Aspatore Special Report

Understanding the Health Care Reform Bill

An Immediate Look at the Potential Impact of the Patient Protection and Affordable Care Act

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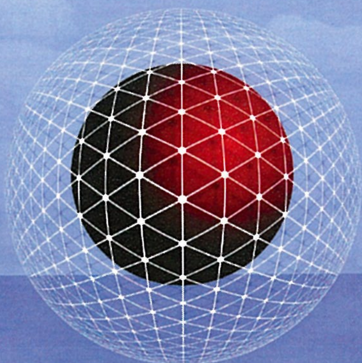

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The U.S. Health Care Industry after Reform: Every Player Gets New Rules and the Details Matter

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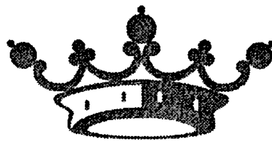

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Health Care Reform

Unless you have been living on Mars for the last year, you know that, after a very contentious, seemingly chaotic and highly partisan legislative process, in March 2010, Congress adopted two major pieces of legislation relating to health care: The Patient Protection and Affordable Care Act, Public Law No 111-148, and the Health Care and Education Reconciliation Act of 2010, Public Law 111-152. (referred to in this article together as the Patient Protection and Affordable Care Act or PPACA). Together, these statutes promise significant changes in virtually every aspect of the health care industry. Now that the heated rhetoric surrounding its passage has subsided (at least for the moment), it is a good time for attorneys with clients in the industry to assess how the law will actually affect day-to-day operations of those clients.

To begin, there is no question that the PPACA enmeshes the federal government even more deeply in the healthcare business than it ever has been before. In literally hundreds of places, the statute calls on the Secretary of Health and Human Services to issue regulations or take other actions to implement the PPACA's provisions. As a result, while the PPACA stops short of making healthcare decisions subject to direct government control, many industry participants face a loss of flexibility in running their businesses, as they grapple with the need to interpret and ultimately implement both the law and the new regulations and standards.

Part of the reason for the scope of new regulatory activity is the continued push, begun with the American Recovery and Reinvestment Act of 2009, Public Law No 111-5 (ARRA), to change the economic model for healthcare delivery. This push is to move toward "value, not volume" – away from "fee for service" and toward compensating providers based on the quality of treatment outcomes. The PPACA creates various incentives for activities believed to encourage both quality and efficiency in healthcare delivery.

For example, the law encourages experimentation with alternative care delivery models, which are believed to offer potential cost savings, such as the "accountable care organizations" or ACOs referred to in Section 3022 of the PPACA. An ACO has been defined as a group of providers—which

could include hospitals or physician groups, and other suppliers of services—that accepts responsibility for the cost and quality of care provided to Medicare beneficiaries within the traditional fee-for-service program. Such an organization would be compensated with what is referred to as "bundled" payments—the payor provides the ACO with a single contracted amount for each "episode" of care to cover hospital care, physician services, tests, and most other aspects of medical care from admission through some period after discharge. If the actual costs of providing the care are less than the payment, the group pockets the difference as profit. If there are complications, the group must absorb the loss.

While theoretically attractive, implementing such a model may prove challenging. At the very least, unless they are all part of a single organization, each provider in the ACO would need to enter into contractual arrangements to determine how that provider will participate in the payment. The various contracts would have to spell out the contributions to be made, risks to be borne and rewards to be realized of each participant in the group with respect to various types of "episodes."

The new law also attempts to bend the cost curve in other ways. It seeks to create awareness of "best practices" through funding for generating, collecting, and publicizing treatment outcomes data. It also adds to provisions in the ARRA offering grants and tax credits to encourage the adoption of health care information technology (HIT) and electronic health records (EHR). This continues a process begun in the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), which was adopted as part of the ARRA. Under HITECH, any provider that does not make "meaningful use" of health care IT in its organization or practices by 2015 will suffer reduced reimbursement rates.

