# Health Care Matters

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## IN THIS ISSUE



## Special Masters in Health Care Antitrust Merger Cases: Resolving the Conflicting Interests

By Barbara Reeves, Esq.

One of the most challenging aspects of antitrust cases in the health care field is the rich mixture of public interest considerations, pro-competitive benefits, anticompetitive concerns, the backdrop of the Affordable Care Act (ACA) and the unknown about what will happen tomorrow. How will the courts rule in the context of the ongoing developments in change, consolidation and competition in health care? Will the challenged mergers and affiliations bring benefits to consumers? To the parties? To health care? How can counsel sort through the conflicting interests while also zealously advocating on behalf of their clients? Mergers, affiliations, patent licensing arrangements and purchasing and pricing arrangements between pharmaceutical companies, hospitals and insurers raise complex issues, and the results will have significant impacts on consumers and businesses in the health care field.

(Continued on page 2)


## Cyber-Attacks in the Health Care Industry

By Daniel B. Garrie, Esq.

### What threats does the health care industry face?

The health care industry today faces a new threat in the form of cyber-attacks, from both internal and external actors. This threat is exacerbated by a lack of institutional support from the government. Thus, the burden is now on health care providers to secure their own data and protect their clients. Unfortunately, health care institutions are uniquely vulnerable, not only to data breaches, where customer data is com-promised, but also to ransomware, which is "a type of malicious software designed to block access to a computer system until a sum of money is paid."[1] While data breaches can have long-term negative effects on a huge number of patients, ransomware has the potential to shut down a health care institution, leaving its patients in dire need of medical aid, without any chance of getting the care they need.

A cyber-attack can happen in the blink of an eye, or more aptly the click of a mouse. A mid-level patient records administrator receives an email inquiring about an

(Continued on page 4)

## Special Masters in Health Care Antitrust Merger Cases: Resolving the Conflicting Interests (Continued from page 1)

Three recent health care antitrust cases illustrate the point: *FTC v. Advocate Health Care, et al.; FTC, et al. v. Penn State Hershey Medical Center, et al.; and ProMedica Health System, Inc. v. FTC*. These cases arose out of challenges by the FTC to hospital mergers in the metropolitan Chicago; Hershey, Pennsylvania; and Lucas County, Ohio, areas, respectively. In each case, the merging hospitals asserted that the merger would produce economic and health care benefits. In *Advocate Health Care*, the hospitals promised that the merger would create a new low-cost, high performing network throughout the Chicago area, bringing benefits to consumers. In the *Hershey* case, the hospitals argued that their merger was in furtherance of finding innovative ways to best serve patients and the community by providing the "highest-quality and most cost-effective care possible." *ProMedica* did not advance precompetitive benefits as a justification for its merger, but rather the absence of anticompetitive impact. The FTC's complaints, on the other hand, alleged that the mergers would create dominant providers of general acute care inpatient hospital services in the relevant markets and would likely lead to increased health care costs and reduced quality of care.

The focus of this analysis is not to argue the pros and cons of each party's antitrust analysis and market definition position, but rather to analyze a more efficient way of approaching cases such as these in today's "evolving landscape of health care" (to quote the court in *Hershey*), including the ACA, changes in Medicare and Medicaid reimbursement and the transition to risk-based contracting, to name but a few.

The *Advocate Health* and *Hershey* cases are just at the beginning of their saga: The FTC's motions for preliminary injunctions were denied and are on expedited appeal, with the prospect of the FTC administrative hearings still ahead. ProMedica is an example of what may lay ahead: The FTC just approved ProMedica's divestiture of nearby St. Luke's Hospital, finally ending *six years of litigation and uncertainty*, following an FTC determination (and federal court decisions affirming the FTC) concluding that the transaction violated the antitrust laws.

These cases involve complex issues and interests, in the framework of an evolving and developing health care system. Predicting the potential outcomes of a merger is such a difficult task that it is unrealistic to expect a judge to understand all the criticisms of an econometric study and all the nuances of provider-payor contracts and then assess what is likely to happen in the years following the merger. Yet in these examples, the cases were put before judges with little or no antitrust experience or health care expertise, presented by expert teams of advocates and teams of experts, in an extremely adversarial situation where time was of the essence, only to be followed, as *ProMedica* illustrates, by years of litigation and uncertainty.

