Insights

Skadden

Excerpted from *2014 Insights*. The complete publication is available at www.skadden.com.

'14

A COLLECTION OF COMMENTARIES ON THE CRITICAL LEGAL ISSUES IN THE YEAR AHEAD

Health Care and Life Sciences: Affordable Care Act Rollout to Impact M&A and Enforcement Activity

CONTRIBUTING PARTNERS

John T. Bentivoglio / Washington, D.C.

Jennifer L. Bragg / Washington, D.C.

Michael K. Loucks / Boston

Gregory M. Luce / Washington, D.C.

Graham Robinson / Boston

Health care and life sciences companies face a variety of issues in 2014, including further difficulties with the Affordable Care Act (ACA) rollout because of legal and logistical challenges, the potential dampening of dealmaking due to ACA and regulatory scrutiny, and continued aggressive government enforcement activities in the industry.

Affordable Care Act Rollout

Much of the health care policy debate in 2013 focused on the Obama administration's botched rollout of the centerpiece of the ACA — the federal- and state-run exchanges where individuals and small-business owners were supposed to easily analyze and purchase health insurance, with generous subsidies for lower-income Americans. As is so often the case with health care issues, it is difficult to separate the administration's policy decisions from political considerations. The administration has been pushed, often by congressional Democrats, to delay or modify many ACA provisions. These measures have included postponing the mandate requiring employers with more than 50 employees to provide coverage to their workers, scaling back enforcement of applicant income verification requirements and — perhaps most controversially — enacting an automatic "hardship waiver" allowing individuals whose plans were cancelled for failing to meet the act's minimum coverage requirements to forego purchasing health insurance without paying the individual mandate tax. While these administrative actions may have answered complaints from some quarters, they have created havoc among insurers and resulted in increased premiums for the 2014 policy year.

The administration also faces continued legal challenges to the ACA, the most serious being a challenge by the Oklahoma attorney general arguing that the law only provides tax credits and subsidies to individuals who buy insurance on state-run exchanges. The complaint claims that Congress intended to limit subsidies as an incentive for states to create their own exchanges and that the administration's decision to extend credits and subsidies to federally run exchanges is not authorized by the ACA. With more than 30 states opting not to create their own exchanges, a successful challenge would upend the ACA and force the administration to work with Congress to address the problem. While a U.S. district judge refused to grant an injunction last month, he scheduled oral arguments on the merits of the case for February 2014.

Implementation Timeline. Despite these challenges, the administration remains committed to implementation of the ACA without further congressional action. The exchanges are just one of several important provisions of the ACA that will come into effect in 2014 and beyond. Among the other key provisions:

- **January 1, 2014:** Expanded Medicaid Coverage. Expands Medicaid to all individuals not eligible for Medicare under age 65 with incomes up to 138 percent of the federal poverty level. More than 1.4 million people signed up for Medicaid or states' Children Health Insurance Programs in October 2013, although 48 percent of those live in expansion opt-out states, making the Medicaid market a less attractive opportunity in the near term for insurers and providers.
- **Annual limits, pre-existing conditions.** Prohibits insurers from charging more or denying coverage to anyone with pre-existing conditions or charging higher rates due

to gender or health status in the individual and small-group market. Also generally prohibits annual dollar limits for plans starting January 1, 2014.

- **March 1, 2014:** Physician-Owned Hospitals. Pursuant to a Centers for Medicare & Medicaid Services (CMS) delay, physician-owned hospitals have until March 1 to report ownership and investment information. The ACA blocked the construction of any new physician-owned hospitals and prevented those operating from adding beds or operating rooms if they wanted to remain eligible for Medicare.
- **October 1, 2014:** New Procedural Coding System. As of this date, health care organizations must convert to the ICD-10 coding system. Under the final rule, all health insurers must use a unique health plan identifier.
- **January 1, 2015:** Employer Obligations. In July 2013, the White House delayed by one year the reform law's mandate that employers provide health insurance coverage for their workers. Employers with at least 50 full-time employees must offer health benefits or pay a penalty of $2,000 per full-time employee, excluding the first 30 employees.
- **January 1, 2018:** Tax on High-Cost Insurance. The ACA will impose a 40 percent excise tax on the cost of health plans that exceed a certain threshold — $10,200 annually for individual coverage and $27,500 for family coverage.

