The Impact of Health Reform on M&A Activity in the Healthcare Sector

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The Patient Protection and Affordable Care Act (as modified by the Health Care and Education Reconciliation Act) (collectively referred to as "Health Reform") was signed into law in March 2010.[1] This legislation represents the most comprehensive reform of the healthcare system in the last 50 years and it promises to affect healthcare and life science companies in every corner of the industry.

Nowhere is the impact of Health Reform more noticeable than in the context of mergers and acquisitions. Recent deal flow suggests that companies in various segments of the healthcare sector have been anticipating the impact of this type of legislation and a number of healthcare companies began developing unique strategies to adjust to expected rules and regulations well before President Obama signed the Health Reform legislation into law. Furthermore, in terms of corporate combinations, movement among healthcare providers and manufacturers suggests that many opportunities are available for healthcare industry members who want to attain a competitive edge and initiate a strategic response to Health Reform.

1. Healthcare Providers

Many post-acute care providers and hospitals have been engaging in mergers and acquisitions in anticipation of changes to the current fee-for-service pay structure. Some entities have used corporate combination strategies to enhance their suite of service offerings, while others (often in financial distress) have looked to mergers and acquisitions to defray reimbursement cuts and improve their financial positions and overall performance.

a. Post-acute and Long-term Care Consolidation

Section 3023 of the Patient Protection and Affordable Care Act directs the Secretary of Health and Human Services to develop a national, voluntary pilot program by January 1, 2013 encouraging hospitals, doctors, and post-acute care providers to improve patient care and achieve savings for the Medicare program through bundled payment models. This National Pilot Program on Payment Bundling ("Pilot Program") will test a bundled payment model which, unlike the current fee-for-service model, offers a single bundled payment for a continuum of healthcare services. The bundled payment will see a patient through an entire episode of care, from inpatient and outpatient acute care through post-acute care, including home health, skilled nursing and rehabilitation.

Given the establishment of this pilot program, Health Reform has the potential to dramatically change how healthcare providers are paid for their services. The Secretary is only required to establish the initial pilot program for a five year period, but should the pilot program improve quality and reduce costs, the Secretary has the authority to expand the program.

Potentially in anticipation of the establishment of a more bundled payment program, some post-acute care providers have been proactive in pursuing corporate combinations to take advantage of the bundled payment model. By focusing on vertically integrating an array of long-term care services, these post-acute care providers appear to be positioning themselves to stretch (i.e., maximize) bundled payments, thereby increasing their return.

The proposed merger of Odyssey HealthCare (a hospice care provider) and Gentiva Health Services (a hospice and home health care provider) in May 2010 exemplifies this type of behavior among post-acute care providers. The merger, pegged at $1 billion, will create the largest healthcare provider focused on home health and hospice services in the United States.[2] The combined entity will boast $1.8 billion in annual revenue, 60 percent of which is expected to be generated from home healthcare and 40 percent of which is expected to be generated from hospice care.

However, while the Odyssey-Gentiva deal has received the most attention, several other post-acute care providers have also used acquisitions as a means to increasing their home health and hospice operations. On May 24, 2010, Idaho Home Health and Hospice entered into a definitive agreement with Louisiana-based LHC Group Inc., which is expected to enhance LHC Group's array of post-acute healthcare services, including its home-based division and its facility-based division.[3] The announcement of this transaction follows LHC's acquisition of Oregon-based Salem Hospital Home Care in March 2010.[4]

The Ensign Group, Inc. appears to be pursuing a similar strategy. In May 2010, Ensign announced plans to acquire Horizon Home Health and Hospice.[5] The acquisition was among a litany of deals recently conducted by Ensign outside the hospice space; Ensign announced in May that it would acquire both the Heritage Gardens Healthcare Center and the Silver Springs Healthcare Center, two Texas-based nursing home operations.[6] Furthermore, these acquisitions came on the heels of Ensign's acquisitions of Emmett Care & Rehabilitation Center and Parke View Rehabilitation & Care Center in January

2010.[7] Moreover, it does not appear that Ensign has any plans to slow down as it has expressed a commitment to actively pursue both well-performing and struggling long-term care targets. This type of behavior suggests that the frequency of mergers and acquisitions among post-acute care providers will remain high for the near future.

b. Non-Profit & For-Profit Hospitals

Health Reform may also spur corporate combination activity because of its effect on the hospital industry.

