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PPACA: What's Next For Life Sciences Companies

Law360, New York (August 24, 2012, 12:57 PM ET) -- Life sciences companies breathed a sigh of relief when the U.S. Supreme Court largely upheld the Patient Protection and Affordable Care Act (PPACA). After all, the PPACA will add millions of Americans to the pool of health care consumers.

But the Supreme Court also held that the federally subsidized Medicaid expansion is optional for the states; therefore, as recently confirmed by the U.S. Congressional Budget Office, fewer people will be added to the pool than originally projected.

As a result, drug manufacturers might not receive the full benefit of the bargain they made with Congress — an estimated $80-110 billion in rebates and discounts, which was based on the assumption that 17 million new customers would be eligible for Medicaid under the PPACA.

Some will gain and some will lose under the PPACA decision. What's for sure is that there will be changes for life sciences companies. The pharmaceutical industry, in particular, is in the midst of patent expirations on major blockbuster drugs, resulting in a staggering loss of revenues estimated at $127 billion over the next 5 years.

However, no life sciences company is immune to the increasing pricing pressure, rising regulatory approval hurdles and the ever-expanding maze of health care providers, payors and regulators.

We highlight below the key provisions of the PPACA and how they affect pharmaceutical, biotech and medical device companies after the Supreme Court's decision.

The PPACA and Biosimilars

One of the most significant undisturbed parts of the PPACA for the biotech industry is the newly established approval pathway for biosimilar products, also known as the Biologics Price Competition and Innovation Act (BPCIA).

The number of marketed biologic drugs has been growing steadily, with many multibillion dollar blockbusters already on the market (Humira, Avastin, Rituxan, Enbrel, Herceptin, Remicade and others). The cheaper, "me-too" versions of these drugs, known as biosimilars, are projected to save consumers more than $300 billion by 2029.

At the individual product level, reports are estimating that biosimilars may cost between 60 and 80 percent of the original drug. The BPCIA permitted the U.S. Food and Drug Administration to exercise discretion in determining the clinical trials necessary to allow an approval of a biosimilar product. In most cases, such trials are expected to be far less expansive than those necessary for an approval of the original drug.

The BPCIA also established the rules regarding exclusivity periods, patent litigation standards and substitution requirements, all of which have had a major impact on the business strategies of both the original biologics and biosimilars developers.

The Supreme Court's decision has removed the looming uncertainty for biosimilar producers who can now proceed with biosimilar products without fear of full legislative overhaul and potential disruption of the abbreviated FDA approval progress.

The ruling, however, does not touch on the administration's prior proposals to change the innovator's market exclusivity period from 12 to seven years and the growing voices to prohibit so-called "pay-for-delay" settlements wherein a generic drug maker agrees to delay the market entry in exchange for dropping the challenge against the original drug patent.

In the recent case In Re: K-Dur Antitrust Litigation, the U.S. Third Circuit Court of Appeals ruled that any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market is a prima facie evidence of an unreasonable restraint of trade under the Sherman Act.

It is likely that the Supreme Court will shortly consider this issue or a legislative action may follow. If the K-Dur decision is upheld, it will make it more difficult for biosimilar manufacturers and innovators to settle patent disputes.

Interested parties should heed the BPCIA-related developments closely, as they are not likely to garner the high visibility enjoyed by the more controversial PPACA provisions.

The Medical Device Tax

The PPACA's 2.3 percent excise tax on medical devices will take effect on Jan. 1, 2013, and device makers must begin to prepare accordingly. The political climate has infused this measure with a dose of uncertainty. The U.S. House of Representatives, spurred by Republican lawmakers, voted to repeal the device tax, but the Democrat-controlled U.S. Senate — not to mention the White House — rejected that effort.

In the world as it is, costs will increase for device makers. It will be interesting to see how they respond.

The PPACA does not distinguish between large device makers and small companies, nor does it care if you are a foreign or a domestic seller. While the law is uniform in its applicability, companies' responses are not likely to be so homogeneous. Some could strive for efficiency inside their walls — perhaps by dissecting budgets and slimming down generally. Other device makers will pass some of the added cost on to purchasers.

With that said, companies' responses might not be terribly drastic, given that many more people are certain to have health coverage in the coming years and device makers know who their customers are.

Individual consumer devices (think: eyeglasses and hearing aids) are not taxed under the PPACA, but those used by — and purchased through — health care providers are.

The actions of the states will determine how well medical device manufacturers do under the PPACA following the court's decision to prevent the federal government from denying Medicaid funding to states that refuse to expand their Medicaid program. The extent to which states embrace the Medicaid expansion will impact how many presently uninsured Americans will gain access to providers' services and the medical devices that they make available.

Sunshine Reporting

The PPACA's transparency provisions also remain law. Device makers and drug manufacturers have to record and report every instance in which they or their sales representatives give something of at least $10 in value to a provider or a doctor.

At the earliest, U.S. Centers for Medicare and Medicaid Services (CMS) will begin collecting this data on Jan. 1, 2013. However, CMS has yet to issue regulations on the Sunshine provisions. And, at least right now, it looks like the Sunshine reporting will not totally preempt existing state law disclosure requirements.

Tech Assessment and Diffusion under PCORI and IPAB

The PPACA creates the Patient-Centered Outcomes Research Institute (PCORI) to evaluate the effectiveness of various medical treatments. PCORI will advise the Independent Payment Advisory Board (IPAB), which the PPACA empowers to issue binding recommendations to cut costs if Medicare gets too expensive too quickly.

Industry members have expressed concern over harm by IPAB's possible cost-cutting measures after 2014.

However, it is worth nothing that IPAB will only so act if Medicare costs rise beyond a certain threshold, making this area perhaps the least certain. We will not see anything binding from IPAB for at least a few years yet, and the Congressional Budget Office projected in March of last year that Medicare spending might not increase enough to trigger IPAB recommendations.

Customers and Patients

The PPACA encourages the adoption of the accountable care organization (ACO) model for care delivery. ACOs are groups of doctors, hospitals and other health care providers, who come together voluntarily to give coordinated high-quality care to their Medicare patients. The goal of coordinated care is to ensure that patients get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors.

When an ACO succeeds both in delivering high-quality care and spending health care dollars more wisely, it will share in the savings it achieves for the Medicare program.

In many states, most notably Massachusetts, the ACO delivery model is being coupled with the expansion of global payment, or so-called "total quality"-based reimbursement by commercial health plans. This means that ACOs will have a greater say in purchasing decisions for drugs and devices. ACOs can share in the cost savings attributable to lower costs for more wisely using and prescribing cost-effective drugs and devices.

In many parts of the country, patients will have first-time access to health plan coverage through Medicaid expansion, subsidized coverage via exchanges and the elimination of pre-existing condition limitation.

And, while we have not yet seen what the final benefit packages will be, including the coverage terms, at least in the commercial health plan space, we can be sure that both cost effectiveness and comparative effectiveness will be taken into account when determining formulary positions for prescription products.

Therefore, whether looking at the purchaser as an ACO, a health plan or the patient, life sciences companies will have to prove the value of their products, both in terms of outcomes and as compared to competing therapies.

Conclusion

Life sciences companies have always had to pay attention to state and regional differences in commercializing their products. However, with the anticipated variations in Medicaid expansion and health exchange adoption, manufacturers must pay even greater attention to states as they contemplate the PPACA's impact on their customer base.

Further, cost control efforts and ACOs are on the horizon. Life sciences companies can thrive under the PPACA, provided they account for areas of uncertainty and focus on proving the value of their products to purchasers and patients.

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