Designing and implementing practices to meet the requirements for receiving various incentives (or avoiding certain penalties) under the PPACA will likely require a significant investment of management and legal time. Determining whether provider practices actually meet those requirements may also become fertile ground for negotiation between clients and their regulators. "Meaningful use" is one example; whether a hospital use of HIT constitutes "meaningful use" is determined by a

complex matrix of factors promulgated by the Secretary of Health and Human Services. Even sophisticated players in the industry will probably need legal help in sorting through the nuances and conflicts that may arise from the new or modified regulations.

In addition to trying to change the overall business model in healthcare delivery, the PPACA also adds or changes numerous other federal laws under the general heading of "program integrity." Within this category are amendments to the Anti-Kickback Statute (42 U.S.C. § 1320a-7b) to facilitate enforcement actions against Medicare and Medicaid fraud and abuse and modification of the public disclosure bar to qui tam actions under § 3730(e)(4) of the False Claims Act (31 U.S.C. § 3729, et seq.).

Another change is Section 6002 of the PPACA, which expands the reach of disclosure requirements imposed on device, drug, medical supply, and biologic companies to report information related to payments and other transfers of value to physicians and hospitals for values of $10 or more (or an aggregate of $100 in a calendar year). Even large companies in these industries will need to review their existing policies to ensure compliance with the new requirements, while smaller companies with limited internal resources may find compliance a significant new burden imposed by the law.

It is not possible in a relatively short article to describe all of the many changes and effects the PPACA is likely to have. Instead, the following discussion focuses on health insurers and hospitals as representative of the challenges the PPACA presents to the industry as a whole. It concludes with a reminder that these statutes, while important, are not the final word on the shape of health care delivery. Therefore, the ultimate impact of the legislation probably lies years in the future.

Health Insurers

Although insurers and their supporters succeeded in getting Congress to reject any government-run alternative insurance program (the "public option"), they nevertheless were forced to accept many restrictions on their practices for managing their risk pools. Specifically, among other things,

Section 1001 and 10101 of the PPACA amend or add various provisions of the Public Health Service Act so that over the next several years:

- Insurers are prohibited from, first, denying coverage to children with pre-existing medical conditions and, eventually, denying coverage to anyone with such a condition.
- Insurers must also begin extending coverage to all children of policyholders until those children reach age twenty-six.
- Insurers cannot rescind coverage except in cases of fraud.
- Insurers can no longer impose annual or lifetime dollar limits on benefits.

Acceptance of these restrictions by the insurers was on condition that all individuals would be required to obtain health insurance (either singly or through their employers), generally referred to as the "individual mandate." Forcing more people to get insurance, particularly younger, healthier individuals who might not otherwise do so, is intended to create a significant new market for the insurance companies, thereby (it is hoped) mitigating the additional costs resulting from their no longer being able to reject sick persons.

However, the mandate for individual coverage (contained in Section 1501 of the PPACA) does not take effect until 2014. Therefore, in the short term at least, insurers' expenses are likely to rise because the collective "health" of the risk pools will deteriorate without the influx of the healthier patient population. This means that premiums must rise to cover these higher costs.

However, even though the PPACA does not prohibit premium increases, Section 10101 requires insurers to expend defined percentages (80-85 percent) of each premium dollar on health care. Insurers that fail to meet this minimum requirement will have to provide rebates to policyholders.

Other aspects of the law will also affect the health insurance business, such as the introduction of state insurance exchanges in 2014 (Section 1311) and the phase-out of subsidies for Medicare Advantage plans (Section 1102 of the Health Care and Education Reconciliation Act). Since the restrictions

on the risk pools take effect relatively quickly, but the individual mandate and the anticipated cost savings will not have a measurable effect for some time, insurers' profit margins will come under increasing pressure, at least for the next several years. Therefore, understanding the precise extent to which the law and regulations constrain the health insurance business will be critical to insurers' success.

Hospitals

The impact of the changes in the PPACA on hospitals is equally complex. Hospitals are also supposed to benefit significantly from the increase in the number of covered patients. By reducing the number of uninsured patients, the law is supposed to relieve hospitals of a substantial amount of their bad debts and better align hospital costs and negotiated reimbursement rates. However, hospitals also pay a price under the bill. To help pay for the costs of covering the newly insured, Medicare and Medicaid reimbursements to hospitals are reduced by approximately $155 billion over ten years.