Is there a more effective, studied and cost-efficient approach to weighing these interests and resolving the dispute to protect the public's interest in both competition and affordable, quality health care?

Courts have recognized that the appointment of a knowledgeable, neutral third-party, or a special master, can streamline discovery, focus the parties on key evidence, settle discovery disputes and explore the pros and cons of settlement alternatives while keeping an eye on the various interests. Special masters, as discovery masters and settlement masters, serve as a knowledgeable neutral between the parties and a helpful buffer between the parties and court to manage discovery plans and assist in reaching a resolution.

Special masters are relatively commonplace in many cases in 2016, including government environmental cases, desegregation cases, water disputes

between states and prison condition cases. Special masters, as discovery masters and attorney's fees referees, are also frequently used in antitrust cases. They do not appear to have been involved in any of the recent health care antitrust cases, ranging from challenges to mergers to disputes involving pharmaceutical companies' biosimilars and generic product hopping. These cases are rich with issues that could have benefited from a discovery special master and/or a settlement special master.

What can a special master do?

### 1. A special master can focus discovery.

The use of discovery masters to manage and supervise complex cases is relatively commonplace. The discovery master can manage a discovery plan, issue orders resolving discovery disputes and make recommendations to the judge. A discovery master experienced in both discovery procedures and computer systems and software can cut through the arguments and objections to determine what information is readily accessible or recoverable and what really matters. How many trial lawyers have ever used more than a small subset of all discovery gathered when it came time to introduce exhibits at trial?

### 2. A special master can focus the issues for trial.

A special master can meet with each party, identify the respective interests and focus the trial on the issues where there are differences, saving trial days, while keeping in mind the need to preserve a record for appeal.

### 3. A special master can be a bridge between parties and develop interim measures.

A special master can explore alternatives with each side confidentially, such as allowing some form of integration or alliance on an interim basis to test the extent to which prices are impacted, costs reduced, savings passed to consumers and quality improved. Pharmaceutical companies battling over generic and biosimilars issues can feel safe exploring their issues with a special master, in confidence if the parties have agreed to mediation confidentiality, to see if there is some option that will keep them out of court while not running afoul of the regulators.

### 4. A special master can guide the parties toward settlement.

A settlement master can enable the parties to consider to what extent the competing interests of each party are reflective of some part of the public interest that could be preserved by careful structuring of the transaction or by modifying the transaction to something less than a merger. In an evolving market such as health care, with competing public interests, can anyone confidently predict the future and identify the public interest, in the black-and-white terms that advocates ask the court to find as a basis for allowing or preventing a merger?

The hospital mergers discussed above presented perfect settings for a neutral special master. For example, the parties might have agreed to focus discovery and analyze the following topics, which would have been critical to understanding the competitive impacts of a merger and could have shed more light on finding a solution: (1) market definition, including whether patients are likely to change their willingness to travel greater distances for health care as price information and quality of service information become more available, combined with incentives to use narrow networks; (2) the views of health insurers on the transaction; (3) an analysis of the rate agreements entered into by the two hospitals with their two largest insurers; (4) the status of recent contract negotiations between these hospitals and commercial health plans, and how they might be expected to change after the merger; (5) the proffered efficiencies; and (6), everyone's favorite, the extent to which antitrust enforcement is complementary to or in conflict with the goals of the ACA. This approach may have led to a decision to prosecute, a decision to abandon the merger or a creative resolution that satisfied all parties that the public interest was being protected as best as anyone can understand at this point in time. ●

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employment opportunity. Although he is not expecting any applications, and he is not a point of contact for employment inquiries, the administrator opens the resume anyway. While he is reviewing the applicant's credentials, a cyber-criminal's malware is delivered to the hospital's network. The malware quickly captures the administrator's login credentials, and because he has broad administrative rights to company systems, the malware quickly spreads across the hospital's network and encrypts patient data. In a matter of minutes to hours, patient records are not available, and health care providers are unable to treat the patients they have and are forced to turn new patients away. Law enforcement is called, but there is no solution. The hospital ends up on the front page of the next day's *New York Times*, and it eventually elects to pay the ransom.

