Top 10 Legal Issues For Health Providers In 2013

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As the end of 2013 approaches, it is time to look back at 2013 and recall the top 10 legal developments affecting hospitals and health care providers. The year was filled with change and uncertainty for providers as the Affordable Care Act was being implemented.

1. Awaiting Health Care Exchanges

At the start of 2013, providers had a sense of anticipation. The U.S. Supreme Court had upheld the individual mandate of the ACA. As providers prepared for the ACA's implementation and the introduction of the exchanges, they were faced with uncertainty and a number of questions.

Would the ACA deliver increased volume of uninsured patients? How many uninsured patients would sign up for insurance or otherwise obtain coverage? What would be the change in Medicaid enrollment? How broad would the provider networks be in the exchanges? What managed care companies would participate in the exchanges? Would young healthy people elect to buy insurance or pay the "tax"? How would various market-place actors adopt to the changes? Would employers elect to modify coverage for its employees?

The technology failures with the Oct. 1 website rollout prolonged the uncertainty and became the most widely covered issue in health care in 2013. The failures have threatened the ability to sign-up people in the open enrollment time frame. When coupled with a large number of people losing their insurance coverage, the website failures have provided fodder for the strident opponents of the ACA. They also raise the potential for longer term implementation issues.

As the year closes, uncertainty and anticipation remain.

2. Tuomey Case

In October, after a federal jury trial, the Tuomey Healthcare System was found to have

violated the Stark Law and the False Claims Act and was ordered to pay approximately $237 million in fines and penalties. The size of the penalty exceeded the Tuomey hospital's annual revenues.

The matter involved a financial transaction in which Tuomey elected to employ 19 specialist physicians on a part-time basis, allegedly to avoid the threatened reduction in surgeries performed by the specialists at Tuomey facilities. The employment agreements had 10-year terms and required the employed specialists to perform their procedures in Tuomey facilities. The compensation included base pay, productivity bonuses equal to 80 percent of net collections seemingly for both the professional and facility components and an incentive bonus. The employment agreements also contained two-year noncompete agreements.

One specialist did not sign the agreement and instead filed a qui tam action. The trial led to the conclusion that the financial relationship violated the Stark Law, with the submission of claims violating the False Claims Act.

The Tuomey case is one that grabbed the attention of hospitals and health systems. It drives home the need for caution and care in understanding and structuring financial relationships. Merely obtaining an appraiser is not
sufficient.

Tuomey is appealing the decision.

3. HITECH Final Rule Issued

In January, the final Health Information Technology for Economic and Clinical Health Act rule was issued. The final rule made a number of changes in the Health Insurance Portability and Accountability Act, including changes that require updating of business associate agreements. The new rule became effective on Sept. 22, 2013, except that the compliance date to bring pre-existing business associate agreements into compliance is Sept. 23, 2014.

Among the changes in the rule are:

- Business associates are now directly subject to the HIPAA security rules and certain provisions of the privacy rule

- There are lowered standards required for determining if a notice of a breach of privacy must be provided

- There is a broader need for a patient authorization for marketing communications paid for by a third party

- There are changes in the use of protected health information in fundraising

- There are changes in the requirements for matters to be included in the notice of privacy practices

4. Pioneer ACO Program Results

In July, CMS publicly announced the first year results of the Pioneer ACO Program. These were the first results announced covering an ACA program that paid on the basis of value instead of volume.

The results were mixed.

On the positive side, CMS reported that the 32 participants generated gross savings of $87.6 million in Medicare savings, a portion of which was shared with 13 of the 32 participants. The growth in Medicare expenditures also were held to a rate below the comparable rate for the fee-for-service Medicare program.

On the negative side, nine of the 32 Pioneer ACO participants elected to discontinue their participation in the Program and two were required to repay the Medicare Program a total of $4 million. One participant that elected to terminate participation indicated that, since it had been focused on reducing costs for many years, it found it difficult to continue to hold its

costs below the lower established cost benchmark.

5. Legal Challenges to ACA

While the Supreme Court upheld the individual mandate of the ACA, legal challenges to other provisions of the ACA continue. Among the more prominent challenges are those attacking the availability of the tax credit subsidies for insurance purchased in those states with federally operated exchanges and a challenge to the coverage requirement that for-profit corporations whose principal shareholders have a religious objection must cover the U.S. Food and Drug Administration's approved birth control for their employees.

The challenge to the tax credit subsidies is based on statutory language of the ACA that provides that the subsidies are available to those in state-operated exchanges, while not specifying whether they are permitted in federally operated exchanges. The Internal Revenue Service attempted to remedy this issue by issuing a regulation defining an "exchange" for this purpose as including federally facilitated exchanges.

36 states have federally operated exchanges. If the subsidies are determined not to be available in such states, the affordability criteria of the ACA that require individuals to obtain health insurance if the cost does not exceed a percentage of the individuals' income after giving effect to the subsidies, may have a significant impact on compliance with the individual mandate.

The Supreme Court has agreed to review whether for-profit corporate employers may invoke their shareholders' religious beliefs to deny coverage for FDA approved contraceptives.