Health Care M&A and Corporate Activity

Health care M&A activity picked up in the second half of 2013 after a relatively lackluster level of activity at the beginning of the year. Deal volume in the third quarter was up nearly 16 percent versus the previous quarter, with 267 deals announced; activity in this period also outpaced the third quarter of 2012 by almost 20 percent. Four of the largest health care sectors — services, pharma/biotech, medical device and supplies, and technology — posted year-on-year increases in deal activity, while five relatively smaller sectors posted decreases: behavioral health care (down 60 percent); home health and hospice (down 50 percent); labs, MRI and dialysis (down 20 percent); physician medical groups (down 6 percent) and medical devices (down 8 percent).

Notable Deals. Multiple factors contributed to the overall acceleration of health care M&A activity in the second half of 2013, including continued low interest rates for corporate borrowers and the imperative among providers to increase volume and scale to offset lower reimbursement rates mandated in the ACA. The largest transactions occurred in the pharmaceutical and hospital/health system sectors. Among the most notable in 2013 were:

- Valeant's $8.7 billion acquisition of Bausch + Lomb, a leading provider of pharmaceuticals and medical devices in the eye care sector (announced in May). The deal reflects continued consolidation in the pharmaceutical industry.
- Amgen's $10.4 billion acquisition of Onyx Pharmaceuticals, a biotechnology company focused on oncology therapies (announced in August). Specialty pharmaceutical and biotechnology companies with novel therapies that can support premium pricing models remain attractive acquisition candidates.
- Community Health Systems, the second-largest U.S. hospital chain, acquired Health Management Associates (announced in July). At $7.1 billion, the deal was the biggest acquisition of a hospital company since 2006.

- Endo's $1.6 billion acquisition of Paladin Labs Inc. (announced in November). The deal reflects the ongoing strategic transformation of certain pharmaceutical manufacturers into global specialty health care companies.

Caution in 2014. Cost pressures in the United States and abroad will squeeze margins for health care companies. Some combination of consolidation, changes in business models and increased use of technology (to improve patient outcomes and/or decrease costs) will be necessary to maintain or increase profitability. Continued turmoil in the implementation of the ACA's health care exchanges could increase regulatory uncertainty in the health insurance market, potentially dampening enthusiasm for major deals in that sector (see Global M&A/"US M&A: Looking Back at 2013 and Forward to a Brighter 2014").

Until recently, China was an especially attractive opportunity for growth for health care manufacturers and others. However, the Chinese government's recent, high-profile investigation of alleged fraud by foreign pharmaceutical companies — starting with a bribery scandal at GlaxoSmithKline and spreading to other major manufacturers — appears to have decreased inbound investment in its life sciences sector in 2013. News that China's National Health and Family Planning Commission plans to publish a blacklist in March 2014 of pharma and medical device manufacturers found to have paid bribes likely will add further complexities to dealmaking in the region. At a minimum, foreign companies are likely to (and should) beef up their preacquisition diligence efforts in the Chinese market, which could slow deal activity.

Enforcement, Compliance and Regulation

Health care enforcement continued to be a top priority for federal and state prosecutors and investigators in 2013, with $2.6 billion in federal civil recoveries in fiscal-year 2013, down slightly from 2012 but still the second-largest annual recovery in health care fraud cases in U.S. history. Three enforcement actions resulted in criminal and civil recoveries of almost $3 billion ($1.5 billion from Abbott Laboratories, $762 million from Amgen and $505 million from Ranbaxy). The Ranbaxy case was notably the largest drug safety settlement to date with a generic drug manufacturer (including two felony charges for the distribution of adulterated products) and one of the largest settlements ever focusing on the manufacturing and quality practices of a pharmaceutical manufacturer. Johnson & Johnson's November 2013 settlement ($2.2 billion in civil and criminal fines and penalties) means the government's fiscal-year 2014 likely will be a near-record year for health care fraud recoveries. However, we believe that settlements exceeding $1 billion (four in the past four years) will decrease over time, as the industry has tightened promotional compliance controls, the number of blockbuster products has decreased, and the largest cases involving multiple products spanning five to 10 years (or more) largely have worked their way through the enforcement process.