## How should the health care industry respond to these threats?

**Training:** The goal of implementing a training program is to change the culture within a company so that every employee believes that information security is their personal responsibility, not just the responsibility of behind-the-scenes IT and information security personnel. With proper training, the situation described above never would have occurred. The employee would have understood that he received a suspicious email, and he would have forwarded it to the individuals responsible for information security, who would promptly detect the threat.

**Backing up and securing data:** This sounds simple, but the sophistication of modern attacks threatens the security of traditional data backups. Even when backing up into the cloud, company data still faces some risks. It is possible to back up data in more secure ways and in doing so render most cyber-threats harmless, but it is not an easy project to undertake. The legal, risk, and compliance teams need to work collaboratively with the IT and information security groups to understand the nuances of the company's systems and develop plans that ensure critical data, such as patient records, is both secure and somewhat readily accessible in the event of a cyber-attack.

**Cyber-insurance:** Even with the two above steps, it is impossible for a health care provider to eliminate the risk of a cyber-attack, which means providers should look to cyber-insurance to mitigate and control its risk exposure. Cyber-insurance is a developing product in the insurance marketplace, and due to the complexities of cyberspace, there is little agreement as to what the product is and what it should cover. Each insurance company builds its own product, which has led to a largely heterogeneous marketplace and makes it nearly impossible for a non-specialist to make an educated comparison of insurance policies. A lawyer experienced in cyber-insurance can be invaluable in assessing the coverage of a particular policy and matching it to the requirements of the company; additionally, certain brokers specialize in cyber-insurance. Between these two specialists, a health care provider will be able to properly control and mitigate its risk exposure. Further, it is important to note that many insurers provide services along with the insurance when an incident occurs.

## What should you do if your security is breached?

To paraphrase FBI Director James Comey, there are two kinds of companies: those who've been hacked and those who don't know they've been hacked. It is an unfortunate inevitability that with the prevalence of cyber-threats, any given health care provider will be forced to deal with a cyber-attack. Even the above steps, if performed perfectly, only mitigate the risk of a cyber-attack. Thus, health care providers should take steps to prepare themselves for the fallout from a cyber-attack. While incident response is critical, as discussed above, your cyber-insurance provider may be able assist in developing an incident response plan. One step that can be taken to help mitigate legal costs associated with a cyber-breach is to employ arbitration as a mechanism for dispute resolution.

Health care providers can include arbitration clauses related to cyber-claims in patient agreements, which will allow any potential litigants to select an arbitrator with significant technical experience, who will be able to expedite the resolution of claims by utilizing his or her expertise to cut away many of the procedural and technical hurdles that may be present in educating a fact-finder without technical expertise. Arbitration is not a magic bullet for dealing with cyber-attacks, but it is certainly a tool that can be utilized to help mitigate time and cost, as well as allow the health care provider to get back to the valuable work of saving people's lives. ●

[1] *Malware and Ransomware, Montana Tech, http://www.mtech.edu/cts/security/malware.htm.*

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# Why FCA Disputes Can Benefit from Mediation—and Even Arbitration

By R. Wayne Thorpe, Esq.

Among the most difficult disputes facing participants in the health care industry are False Claims Act (FCA) cases brought by federal or state agencies (often initiated by relators) for alleged fraud in connection with payments under government health care programs, including Medicare and Medicaid. The high stakes involved in these cases is one important reason why parties should carefully consider attempting settlement through mediation.

Despite the fact that at least three organizations (JAMS, American Arbitration Association and American Health Lawyers Association) offer panels of mediators and arbitrators specializing in health care, there has historically been resistance to mediating health care disputes. One possible explanation is that health care lawyers, especially in the health fraud bar, have come to health law practice after years of practice in white collar criminal prosecution and defense work with little ADR experience.

Some private lawyers in fraud cases are skeptical about whether government agencies are genuinely interested in mediating fraud cases, although anecdotal interviews with both private and government lawyers, as well as our experience with these cases at JAMS, reflect both genuine interest and successful experiences regarding both federal and state governments in mediating appropriate health fraud cases.

