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Health Care Regulatory and Legislative Update

Chapman Insights
February 10, 2017

Weekly Health Care Criminal and Civil Fraud Enforcement Round-Up

The following highlights notable health care fraud and abuse news, settlements and enforcement actions in the previous two weeks.

1. **TeamHealth Holdings to Pay $60 Million to Settle Medicare and Medicaid False Claims Allegations Relating to Acquired Hospitalist Company.** On February 6, 2017, the Department of Justice ("DOJ") announced a $60 million civil settlement with TeamHealth Holdings (a large physician services organization) as successor in interest to IPC Healthcare Inc., f/k/a IPC The Hospitalists Inc. ("IPC"). TeamHealth acquired IPC in late 2015. The government specifically alleged that IPC knowingly and systematically engaged in up-coding for its hospitalist services, encouraging lower billing physicians to "catch-up" with their peers, and at times, billing for more services in one day than could have been provided in a 24-hour period. The allegations were brought under the whistleblower provisions of the False Claims Act by a physician formerly employed by IPC as a hospitalist. The former employee will receive a $11.4M reward for bringing the case. Although TeamHealth reports that the allegations at IPC predate the acquisition and that TeamHealth was aware of the matter, this settlement serves as an important reminder of successor-in-interest liability and the importance of conducting thorough due diligence on the billing and coding practices of target health care provider companies.

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2. **Former Tenet Executive Indicted for Alleged Role in $400 Million Medicare/Medicaid Fraud Scheme.** On February 1, 2017, the DOJ announced the indictment of a former senior executive of Tenet Healthcare Corporation ("Tenet") due to his alleged role in an over $400 million scheme to defraud the Medicare and Medicaid programs. According to the indictment, the former Tenet Senior VP of Operations caused the payment of bribes and kickbacks in exchange for patient referrals and made false and fraudulent statements to the government in connection with Tenet's 2006 Corporate Integrity Agreement (the "CIA") — which required that he certify on a yearly basis that Tenet was in compliance with health care laws. This settlement underscores the DOJ's intention to hold both corporations and individuals accountable for fraud and the importance of good faith compliance with Corporate Integrity Agreements. See our October 11, 2016 Regulatory and Legislative Update for more information on the underlying 2016 Tenet settlement.

Office of Budget Management Withdraws Proposed Omnibus Guidance for 340B Drug Pricing Program

The federal Office of Management and Budget ("OMB") has withdrawn its proposed "mega-guidance" rules ("Omnibus Guidance") for the 340B Drug Pricing Program ("340B Program"). The 340B Program requires drug manufacturers to provide outpatient drugs to eligible health care providers at significant discounts in order to have their drugs covered by Medicaid. Eligible health care providers under the 340B Program are defined in the statute and include safety net providers who treat a disproportionate share of low-income patients, including government-supported health centers, Ryan White clinics and State AIDS Drug Assistance programs, "disproportionate share hospitals," and children's hospitals. According to the Health Resources and Services Administration ("HRSA"), the 340B Program saved eligible safety-net providers $3.8 billion on outpatient drugs in fiscal year 2013. The Omnibus Guidance, which has been pending since August 2015, would have tightened controls on which patients, drugs and providers qualify for the drug discounts. While hospitals praised the decision to withdraw the Omnibus Guidance, drug manufacturers will likely view the decision negatively, as many have argued the program has become overbroad. Interestingly, the withdrawal coincided with a meeting between President Trump and the heads of major drug manufacturers. We will continue to monitor proposed rules and other sub-regulatory guidance relating to the 340B Program. Until then, 340B stakeholders should rely on previous guidance.

Failure to Respond Timely to HIPAA Notice of Proposed Determination Results in $3.2 Million Civil Monetary Penalty for Pediatric Hospital

On February 1, 2017, the U.S. Department of Health and Human Services, Office for Civil Rights ("OCR"), announced a $3.2 million Health Insurance Portability and Accountability Act of 1996 ("HIPAA") civil money penalty against Children's Medical Center of Dallas based on the hospital's impermissible disclosure of unsecured electronic protected health information ("ePHI") and non-compliance with multiple standards of the HIPAA Security Rule. The ePHI disclosure resulted from the 2009 loss of an unencrypted BlackBerry device, and the 2013 theft of an unencrypted laptop. After the hospital disclosed these breaches to OCR, OCR's investigations revealed noncompliance with HIPAA Rules, "specifically, a failure to implement risk management plans, contrary to prior external recommendations to do so, and a failure to deploy encryption

or an equivalent alternative measure on all of its laptops, work stations, mobile devices and removable storage media until April 9, 2013." On September 30, 2016, OCR issued a Notice of Proposed Determination in accordance with HIPAA, which included instructions for the hospital to request a hearing within 90 days. After the hospital failed to request a hearing within 90 days, OCR issued a Notice of Final Determination imposing the full $3.2 million civil money penalty on the hospital, with no right to an appeal.

Anthem-Cigna Merger Blocked by Federal Judge, Marking Second Major Insurance Company Merger to be Blocked in as Many Months

On Wednesday, Judge Amy Berman Jackson of the U.S. District Court for the District of Columbia blocked the proposed $48 billion Anthem-Cigna merger, reasoning that a merger between the nation's second and third largest medical health insurance carriers would substantially lessen competition in violation of federal antitrust rules. The full order, which can be found here, states that "[t]he evidence has also shown that the merger is likely to result in higher prices, and that it will have other anticompetitive effects: it will eliminate the two firms' vigorous competition against each other for national accounts, reduce the number of national carriers available to respond to solicitations in the future, and diminish the prospects for innovation in the market." Anthem has announced that it plans to appeal. Last month, U.S. District Court Judge John Bates blocked the Aetna-Humana merger on the similar grounds. This second major antitrust win for the DOJ in as many months serves as notice that the government's focus on health care antitrust is alive and well and that health care companies should continue to carefully assess whether proposed mergers or business practices raise anti-competitive concerns.

Joint Commission Clarifies That It Prohibits Secure Texting for Patient Orders

The Joint Commission, in collaboration with the Centers for Medicare & Medicaid Services ("CMS'), has published new recommendations with respect to the secure text messaging of patient care orders. The recommendations clarify that although the Joint Commission and CMS will continue to monitor advancements in secure text messaging systems, they have determined that the use of text messaging for patient orders is not permitted as the safety of patient health information remains unclear. This clarifying guidance reverses the Joint Commission's May 2016 guidance which stated that providers could "text orders as long as a secure text messaging platform is used and the required components of an order are included."