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Health Care Regulatory and Legislative Update

Chapman Insights
January 27, 2017

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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. Walgreens to Pay \$50 Million to Settle Kickback and False Claims Allegations.** On January 19, 2017, the Department of Justice (“DOJ”) announced a \$50 million civil settlement with Walgreens to resolve claims that the company violated the Anti-Kickback Statute (“AKS”) and False Claims Act (“FCA”) by enrolling hundreds of thousands of beneficiaries of government healthcare programs in its Prescription Savings Club program (“PSC program”). The government alleged that Walgreens violated the AKS and FCA by providing government beneficiaries with discounts and other monetary incentives under the PSC program, in order to induce them to patronize Walgreens pharmacies for all of their prescription drug needs. The government further alleges that Walgreens understood that allowing government beneficiaries to participate in the PSC program was a violation of the AKS, but that it nevertheless marketed the program to government beneficiaries and paid its employees bonuses for each customer they enrolled in the program, without verifying whether the customers were government beneficiaries. The allegations resolved by the settlement were brought under the *qui tam*, or whistleblower, provisions of the FCA, which permit private parties to sue on behalf of the government for false claims and to receive a share of any recovery. The whistleblower reward for this settlement has not yet

been announced.

- 2. Medstar Ambulance to Pay \$12.7 Million to Resolve False Claims Act Allegations Involving Medically Unnecessary Transport Services and Inflated Claims to Medicare.** On January 13, 2017, the DOJ announced a \$12.7 million settlement with Medstar Ambulance to settle allegations that the ambulance company routinely submitted false claims for ambulance transports that were unnecessary or at a higher rate than could be medically justified. The allegations were brought under the whistleblower provisions of the False Claims Act by a former billing office employee. The former employee will receive a \$3.5 million reward for bringing the case.

[\\$2.2 Million HIPAA Settlement Demonstrates Importance of Conducting Required HIPAA Security Risk Assessments and Implementing ePHI Safeguards](#)

On January 18, 2017, the U.S. Department of Health and Human Services, Office for Civil Rights (“OCR”) announced that MAPFRE Life Insurance Company of Puerto Rico (“MAPFRE”), which underwrites and administers a variety of insurance products and services in Puerto Rico, agreed to pay \$2.2 million and enter into a corrective action plan to settle potential noncompliance with the HIPAA Privacy and Security Rules. That settlement relates to a 2011 breach notification MAPFRE filed with OCR indicating that a USB “pen drive” containing ePHI for 2,209 individuals was stolen from its IT department, where the device was left without safeguards overnight. OCR’s subsequent investigation revealed MAPFRE’s noncompliance with the HIPAA Rules, specifically a failure to conduct the required “security risk analysis” and implement risk management plans, and a failure to use encryption or an equivalent alternative measure on its laptops and removable storage media until September 1, 2014.

While OCR stepped-up HIPAA enforcement in 2016, it is yet to be seen whether the new administration’s Secretary of HHS will scale back HIPAA enforcement and/or relax regulations in 2017. President Trump’s current pick for HHS Secretary, Dr. Tom Price, has been a critic of what he describes as burdensome regulations on health care providers and previously sponsored legislation to scale back certain regulations. We will continue monitor the changing of the guard at HHS and other federal agencies and any trickle down effects on rules and regulations. As always, please feel free to contact us to learn more about HIPAA Privacy and Security Rule requirements or OCR’s breach notification rules.

[CBO Releases Report on How Repealing Portions of the ACA Would Affect Health Insurance Coverage and Premiums](#)

In a report released on January 17, 2017 (“Report”), the Congressional Budget Office (“CBO”) estimated the changes in health insurance coverage and premiums that would result from leaving the Affordable Care Act’s (“ACA”) insurance market reforms in place while repealing the law’s insurance mandate penalties and subsidies. In brief, CBO and the staff of the Joint Committee on Taxation (“JCT”) estimate that enacting a 2015 ACA repeal bill (“ACA Repeal Bill”) would substantially decrease the number of individuals with health insurance, triggering substantial increases in insurance premiums. The Report summarizes these two primary effects as follows:

- “The number of people who are uninsured would increase by 18 million in the first new plan year following enactment of the bill. Later, after the elimination of the ACA’s expansion of Medicaid eligibility and of subsidies for insurance purchased through the ACA marketplaces, that number would increase to 27 million, and then to 32 million in 2026.
- Premiums in the non-group market (for individual policies purchased through the marketplaces or directly from insurers) would increase by 20 percent to 25 percent—relative to projections under current law—in the first new plan year following enactment. The increase would reach about 50 percent in the year following the elimination of the Medicaid expansion and the marketplace subsidies, and premiums would about double by 2026.”

The Report reinforces the fears of many legislators that a repeal of the ACA without a simultaneous replacement would increase the uninsured rate and destabilize insurance markets. Although Republicans are currently using the 2015 ACA Repeal Bill as a starting point for 2017 repeal legislation, the exact details of repeal, and any replacement, are still being determined. To the extent a 2017 repeal bill varies significantly from the 2015 ACA Repeal Bill, or includes replacement measures, the CBO acknowledges that the estimated effect could differ from those described in the Report.