The stakes are high in federal FCA cases, which can result in civil penalties, corporate and individual criminal liability and exclusion from government health care programs. Most states provide for similar liabilities. The U.S. Department of Justice (DOJ) has reported that it recovered more than $2.5 billion in 2010 and $4.6 billion since January 2009 in health care fraud cases. Several reported recoveries against pharmaceutical and device companies have exceeded $100 million. According to the DOJ, "Fighting fraud committed against public health care programs is a top priority for the Obama Administration." Recent legislative changes have enhanced the ability of the federal government and FCA *qui tam* relators to pursue claims:

- The Affordable Care Act (ACA) § 6402 amended the federal Anti-Kickback Statute to make clear that violations of that statute can be brought under the FCA.
- The Fraud Enforcement and Recovery Act imposed FCA liability for overpayments, expanded the DOJ's power to

issue civil investigative demands and amended the FCA anti-retaliation provisions to protect contractors and agents in addition to employees.

- The ACA further defined overpayment liability to provide that retention of an overpayment for over 60 days after identification by a provider can become a false claim.

Government investigations of possible FCA cases provide opportunities to use mediation to satisfy important goals and interests of both the government and the accused, while also potentially saving time, money and other important resources.

A mediated settlement agreement may avoid (or at least diminish) exclusion and criminal responsibility while quantifying civil monetary exposure at a known, agreed-upon level. Even where a potential FCA defendant genuinely (and perhaps correctly) views a potential claim as defensible, such an approach to mediation and settlement may often have some merit because, among other reasons, a defendant can utilize a mediated settlement to avoid the potentially enormous financial cost of lengthy further investigation, discovery, motion practice and trial; the adverse impact on relationships; and the drain on the time and energy of senior management and legal personnel. From the government's perspective, substantial and adequate financial payments can be recovered without the time, risk and cost attendant to a trial against a well-heeled and committed defendant. Similarly, governments can devote very substantial, but nonetheless limited, financial, legal and investigatory resources to health care fraud cases, and a mediated settlement may allow government agencies to move on to other important investigations.

When a mediation occurs prior to the unsealing of a relator's FCA complaint, a defendant may also have a chance to vindicate an interest in privacy, or at least in diminished public and media scrutiny. A defendant's settlement of an FCA case will be public and likely publicized with some fanfare. But on the day after the announcement, investors, lenders, financial analysts, employees, vendors, customers and other key constituencies will start to view the issue in the rear-view mirror, rather than through the continuing scrutiny of a pending case with an uncertain outcome. The government in turn gets a chance to make a splashy announcement, satisfying the important goal of potentially deterring future putative wrongdoers, without the cost of a longer investigation and trial and without the risk of sending the wrong deterrence message if the trial is not successful.

Further, use of mediation in government fraud cases provides a forum for the resolution of issues with multiple parties and agencies. Settlement of *qui tam* matters under the FCA can be particularly challenging because each settlement typically has multiple parties, including the DOJ, the Inspector General of HHS (which has administrative authority to exclude the defendant from Medicare), the relator(s) and the defendant(s). If a defendant seeks a release of any state liability for Medicaid claims, a settlement will also require the involvement of state authorities, which ordinarily include a state Assistant Attorney General, sometimes many of them. Although the DOJ and most state Attorneys General will require most FCA settlements to be approved at various levels of management (for example, Assistant U.S. Attorneys and trial counsel at the DOJ cannot ordinarily make binding settlement offers and commitments), this challenge should rarely be significant because final, "official" higher levels of approval are obtained routinely in the mediation and settlement of many types of cases involving federal, state and local governments.

Finally, here is a note on an unusual but effective use of ADR for FCA matters in which multiple adverse defendants have a common interest in settling with governments and relators. In cases of this sort, the most difficult problem may be reaching agreement among defendants on how to address the government/relator claims. Or more to the point, which defendant has to pay how much? One remarkably simple solution is to make a tentative agreement on who pays how much to the government/relator and then arbitrate among two or more settling defendants on ultimate assessment of liability among those defendants. It can be done quickly and relatively inexpensively, and it avoids having the private defense side controversy wreck a possibly significant settlement.

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