For example, Section 9007 of the Patient Protection and Affordable Care provides new requirements applicable to non-profit hospitals. Among these requirements, a non-profit hospital loses its status as a Section 501(c)(3) Charitable Hospital Organization unless it conducts a periodic "Community Health Needs Assessment" which "takes into account input from persons who represent the broad interests of the community served by the hospital facility, including those with special knowledge of or expertise in public health." The non-profit hospital must also "adopt an implementation strategy to meet the community health needs identified through the [Community Health Needs Assessment]."

Furthermore, Health Reform imposes more transparency requirements on non-profit hospitals. Section 9007 requires non-profit hospitals to develop written financial assistance policies and "widely publicize the policy within the community to be served by the organization."

These, and other requirements imposed on hospitals under Health Reform, may be burdensome for some non-profit hospitals that are already experiencing capital shortages. To survive, non-profit hospitals may seek to merge with (or be acquired by) their peers. Indeed, smaller players may not have the resources to address new guidelines and potential financial penalties for noncompliance.

Consequently, many non-profit players have been targeted for acquisition. In fact, in June 2010, Vanguard Health Systems, Inc. signed a purchase agreement to acquire the eight-hospital system of non-profit Detroit Medical Center ("DMC").[8] Under the terms of the agreement, Vanguard will purchase DMC for approximately $417 million in cash, which will enable DMC to retire its debt. In addition, Vanguard has committed to providing DMC with $350 million for on-going capital needs and at least $500 million for new capital investment over the next five years. The deal represents the single largest private sector investment in Detroit's history and it epitomizes the struggle hospitals across the country are facing. However, the combination is expected to help Detroit Medical Center better manage the financial difficulties associated with serving a large urban community.

Another example of M&A activity among non-profit and for-profit hospitals is that in June 2010, for-profit hospital operator LifePoint Hospitals, Inc. was granted judicial approval to acquire Sumner Regional Health Systems of Tennessee, which had filed for bankruptcy in late April.[9] LifePoint offered to purchase Sumner for $145 million cash and provide $60 million of additional capital over the next decade, which will give Sumner the capital it needs to address its debt burden, finance its daily operations, and update its facilities.

Joint ventures are another viable option for non-profit hospitals that need capital but do not want to give up complete operational control. Saint Joseph's Hospital of Atlanta, a non-profit hospital with $400 million in reported annual revenue, and Piedmont Healthcare, Inc., another non-profit hospital with $1.1 billion in annual revenue, signed a letter of intent to enter into exclusive negotiations to create a joint operating company.[10] Should the joint operating company come to fruition, it would allow both parties to reduce their costs and increase the quality of provided medical care. The deal is estimated to reduce annual expenses by $20 million for Saint Joseph's Hospital and $10 million for Piedmont.[11]

2. Life Sciences and Medical Devices

While corporate combinations among hospitals and other healthcare providers have been—and will continue to be—driven largely by changes in reimbursement mechanisms and reporting requirements, M&A activity in the life sciences industry (i.e., biotechnology, pharmaceutical and medical device companies) may be motivated by several of Health Reform's provisions supporting new input and competing technologies, as well as new tax provisions.

a. Biotech and Pharmaceutical Consolidation

Competition from generic manufacturers is not a new challenge for existing members of the biotechnology and pharmaceutical industries. However, with the passage of Health Reform, generic competition may become a more significant player.

Section 7002 of the Patient Protection and Affordable Care Act provides for a "biosimilars pathway," which establishes a process under which the Secretary of Health and Human Services is required to license a biological product that is shown to be "biosimilar to" or "interchangeable with" a licensed biological product (i.e., a reference product). A biological product is "biosimilar" to a reference product if it is "highly similar to the reference product notwithstanding minor differences in clinically inactive components" and "there are no clinically meaningful differences between the biological product and reference product in terms of the safety, purity, and potency of the product." A biological product is "interchangeable" with a reference product (meaning it can be substituted for the reference product without the intervention of the healthcare provider who prescribed the reference product) if it is "biosimilar" and "can be expected to produce the same clinical results as the reference product."

The Secretary of Health and Human Services has yet to issue guidance regarding the approval process for biosimilars, and Section 7002 does prohibit approval of an application for "biosimilarity" or "interchangeability" for twelve years from the

date on which the reference product was first approved for license. However, it is clear that these and other provisions of Health Reform are paving the way for an increase in the use of generic products. Consequently, many biotechnology and pharmaceutical firms in the United States are pursuing strategies involving new corporate combinations to either diversify their product offerings or gain access to the generics in their respective fields.