These cuts result from several provisions of the PPACA that provide adjustments to various formulas used to calculate hospital reimbursement rates. Because of these and other changes, it is particularly challenging for hospitals to anticipate how their income is going to be affected over the coming years. For example, the new law provides for reductions in fiscal 2010 of 0.25 percent to the hospital's Inpatient Prospective Payment System (IPPS) market basket (in Section 3401(a)), of 0.25 percent to the Long Term Care Hospital's (LTCH) market basket (in Section 3401(c)) and of 0.25 percent to the Inpatient Rehabilitation Facility market basket (in Section 3401(d)). (The "market baskets" measure how much more, or less, it would cost at a later time to purchase the same mix of goods and services as purchased during a base period. According to CMS, "the percentage change in the market basket reflects the average change in the price of goods and services hospitals purchase in order to furnish inpatient care.")

Furthermore, beginning in 2014, Section 2551 of the statute reduces the Medicare and Medicaid disproportionate share hospital (DSH) payments, which go to hospitals with high percentages of uninsured and Medicaid patient populations. Many administrators of hospitals previously entitled to receive such payments are concerned that the payments should not be

ratcheted down until there is a clearer picture of how other changes in reimbursements for Medicaid patients will affect their bottom lines. *The Wall Street Journal* recently quoted Steven Safyer, president and CEO of Montefiore Medical Center, a private nonprofit in the Bronx borough of New York City, as saying that his hospital could lose half of its $100 million in annual DSH payments.

Another area of uncertainty for hospitals relates to the Obama Administration's efforts to encourage the adoption of electronic health records (EHR). The stimulus bill (ARRA) includes more than $40 billion in funding for development of a national health information infrastructure. This funding represents Medicare and Medicaid incentive payments to eligible hospitals and health care professionals who demonstrate "meaningful use" of electronic health records (EHR). There is, however, substantial concern that incentive payments available to hospitals will not be enough to cover the total costs of conversion to electronic record keeping, including not only the expenses for the hospital's equipment, but those for staff retraining and other adjustments.

The law raises other pressures on hospitals. For example, Sections 3403 and 10320 of the PPACA create an Independent Payment Advisory Board, which will have the power to affect payments to providers and suppliers if, in a given year, spending exceeds growth targets (although hospitals are not subject to cost reductions until 2019). As noted above, Section 6402 of the new law also imposes new reporting obligations and expanded enforcement activity related to exposing and punishing Medicare and Medicaid fraud and abuse, and in the two statutes comprising the PPACA adds a total of $350 million in funding to support the increased enforcement activity.

Hospitals will also have to grapple increasingly with a transition required by the statute from "pay-for-reporting" to "pay-for-performance." Under Section 3001, if certain quality-based performance scores are not met, beginning in 2013, reimbursements will begin to be reduced, initially by 1.0 percent and by 2017 by 2.0 percent. These reductions are intended to fund incentive payments for hospitals that do achieve the required scores.

As with insurers, a detailed review of the changing landscape faced by hospitals is beyond the scope of this article. Suffice it to say that, while they

should benefit from the millions of newly covered patients resulting from enactment of the PPACA, their income may be challenged by their new obligations to deliver quality care satisfying the standards established under the new law.

The Evolving Nature of Health Care Reform

For all of the players in the health care industry, and for the attorneys who represent them, it is important to remember that passage of the PPACA is really only a significant step in a process which started several years ago and is expected to continue for the foreseeable future. Many provisions build on existing law, while others do not take effect immediately. As noted above, for many of the law's provisions, implementing regulations will be necessary, some of which will have to be reconciled with other regulations currently in force. For example, the Centers for Medicare and Medicaid Services (CMS) recently announced a proposed IPPS rule for hospitals that would result in a 0.1 percent reduction in reimbursement rates for inpatient stays. However, this reduction does not reflect any of the changes specified in the IPPS specified in the PPACA. CMS expects to issue another rule in the "near future" to reflect those payment changes.

