

# The Metropolitan Corporate Counsel®

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## *Hot Issues Alerts – Law Firms*

### **An Insider's Insights On The Future Of Health Care**

*The Editor interviews Katherine M. Keefe, Chair of the Health Care Practice at Dilworth Paxson LLP.*

**Editor:** Please tell us about your background and experience leading to your recent arrival at Dilworth Paxson LLP.

**Keefe:** I have had a fairly nontraditional career path in that when I graduated from law school in 1986, health law was just emerging as an option for practitioners. I had literally pulled an index card off of a job board at Temple Law School to become a part-time intern at Hahnemann University Hospital. There I learned about the various ways that lawyers could interact with health care clients. The general counsel of Hahnemann hired me on as a staff attorney when I graduated from law school. After a couple of years I joined a small solo practice where I learned about Medicare reimbursement principles, particularly for physicians whom I represented.

Wanting to go back in-house, I took a position as the first general counsel of Keystone Health Plan East, at a time when managed care was first taking hold in the Delaware Valley. At that time, Keystone was the HMO subsidiary of Independence Blue Cross; then it became merged into the operations of Independence Blue Cross, and I became deputy general counsel responsible for managed care issues for Independence Blue Cross. I spent nine years in-house representing the interests of the insurance company on managed care issues ranging from provider contracting to physician credentialing, to quality of care issues, issues under Medicare and Medicaid managed care. I have been back in private practice since 1991, and I am very excited to have recently joined Dilworth Paxson to head Dilworth's Health Care Practice.

**Editor:** Very few people have the kind of expertise that you have.

**Keefe:** It has been really interesting for me because each career step along the way has

been a building block in understanding the health care landscape. As a result, I know the regulatory pieces and the reimbursement pieces and have a unique perspective, having been in-house on both the health care provider and payer sides. These perspectives are very useful to my health care provider and health plan clients.



**Katherine M. Keefe**

**Editor:** Please discuss the uncertainty of health care reform. What are the hot issues from your perspective and which are likely to cause the greatest legislative debate?

**Keefe:** There is a lot of uncertainty. Until the Patient Protection and Affordable Care Act (PPACA) is repealed or overturned by the Supreme Court, it is the law of the land. However, as we all know, it was subject to repeal attempts and is being litigated around the country in 25 separate actions, including those brought by state attorneys general, to attempt to overturn either certain provisions of PPACA or the whole act. Meanwhile, there are different pieces of the law that have taken effect. Regulations have already been and will continue to be issued. There are over 40 provisions in PPACA that require or permit the issuance of regulations, and regulations are always subject to interpretation. Some of these rules have already changed as a result of criticisms leveled against them.

The individual insurance mandate is the hot button among the legal challenges brought by the attorneys general who are alleging that this aspect of PPACA cannot withstand constitutional scrutiny. The concept of severability was touched on by Judge Vinson in the Florida case who determined that because PPACA lacks a severability provision, if one provision is struck down, then the entire law is invalid. This will continue to be a hot issue.

The expansion of the Medicaid program is also a controversial area as are the many new

forms of Medicare payments, including those that would be paid to new Accountable Care Organizations (ACOs), which are intended to incentivize health care providers to provide better quality care.

**Editor:** Does the Department of Health and Human Services (HHS) develop the regulations or do they also come from other sources?

**Keefe:** HHS, and specifically the Centers for Medicare and Medicaid Services (CMS), is the agency charged with implementing a number of regulatory initiatives, such as new Medicare and Medicaid payment models.

As to the insurance mandate and tax reform, there are other agencies that become involved, including the Department of Labor and the Department of Treasury (the Internal Revenue Service). The Federal Trade Commission is also supposed to weigh in on potential antitrust implications of implementing new health care provider payment models.

**Editor:** How is the uncertain fate of PPACA currently affecting health care clients?

**Keefe:** Strategic thought is going into how health care systems, physician groups and health insurance companies want to be positioned, given the potential for this law to remain in effect. Until the Supreme Court rules that PPACA is invalid in whole or partially, health care clients and entities that service the health care industry are meanwhile moving forward, dealing with the everyday challenges of being in a highly regulated environment as well as feeling the pressures that result from lower reimbursements. The uncertainty surrounding the health reform legislation is really not having a huge impact on the daily lives of health care providers who still must deliver care despite PPACA. Health insurers certainly felt the initial force of the law because many of the initial provisions that have now taken effect impact that market segment. Our clients are obviously continuing

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to provide coverage and care regardless of the uncertainty of the law.