In May 2010, Abbott Laboratories announced a definitive agreement with Piramal Healthcare Limited to acquire full ownership of Piramal's Healthcare Solutions business for an up-front payment of $2.12 billion, plus $400 million annually for the next four years.[12] Mumbai-based Piramal Healthcare Solutions has a comprehensive portfolio of branded generics with annual sales expected to exceed $500 million next year in India, and market-leading brands in multiple therapeutic areas, including antibiotics, respiratory, cardiovascular, pain and neuroscience. The deal exemplifies one pharmaceutical manufacturer's strategy to reinforce its position in branded generics, strengthen its presence in new markets, and complement its proprietary pharmaceutical offerings and pipeline.

Smaller firms also are engaging in corporate combination activity as well. On June 3, 2010, Sandoz, Inc. completed its acquisition of Oriel Therapeutics, Inc., a privately held pharmaceuticals company based in the United States that focuses on developing respiratory products with known pathways as generic alternatives to patented drugs for asthma and chronic obstructive pulmonary disease.[13] As a result of the deal, Sandoz will gain exclusive rights to Oriel's portfolio of generic drug candidates in addition to certain technologies for the inhalable respiratory drug market. In announcing the deal, Sandoz cited industry estimates that approximately 50 percent of the $32 billion global market for asthma and chronic obstructive pulmonary disease medicines will lose patent protection by 2016.

b. Medical Device Manufacturers Respond

Section 1405 of the Health Care and Education Reconciliation Act (HCERA) imposes an excise tax equal to 2.3 percent of the sales price on the sale of medical devices by a manufacturer or importer, effective on December 31, 2012,[14] and it is expected to provide the federal government with $20 billion over the next 10 years. Though gauging the impact of this specific provision on merger and acquisition activity among medical device manufacturers is difficult, it is conceivable that many device manufacturers are seeking to offset this future reduction in net income through synergies realized as a result of corporate combinations. Furthermore, recent activity suggests that some medical device manufacturers are preparing for the impact of the upcoming excise tax by using mergers and acquisitions to cut costs, expand service offerings, and/or prioritize core operations.

As a result of Section 1405, Medtronic, Inc., one of the leading medical device manufacturers in the United States, is expected to lose $150 million to $200 million in profit annually.[15] Perhaps in anticipation of the tax (and in an attempt to offset it), Medtronic has made a string of strategic acquisitions. Most recently, on April 29, 2010, Medtronic and ATS Medical, Inc., a leading developer, manufacturer and marketer of products and services focused on cardiac surgery, signed a definitive agreement under which Medtronic will acquire ATS Medical in a transaction valued at $370 million.[16]

This past May, CareFusion Corporation, a medical device provider, completed the acquisition of Medegen LLC from the private equity firm Nautic Partners LLC for $225 million in cash.[17] Medegen manufactures and markets disposable intravenous therapy products and also provides contract manufacturing to other medical device manufacturers and pharmaceutical companies. The acquisition complements CareFusion's current research and development efforts and enables both companies to expand their respective product lines and customer bases. CareFusion is also simultaneously focusing on slimming down its operations. On April 29, 2010, eResearch Technology, Inc., which provides services and technology for collecting, analyzing and distributing information about clinical-trial participants, agreed to acquire the research services division of CareFusion Corporation for $81 million in cash.[18]

Elsewhere, companies are making similar moves to shed their non-core businesses. On April 26, 2010, Thoratec Corporation, a leader in device-based mechanical circulatory support therapies to save, support and restore failing hearts, signed a definitive agreement to sell its International Technidyne Corporation ("ITC") division to Danaher Corporation for $110 million in cash and an earn-out expected to total $26 million over three years.[19] In the press release announcing the deal, Thoratec stated the sale enabled Thoratec to focus its attention and resources on the fast-growing Ventricular Assist Device business and the cash generated by the transaction facilitated new investments in Thoratec's existing product pipeline.

Conclusion

While many of the repercussions of the passage of Health Reform have yet to be realized, companies throughout the U.S. Life Sciences & Healthcare sector are already preparing for a costlier and more burdensome regulatory environment. As part of these preparations, some organizations have streamlined their operations, while others have aligned with complementary providers in an attempt to raise revenue or cut costs. Health Reform will inevitably touch every individual of every company from the entire spectrum of the healthcare sector, and those who consider strategic alliances now may find themselves uniquely positioned to take advantage of Health Reform's many provisions when they do come into effect over the next four years. From changes in reimbursement models to new taxes and regulatory requirements, Health Reform has proven—and will continue—to be an important driver of corporate combination activity.

