A Look At The Health Care M&A Horizon

Law360, New York (March 06, 2013, 11:16 AM ET) -- The U.S. Supreme Court's decision narrowly upholding the core provisions of the Affordable Care Act paved the way for continued implementation of the law, including health insurance market reforms, new employer coverage mandates, reforms in Medicare payment and reimbursement, and new taxes on drug and device manufacturers.

However, the landmark ruling also has created a significant degree of uncertainty. The court held that the act's Medicaid expansion violates Congress' spending authority: Capitol Hill cannot cut a state's entire Medicaid funding (as opposed to the incremental funds provided in the act) if the state chooses not to implement the expansion. Many states are poised to forego operating their own exchanges, and lawsuits have been filed challenging subsidies to federally run exchanges.

In addition to the legal challenges that surfaced after the June 28, 2012, decision, the previous speculation leading up to the ruling, coupled with the debate during the second half of last year over how the U.S. presidential election would affect the ACA's implementation — or potential repeal — had a major impact on health care M&A and enforcement activity.

While the Supreme Court has ruled and the elections are over, lingering factors — the ACA's payment reforms, downward pressure on costs, enhanced focus among payers on outcomes and quality, and expanded Medicaid roles — will continue to influence M&A activity across industry sectors, increase regulatory and compliance costs, and provide additional incentives to federal and state enforcement agencies to boost enforcement efforts.

Health Care Reform Proceeds, Coupled With Uncertainty

The Supreme Court's decision and the 2012 election cleared the way for further implementation of the ACA. The following timetable provides key milestones of the ACA's numerous provisions.

Since Jan. 1, 2013:

- State and federally run health exchanges must be up and running by Oct. 1, 2013, so individuals and businesses can purchase health insurance by Jan. 1, 2014.

- The amount of contributions to a flexible spending account for medical expenses will be limited to $2,500 per year, increased annually by the cost-of-living adjustment.

- Employers who receive Medicare Part D retiree drug subsidy payments will not be able to deduct those subsidies.

- An excise tax of 2.3 percent will be imposed on the sale of any taxable medical device.

- The Sunshine Act will be implemented, requiring disclosures by drug, device and medical supply manufacturers of payments to teaching hospitals and physicians. The Center for Medicare & Medicaid Services (CMS) delayed implementation, announcing in May 2012 that data collection requirements would not begin before 2013.

On or After Jan. 1, 2014:

- Funding for the Children's Health Insurance Program (CHIP) will be extended.

- A fee of $2,000 per full-time employee, excluding the first 30 employees, will be assessed on employers with more than 50 employees that do not offer coverage and have at least one full-time employee who receives a premium tax credit. Employers with more than 50 employees that offer coverage but have at least one full-time employee receiving a premium tax credit will pay the lesser of $3,000 for each employee receiving a premium credit or $2,000 for each full-time employee, excluding the first 30 employees.

- The Independent Payment Advisory Board (IPAB) will submit its first annual report of legislative proposals to reduce the per capita rate of growth in Medicare spending (in the event that spending growth exceeds a target growth rate).

On or After Jan. 1, 2016:

- States will be permitted to form health care choice compacts that allow insurers to sell policies in any state participating in the compact.

- An excise tax will be imposed on insurers of employer-sponsored health plans with aggregate expenses that exceed $10,200 for individual coverage and $27,500 for family coverage.

Many important aspects of the ACA's implementation remain unclear, including how many states will elect not to operate their own exchanges, whether states will accept federal subsidies to expand Medicaid coverage, the process and criteria the IPAB will use to make recommendations to reduce health care costs, and the contours of the health care choice compacts allowing the sale of health insurance across state lines, among others.

Payment Cuts, Increased Regulatory and Compliance Costs Continue to Drive M&A Consolidation, New Business Models

The 934 deals worth $159.3 billion in 2012 were down from the 993 deals worth

$196.5 billion in 2011 (merger market). Pharmaceuticals and biotechnology deals increased in the past year, but these gains were offset with declines in other major health care sectors, including medical equipment and supplies, hospitals and services.

With the Supreme Court's ACA ruling and U.S. presidential election decided, we expect the same factors that drove M&A activity in 2010 and 2011 — compressed margins due to payment cuts, increased regulatory and compliance costs, a desire for increased exposure to high-growth markets outside the United States — to increase activity in 2013 and beyond.

Financially struggling providers will seek lifelines from larger, healthier systems. Larger systems will seek to offset a decline in reimbursement rates with increased scale. Similarly, payers will continue to seek enrollment expansion through M&A. Large pharmaceutical companies likely will continue to reshuffle their business portfolios and seek new avenues for growth in emerging markets and to fill near-term gaps in their pipelines due to patent expirations and the unpredictable results of their internal R&D efforts. Small- and medium-size medical device companies will explore the need to gain scale in the U.S. and abroad in their still-fragmented sector.

Federal and State Enforcement Continues to Increase, With Ever-Larger Settlements, More Suits in the Pipeline, and Strong Incentives to Continue or Boost Prosecution

The 2012 federal fiscal year set a new record for recoveries for civil and criminal cases against health care companies. The largest settlements included the $3 billion combined criminal and civil settlement with GlaxoSmithKline over sales, marketing and pricing allegations across a range of products, and the $1.5 billion settlement with Abbott Laboratories over the marketing of a neuroscience product.

GSK paid $1.5 billion to resolve False Claims Act allegations that the company (1) promoted off-label use for the drugs Paxil, Wellbutrin, Advair, Lamictal and Zofran, and paid kickbacks to physicians to prescribe those drugs as well as the medications Imitrex, Lotronex, Flovent and Valtrex; (2) made false and misleading statements concerning the safety of the drug Avandia; and (3) reported false best prices and underpaid rebates owed under the Medicaid Drug Rebate Program.

As in past years, the primary driver of civil recoveries generally, and health care settlements specifically, was the whistleblower provisions of the False Claims Act. Of the $4.9 billion in recoveries in fiscal year 2012, a record $3.3 billion was recovered in whistleblower suits. In fiscal year 2012 alone, relators filed 647 qui tam suits. Of the nearly 8,500 qui tam suits filed since the 1986 amendments, nearly 2,200 were filed since January 2009. Looking at qui tam recoveries for the same periods, the U.S. Department of Justice tallied $24.2 billion since 1986, with nearly $10.5 billion of that amount recovered from January 2009 through fiscal year 2012. Since 1986, whistleblowers have been awarded nearly $4 billion, with $439 million in awards in fiscal year 2012. The vast majority of these recoveries involved health care companies.

The number of qui tam suits likely will increase in response to whistleblower-friendly amendments to the FCA. Although the DOJ has lost several significant cases in the trial and appellate courts (including the U.S. Court of Appeals for the Second Circuit's rejection in United States v. Caronia of the government's core theory in the prosecution of off-label promotion by drug and device makers), considering the dollars at stake, these reversals are not expected to lessen the government's commitment to pursuing them — nor should it dampen the willingness of plaintiffs' lawyers to pursue such cases, even when the government declines to intervene.

The continued focus on criminal and civil prosecution of health care companies makes the development and implementation of robust and comprehensive compliance programs more important than ever, with new emphasis on top-level oversight and reporting mechanisms; enhanced accountability measurers for executives and

employees; compliance safeguards to ensure incentive compensation plans and performance measures do not reward improper behavior; and comprehensive monitoring and auditing plans to ensure that compliance safeguards are effective and achieve proper behavior at all levels within the organization.

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