6. Antitrust Developments

With changes in the ACA, providers have sought to consolidate through acquisitions and affiliations to improve their ability to coordinate care. Such acquisitions allow providers to integrate easily and to make electronic health records and other capital investments available to controlled entities. The implementation of care protocols and increased quality and efficiencies in the delivery of care are byproducts of such consolidation.

Antitrust authorities seemed to generally approve of behavior designed to recognize care coordination efficiencies, such as accountable care organizations ("ACOs"). In 2011, the Federal Trade Commission and U.S. Department of Justice jointly issued a statement of Antitrust Enforcement Policy Regarding ACOs which seemed to encourage ACO development. In 2013, however, the FTC has challenged certain acquisitions, notably the acquisition by St. Luke's Medical Center of Boise, Idaho of Saltzer Medical Group, Idaho's largest independent practice, asserting that the acquisition violates antitrust laws and the efficiencies of care coordination could be obtained without the need for an acquisition.

Such position of the federal antitrust authorities may indicate that acquisitions that providers view as important to allow for recognition of efficiencies may still lead to legal challenges because the efficiencies could be obtained without an acquisition.

7. Final Mental Health Parity Regulation Issued

In November, the government issued final rules implementing the Mental Health Parity and Addiction Act of 2008 ("Parity Act"). The final rule is effective on July 1, 2014; until then the interim final rules published in February 2010, will remain in effect.

The regulations generally preclude group health plans, including individual health plans, whether sold through the exchanges or not, from imposing more restrictive limitations on mental health and substance use disorder benefits than on medical/surgical benefits (the "parity requirement"). While a plan is not required by the Parity Act to offer mental health or substance abuse disorder benefits — though under the ACA coverage of such benefits are required for plans that cover essential health benefits — if it does so it must meet the regulation's parity requirement.

The parity requirement applies to financial or quantitative requirements (such as deductibles, copayments, out-of-pocket caps, annual or day visit limits) as well as to "non-quantitative treatment limitations" (such as medical management limits based on medical necessity, formulary design, network tier design or participation standards for provider networks). The final regulations eliminated the exception to the parity requirement for non-quantitative treatment limitations to the extent that recognized clinically appropriate standards of care constitute a difference, because of the belief that some plans may be misusing this exception. Notwithstanding elimination of this exception to the parity

requirement, the regulations still allow plans flexibility to make determinations based on "clinically appropriate standards of care" in determining benefits.

The regulations also include transparency requirements, including the requirement that a plan disclose information concerning medical necessity denials. The regulations provide that plans must provide documents, records and other information related to the denial that are relevant to a patient's claim for benefits.

8. Payment for Value Not Volume

In 2013, a key question for providers was how quickly will the shift to reimbursement reform based on payment for volume to payment for value occur. Providers continued to test programs that compensated them for delivering quality care while restraining costs and improving the health of the community served. Value-based purchasing and hospital readmission limits were implemented by CMS. Providers also voluntarily participated in government programs such as the Medicare Shared Savings Program and the Pioneer ACO Program, and commercial market accountable care programs with managed care companies. Medical home programs were also offered with increased frequency.

While the majority of provider's compensation remained fee-for-service, there was an increased commitment by providers to prepare themselves for a changed reimbursement system. Providers were asking increasingly how quickly the transition to value would occur, as they consider revising their employed physician compensation arrangements and make other decisions.

9. Physician Payment Sunshine Act

In February, the Centers for Medicare & Medicaid Services issued final regulations implementing the Physician Payment Sunshine Act. The law and its regulations place requirements on (a) manufacturers of, and (b) group purchasing organizations ("GPOs") that purchase, arrange or negotiate the purchase of, drugs, devices, biological and medical supplies for which payment is available under government health care programs. Such manufacturers and GPOs are required to disclose publicly information concerning ownership or investment interests in them held by physicians or their immediate family members and also payments they make to physicians or teaching hospitals.

The obligation is to report such payments commencing with the year starting Aug. 1, 2013; the law does not regulate the propriety of any payment. The reporting obligation applies to any item of a value of $10 or more or payments that in aggregate exceed $100 in any year, with certain specified exceptions. The content of the reports must also contain a variety of specified details concerning the arrangement.

The government's belief is that the reports will, by putting a light on the payment arrangements, allow patients to make better informed decisions and help to deter inappropriate relationships. Many have also thought that the public reporting will assist potential qui tam relators in developing cases.

10. Provider Self-Disclosure Protocol Issued

In April, the Office of Inspector General and CMS issued a new self-disclosure protocol for providers to self-disclose certain violations of health care laws. The protocol lists the benefits of a provider's self-disclosure, including a presumption against a corporate integrity agreement, use of a lower multiple in determining damages, and mitigation of potential exposure for failing to identify and return overpayments.

The protocol also describes who is eligible to use it — it may not be used if only a Stark Law violation is involved or to report on another entity's behavior — and the required content of any disclosures under the protocol, including the behavior involved, an estimate of damages, and when appropriate how fair market value was determined.

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