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[1] Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119 (2010); Health Care and Education Reconciliation Act of 2010, Pub L. No. 111-152, 124 Stat. 1029 (2010).

[2] *See* Press Release, Gentiva Health Services, Gentiva Health Services to Acquire Odyssey HealthCare, Creating A Leading US Hospice Care Provider (May 24, 2010), *available at* http://investors.gentiva.com/releasedetail.cfm?ReleaseID=472656.

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[4] *See* Press Release, LHC Group, LHC Group Signs Definitive Agreement to Acquire Salem Hospital Home Care (Mar. 10, 2010), *available at* http://investor.lhcgroup.com/releasedetail.cfm?ReleaseID=450712.

[5] *See* Press Release, The Ensign Group, The Ensign Group Acquires Idaho Home Health and Hospice Agency (May 3, 2010), *available at* http://investor.ensigngroup.net/releasedetail.cfm?ReleaseID=465720.

[6] *See* Press Release, The Ensign Group, The Ensign Group Acquires Two Texas Skilled Nursing Facilities (May 3, 2010), *available at* http://investor.ensigngroup.net/releasedetail.cfm?releaseid=465719.

[7] *See* Press Release, The Ensign Group, The Ensign Group Acquires Two Idaho Skilled Nursing Facilities (Jan. 4, 2010), *available at* http://investor.ensigngroup.net/releasedetail.cfm?ReleaseID=433817.

[8] *See* Press Release, Detroit Medical Center, Detroit Medical Center Purchase Within Reach; Purchase Agreement with Vanguard Signed; AG Review Next Step (Jun. 11, 2010), *available at* http://www.dmc.org/news/?sid=1&nid=178.

[9] *See* Press Release, Sumner Regional Medical Center, Court Approves Lifepoint Hospitals' Purchase of Sumner Regional Health Systems (Jun. 11, 2010), *available at* http://www.sumner.org/news/news-releases/court-approval.html.

[10] *See* Press Release, Saint Joseph's Hospital Saint Joseph's and Piedmont Healthcare Announce Letter of Intent to Form Joint Operating Company (Apr. 8, 2010), *available at* http://www.stjosephsatlanta.org/news/04-08-10-JOC.html.

[11] *See* Urvaksh Karkaria, Rival Hospital Deal Could Spell New Owner for Saint Joseph's, ATL. BUS. CHRON., Apr. 9, 2010, *available at* http://www.bizjournals.com/atlanta/stories/2010/04/12/story3.html?b=1271044800%5E3162421.

[12] *See* Press Release, Abbott Laboratories, Abbott to Become No. 1 Pharmaceutical Company in India with Acquisition of Piramal's Healthcare Solutions Business (May 21, 2010), *available at* http://www.abbott.com/global/url/pressRelease/en_US/60.5:5/Press_Release_0861.htm.

[13] *See* Press Release, Sandoz, Inc., Sandoz Completes Acquisition of Oriel Therapeutics, Strengthening Potential for Global Leadership in Respiratory (Jun. 3, 2010), *available at* http://www.sandoz.com/site/en/media_room/press_releases_news/100603.shtml.

[14] HCERA, §1405, 124 Stat. 1066.

[15] *See* Medtronic Statement On Impact of Health Care Reform Bill (March 22, 2010), *available at* http://wwwp.medtronic.com/Newsroom.

[16] *See* Press Release, Medtronic, Inc., Medtronic Signs Agreement to Acquire ATS Medical (Apr. 29, 2010), *available at* http://wwwp.medtronic.com/Newsroom/NewsReleaseDetails.do?itemId=1272541176428&lang=en_US.

[17] *See* Press Release, CareFusion Corporation, CareFusion Completes Medegen Acquisition (May 17, 2010), *available at* http://media.carefusion.com/index.php?s=43&item=63.

[18] *See* Press Release, eResearch Technology, Inc., ERT Agrees to Acquire the Research Services Division of CareFusion (Apr. 29, 2010), *available at* http://ert.investorroom.com/index.php?s=43&item=377.

[19] *See* Press Release, Thoratec Corporation, Thoratec Announces Sale of ITC Division to Danaher Corporation for $110 Million (Apr. 26, 2010), *available at* http://phx.corporate-ir.net/phoenix.zhtml?c=95989&p=irol-newsArticle&ID=1417652&highlight=.