**Editor: Is there a sense many organizations are hedging their bets in doing a minimal amount to conform to the law?**

**Keefe:** That is correct to some extent, but there are several PPACA provisions for which compliance is already required, such as closing the Medicare Part D donut hole for prescription drugs, extending coverage to young adults who may stay on their parent's policy until they turn 26 and also providing insurance for those with pre-existing conditions. With respect to ACOs and the other new Medicare and Medicaid payment models, there are some strategic decisions to be made given the uncertainty as to how those models would be implemented through regulations. One area that gives pause is the recognition that in order for models such as ACOs to be safely launched from a legal perspective, certain existing fraud and abuse laws and antitrust laws may need to be revised or modified. This is because the kinds of behavior that those laws were originally designed to prevent are the very behaviors that the new ACO models are trying to encourage. While the fraud and abuse laws were designed to prevent unnecessary utilization of services based on inappropriate financial incentives, the ACO model is trying to encourage proper quality of care through financial incentives. Whereas the antitrust laws were designed to prevent inappropriate collaboration among competitors and exertion of too much market power, the ACO model stands for the principle that collaboration and coordination among health care providers, even those who may be competitors, is desired. The health care reform legislation acknowledges this tension by stating that fraud and abuse laws can be waived in order to implement PPACA. The Department of Justice, the Office of Inspector General and the Federal Trade Commission are working now to address these issues, and the health care industry is eagerly awaiting some clarification as to how the existing fraud and abuse and antitrust laws would be applied in the new environment.

**Editor: How does the uncertain fate of the PPACA impact your practice?**

**Keefe:** It provides an opportunity for a practice such as ours to continue in a very close counseling role in keeping clients abreast of developments, complicated and numerous as they may be. I have been involved in a number of initiatives for my health care provider clients who are developing new models of care regardless of the outcome of health care reform. I have several clients who have succeeded in more comprehensively managing the care of patients. There are some contractual arrangements between and among vari-

ous stakeholders to collaborate with commercial insurers to pay for new models of care. The market recognizes that there is opportunity in cost savings and success with patients when care is better coordinated. And in order to do that I have also been involved on the health information data side involving electronic health information which will be the basis for providing solid evidence of good quality care. I counsel clients with respect to participation in health information exchanges and in purchasing new health data information platforms to enable providers to capture the data that is essential to prove and be paid for good quality of care. We also deal with the fallout of placing health information in electronic formats and the resulting privacy and information security issues. The more information that is put in electronic format, the odds suggest the inevitability of data breaches.

**Editor: What key legal issues are faced by health care clients? HIPAA has raised quite a number of issues.**

**Keefe:** Significant HIPAA changes were part of the stimulus law under the HITECH Act (Health Information Technology for Economic and Clinical Health Act) passed in 2009. One of its key provisions created for the first time a federal breach notification responsibility. So if an entity covered by HIPAA, primarily health care providers and health plans, or their business associates, experiences a breach of patient or enrollee data, they now have an obligation to affirmatively notify individuals whose health information was breached. That has created new issues for health care organizations who now are required to have breach response plans and notification protocols when data is breached. If the breach covers over 500 individuals, the health provider must notify the media and must immediately notify the federal Office of Civil Rights (part of HHS).

**Editor: Is there a new industry emerging to deal with data breach issues?**

**Keefe:** There certainly is. One driver is the emergence of cyber liability insurance coverage. Some of the insurance carriers who write directors and officer's liability insurance coverage for the health care industry have new specialized lines that cover data breaches. Also, when the breaches are large enough, there is often the need for not only legal counseling but specialized forensic assistance because sometimes these breaches are perpetrated by expert hackers. Forensic organizations or consultants are often brought in to examine the computer system and investigate whether and how the data was compromised. We have seen such widespread breaches that some providers have had to engage mail houses and call centers to assist them in notifying affected persons and to assist in fulfill-

ing the HITECH requirement for a point of contact so that an individual receiving a letter can have any questions answered.

**Editor: What is the government looking at in terms of health care enforcement activities?**

**Keefe:** PPACA contains additional funding for health care fraud investigations and enforcement. As the Medicare and Medicaid program dollars grow more precious, there is always a corollary of enforcement activities with specific areas of focus. For example, the Office of Inspector General (the investigative arm of HHS) every year publishes a work plan of issues it will examine, sometimes alongside the Department of Justice, such as irregular billing, under- or over-utilization of care, kickbacks and Stark law violations. Between the Department of Justice and the Office of Inspector General there is a continual roster of projects going on with respect to investigating health care fraud. There are also existing and ongoing programs targeted to the recovery of dollars paid by Medicare and Medicaid, such as the Recovery Audit Contract or RAC program. In this case the government hires outside contractors to identify inappropriately paid claims and recoup money for the government. Many organizations are working with their counsel to do pre-audits and self-examinations of billing and coding compliance to get the house in order before they are audited by a government contractor.

**Editor: With the Medicare and Medicaid budgets under pressure, how is that pressure felt by health care providers?**

**Keefe:** These pressures are challenging health care providers to hopefully discover new ways of working together under models such as the ACO and medical home to capture revenue in the most optimal fashion and benefit patients, especially if performance is measured by the quality of services. Many in the health care industry see opportunity in the direction that health care reform would take reimbursement.

**Editor: Would you summarize where you think health care services will be in five years?**

**Keefe:** What attracts me to this area is how pervasive these issues are. There is really no other area in the law that so fully touches so many lives. Health care costs today constitute and astounding 17.5 percent of our GNP. Given how unpalatable a single payer system may be, if we continue our fragmented system with its myriad of government and commercial payment systems and regulations on both the federal and state levels, we are going to have a lot of interesting opportunities and challenges for many more years to come.