> "While the number of billion dollar settlements may decrease in the coming years, enforcement is likely to continue at a torrid pace."

False Claims Act Violations. While the number of billion dollar settlements may decrease in the coming years, enforcement is likely to continue at a torrid pace. One area of scrutiny likely will center on the ACA's requirement that providers report and repay overpayments within 60 days of identification, or face potential liability under the False Claims Act (FCA) for the knowing retention of an overpayment. Though the comment period for CMS's proposed rule closed in April 2012, CMS has yet to issue a final rule. 2014 might be the year that this program requirement gets off the ground,

and providers quickly institute safeguards to ensure compliance, given that deferred action on internal (or third-party) audits that uncover overpayments is an easy mark for potential whistleblowers.

Hospitals and physicians should be on notice that their relationships are a target-rich environment for prosecutors looking for significant recoveries under the FCA, which often is used to prosecute alleged violations of the federal Stark Law. This is notable in the wake of the $237 million judgment against Tuomey Healthcare System for improper financial relationships between the hospital system and physicians. Tuomey's settlement is based on $39 million of claims it submitted over a two-year period. The judgment factored in treble damages (roughly $117 million), plus an additional $120 million penalty (or approximately $6,000 per claim).

Stark Law compliance often relies on a hyper-technical reading of the statute and regulations, and hospitals should not only ensure that new contracts with physicians fully comply with the law, but also that they have in place a tracking mechanism to confirm that existing contracts remain compliant or are renewed as necessary.

FDA Enforcement Agenda. On the FDA front, there has been a relatively profound change in the agency's enforcement priorities. In the past two to three years, the FDA appears to have been less focused on, and devoting fewer resources to, drug promotion issues as reflected in a downward trend in the number of warning letters and notices of violations (known as untitled letters), while intensifying its focus on manufacturing and quality issues. This change coincides with the approach championed by FDA Commissioner Margaret Hamburg, who has directed the agency's enforcement and regulatory units to embrace a risk-based approach in allocating its enforcement resources, with priority placed on practices posing a significant risk to patient health and safety.

Fraud Settlements. Finally, notable changes have occurred during the past few years in the compliance provisions in health care fraud settlements. The Department of Health and Human Services Office of Inspector General (HHS OIG) continues to push for changes in what it perceives as drivers of corporate behavior — including incentive-based compensation for sales representatives and compensation packages and bonuses for executives. Several recent corporate integrity agreements (CIA) imposed by the HHS OIG have required companies to move away from territorial-based sales incentives while also implementing compliance-related financial "clawbacks" for more senior executives. Recent CIAs also have imposed significant oversight obligations on boards of directors and senior management, reinforced by annual compliance certifications.

More onerous compliance obligations are not limited to CIA requirements, however. In 2011, a U.S. district court judge accepted a proposed $296 million settlement between Guidant Corporation and the U.S. Department of Justice involving the company's alleged concealment of safety data about one of its cardiac devices only after the judge added a three-year term of probation to the settlement; the judge had rejected a prior settlement that did not contain a term of probation. Since that time, several courts have included compliance obligations in the conditions of probation imposed on companies following the entry of criminal pleas. In other instances, the Department of Justice (DOJ) has incorporated compliance and reporting obligations in plea agreements, establishing new links between a company's post-settlement conduct and oversight by DOJ prosecutors. Both trends — *i.e.*, court-imposed conditions of probation and DOJ-imposed compliance obligations — will increase scrutiny of companies that have resolved health care fraud settlements and could expose companies to significant fines and penalties for future violations.