, Medicaid eligibility expanding to 133% of the Federal Poverty Level, and Medicare donut hole financial obligations that both branded and generic manufacturers will face.

There will also be greater incentives for the use of generic drugs. Elements of the law such as new Medicare bundled payment models, thresholds for Medicare Part B premiums being frozen, and decreases in annual market basket updates affecting reimbursement for hospitals and long-term care all will motivate healthcare administrators to increase the use of generic products over their branded counterparts.

Another issue pharma will face is an even more cost-conscious consumer as a result of insurers continuing to pass on additional costs to their members. Insurers will face increased financial regulation as a result of the law—which will promote additional cost shifting. Some of these additional financial regulations include: maintaining medical loss ratios no lower than 85% in most instances; expanding dependent coverage to age 26; increasing limitations on deductibles; eliminating lifetime coverage limits; decreasing Medicare Advantage reimbursement; and eliminating rescission of coverage except in cases of fraud.

85% is the minimum income insurers must spend on direct care and quality improvement efforts

Health literacy challenge

The law also poses a number of challenges for the industry. Thirty-two million newly covered—but less sophisticated—healthcare purchasers will enter the system with varying degrees of health literacy. Educating these new healthcare consumers about products is fraught with health literacy challenges. Furthermore, ensuring medication adherence in this population will prove to be an even greater challenge than it already is today with some of the most sophisticated patients.

Another challenge is that the increased focus on quality improvement will place a greater burden on manufacturers to demonstrate clinically and financially meaningful outcomes. Historically, health economics and outcomes research generated by pharma has been met with skepticism by the healthcare community due to study design and bias concerns.

Manufacturers will be required to invest to a much greater degree and develop more sophistication in this area. Lastly, market share growth and utilization will become more difficult for a variety of reasons: greater payer scrutiny and management, increased cost shifting to patients and more incentives for generic drug use.

Expanded coverage and other opportunities

Healthcare reform presents many issues and challenges for the pharmaceutical industry. However, companies shouldn't worry: reform also brings about numerous opportunities. With 32 million newly covered patients entering the system, opportunity exists to incrementally increase sales and market share within this insured population.

32M is the number of newly insured patients entering the system under the affordable care act

Also, decreases in Medicare payments for hospital readmissions and instances of "never events"—a list of adverse events that are serious and largely preventable—should result in more aggressive use of pharmacotherapies.

And while these 32 million newly insured patients represent a greater business opportunity for many stakeholders beyond pharma, they will undoubtedly put a strain on the dwindling US primary care physician population. As such, ancillary providers and sites of care such as nurse practitioners, physician assistants, and minute clinics—traditionally a more accessible and receptive promotional audience—will play a more prominent role.

We can also expect even greater physician and hospital consolidation because of pricing and reimbursement pressures associated with the new law. Consolidation will only help the pharmaceutical industry be more efficient and effective in its selling efforts, and will require an even greater emphasis on an account management-based sales model.

The industry also has the opportunity to embrace and invest in prevention and wellness. Numerous elements of the healthcare reform law focus on these areas:

- Establishment of a council to coordinate wellness program activities;
- Requiring a comprehensive risk assessment and development of a personalized prevention plan for Medicare beneficiaries;
- Covering only proven preventive services; and
- Providing grants for employers to develop wellness plans and allowing them to offer rewards for wellness and prevention behaviors.

This greater focus on wellness and prevention aligns nicely with the value propositions for many pharmaceutical brands and product types (e.g., vaccines, anticoagulants).

Risk and reward

The Affordable Care Act, signed into law almost a year ago, poses challenges and opportunities for brand marketers.

CHALLENGES

- Upping health literacy, adherence among 32 million newly covered patients
- Demonstrating meaningful health outcomes
- Greater payer scrutiny, management
- Increased cost shifting to patients
- More incentives for generic drug use

OPPORTUNITIES

- Decreases in Medicare payments for hospital readmissions may lead to more aggressive use of pharmacotherapies
- Greater focus on ancillary providers, a more receptive promotional audience
- Hospital consolidation puts bigger emphasis on account management-based sales model
- Wellness/prevention aspects align with vaccine/anticoagulant use
- ACOs and other components foster medication adherence

Lastly, many components of the new law will help improve medication adherence. A greater emphasis on coordination of care in general, the establishment of accountable care organizations (ACOs) and patient-centered medical homes, requiring documented care coordination for dual eligibles and providing greater financial assistance to keep Medicare patients compliant on prescrption drugs once they reach the donut hole will benefit all stakeholders involved in the medication adherence battle.

133% Federal Poverty Levels are expanding to this point while Medicaid rebates are also being increased

The above are just a handful of elements within the PPACA that will clearly impact how the industry markets and sells drugs in the near future and mid-term. And there is no doubt that many actionable and implementation-related details must be thought through in the coming months and years.

Payer marketers ascendant

But it is critical that brand marketers understand the core elements of the law, monitor how these elements are implemented within our current healthcare system, and adjust strategic and tactical marketing plans accordingly. Much of this expertise and responsibility falls on the payer marketer, and continues to validate the growing importance of payer marketing within the overall marketing mix for a brand.

So, stay tuned. As with everything in the managed markets space, when you think you have it figured out, things will change. And inevitably, we are in for significant change within our healthcare system over the next few years. ■

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