New regulations, other legislation, and court cases may yet shape the ultimate impact of the PPACA reforms. For example, the mandate in the law that individuals buy insurance has been attacked as an unconstitutional exercise of congressional power. A number of states have proposed (and some have adopted) their own statutes (or in some cases state constitutional amendments) prohibiting such mandates. Attorneys general in several states, as well as one religiously motivated private legal organization, have commenced lawsuits based on the unconstitutionality of the mandate. See, e.g., *State of Florida et al. v. U.S. Dept. of Health and Human Services et al.*, Case No. 3:10-cv-91 (N.D. Fla., 2010); *Thomas More Law Center et al. v. Obama et al.*, Case 2:10-cv-11156 (E.D. Mich., 2010). If one or more of these suits is successful in invalidating the mandates, it would almost certainly upset the balance which the PPACA attempts to strike, making the economics of the new law unworkable.

Finally, the leadership of the Republican Party has indicated that it intends to make the PPACA a major issue in 2010 congressional and senatorial

races. Some have expressed the hope that a significant change in the balance of power in the Congress after those elections could result in significant changes or even repeal of the law. If, for example, if a Republican-majority Congress could somehow bring about a repeal of the individual mandate, the impact would be similar to that of a successful court challenge.

There is also some concern about the effectiveness of the mandate even if it survives all of these potential challenges. Enforcement is lodged with the Internal Revenue Service, but the only power it has is to withhold refunds from individuals who have incurred a penalty for not having insurance. (By 2016, the penalty is the greater of $695 per year, or 2.5 percent of household income up to $2,085.) But those who are not required to file a tax return because their income is below the filing threshold are not subject to penalties. If this "enforcement" mechanism is too weak to force enough people into the insurance marketplace, the economics of the PPACA will be challenged.

In short, it is particularly important for attorneys serving clients in the health care industry is to stay current on developments from Washington and state capitals. To provide clients with maximum flexibility, attorneys need to alert them to new regulations and court decisions as soon as possible, and can best assist them by providing cogent analysis regarding the implications of these pronouncements on the clients' business practices. Lawyers can also assist in managing the heightened risks related to the law's increased emphasis on transparency in reporting on relationships between providers and the drug industry and on enforcement of prohibitions on fraud and abuse in reimbursement practices.

Fortunately, providers, payors, and patients all have organized trade groups that spend significant time addressing industry issues on behalf of their members. Trade associations, such as the American Hospital Association (*http://www.aha.org/*) and America's Health Insurance Plans (*www.ahip.org*) not only offer access to industry leaders, but also each association generally publishes newsletters keeping members apprised of legislative and regulatory developments. Other groups, such as The Henry J. Kaiser Family Foundation (*http://www.kff.org/*) and the American Association of Retired Persons (*http://www.aarp.org/*) also offer Web sites and other resources that

provide significant background and analysis regarding emerging health care issues. For a busy lawyer navigating a complex field, these resources are invaluable.

One thing is certain: The health care industry in the United States will be going through significant changes over the next decade. Participants will need to be alert and responsive to these changes if they expect to stay afloat, and lawyers are in a position to render invaluable assistance if they are well-informed and proactive.

Stephen M. Goodman is the co-head of the Mergers and Acquisitions Group at Pryor Cashman LLP, a New York City-based full service law firm. His practice includes counseling a variety of public and private companies on securities transactions, mergers and acquisitions and he has negotiated agreements for the acquisition, sale, development and commercialization of patents, software and other intellectual property with pharmaceutical and biotechnology companies, hospitals, computer and internet companies and other institutions. He has written on topics ranging from export controls relating to biotechnology research personnel, research incentives in the Patient Protection and Affordable Care Act, and raising seed capital for entrepreneurial companies. He is about to join the governing council of the Science and Technology Section of the American Bar Association and is deputy editor in chief of that Section's publication, The SciTech Lawyer.

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