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Health Care Regulatory and Legislative Update

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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 from the previous week. In a busy two weeks, the United States Department of Health and Human Services Office of the Inspector General (*"OIG"*) posted 10 criminal and civil enforcement actions to its archive since our November 22, 2016 newsletter — two of those are highlighted below.

1. **Addiction Treatment Center Settles Allegations of Unlicensed Prescribing and False Billing for $750,000.** On November 22, 2016, the Department of Justice (*"DOJ"*) announced that it had reached a $750,000 civil settlement with CleanSlate Centers, Inc. and Total Wellness Centers, LLC d/b/a CleanSlate, to resolve allegations that the opioid addiction treatment centers improperly prescribed buprenorphine for opioid addiction treatment in violation of the Controlled Substances Act and improperly billed Medicare in violation of the False Claims Act. The government specifically alleged CleanSlate clinics routinely represented to pharmacies that physicians had prescribed buprenorphine for patients when, in fact, only midlevel practitioners had seen the patients. Days later, after patients had already picked up their medication from the pharmacies, part-time physicians employed by CleanSlate would sign and backdate prescriptions. The government also alleged that CleanSlate repeatedly billed Medicare for patient visits using physicians' identification numbers when, in fact, the patients saw unsupervised midlevel

practitioners. Had CleanSlate properly billed under the midlevel practitioners' identification numbers, Medicare would have paid less.

2. **Hospice Care Provider Agrees to Pay $200,000 to Resolve False Claims Act and Anti-Kickback Allegations.** On December 2, 2016, the DOJ announced that Vistas Health Corporation Midwest and related entities agreed to pay $200,000 to resolve allegations that they violated the False Claims Act and Anti-Kickback Statute. The claims, which were originally brought by a whistleblower-employee, alleged that the hospice provider donated $15,750 to a physician's cancer charity in exchange for the physician's referral of 23 patients for hospice care. In an earlier unrelated criminal matter, the referring physician pleaded guilty to health care fraud, conspiracy to pay and receive kickbacks and promotional money laundering, and was sentenced to a term of 45 years in prison.

CMS Releases National Health Expenditure Data for 2015 — U.S. Health Care Spending Grew 5.8 Percent and Accounts for 17.8 Percent of the GDP

According to recently released National Health Expenditure Data for 2015 from the Centers for Medicare & Medicaid Services (*"CMS"*) Office of the Actuary, U.S. health care spending grew 5.8 percent in 2015, reaching $3.2 trillion or $9,990 per person. As a share of the nation's Gross Domestic Product (*"GDP"*), health spending accounted for 17.8 percent. According to the report, the coverage expansion that began in 2014 as a result of in the Affordable Care Act continued to have an impact on the growth of health care spending in 2015, with 20 million individuals gaining either private health insurance or Medicaid coverage. Additionally, faster growth in total health care spending in 2015 was driven by stronger growth in spending for private health insurance (growth of 7.2 percent), hospital care (5.6 percent), and physician and clinical services (6.3 percent), and continued strong growth in Medicaid (9.7 percent) and retail prescription drug spending (9.0 percent). In 2015, the federal government accounted for the largest share of health care spending (29 percent), followed by households (28 percent), private businesses (20 percent), and state and local governments (17 percent). Summaries of health spending by type of service or product can be found on CMS's National Health Expenditures 2015 Highlights page.

UMass Settles Potential HIPAA Violations Following Malware Infection

On November 22, 2016, the United States Department of Health & Human Services Office for Civil Right (*"OCR"*) announced that the University of Massachusetts Amherst (*"UMass"*) agreed to settle potential violations of the Health Insurance Portability and Accountability Act of 1996 (*"HIPAA"*) Privacy and Security Rules. The settlement includes a corrective action plan (available here) and a monetary payment of $650,000, which OCR stated is reflective of the fact that UMass operated at a financial loss in 2015. The settlement came after UMass informed OCR that a workstation infected with a malware program resulted in the impermissible disclosure of electronic protected health information (*"ePHI"*) of 1,670 individuals, including names, addresses, social security numbers, dates of birth, health insurance information, diagnoses and procedure codes. UMass determined that the malware infiltrated their system because UMass did not have a firewall in place. During its investigation, OCR determined that UMass did not have appropriate HIPAA policies and procedures in place, failed to implement technical security measures, and did not conduct the required HIPAA security risk analysis until September 2015. This action highlights the importance of

conducting HIPAA security rule risk assessments to determine potential risks and vulnerabilities to ePHI. The Office of the National Coordinator for Health Information Technology (*"ONC"*) and OCR have jointly launched a HIPAA Security Risk Assessment (*"SRA"*) Tool to help guide entities subject to HIPAA through the process. The SRA Tool is available here.

Highlights of the OIG Semi-Annual Report to Congress

The OIG recently released its Semi-Annual Report to Congress, which describes OIG's work on identifying abuses of HHS programs for the six-month reporting period ending September 30, 2016. The Report highlighted the following:

- For FY 2016, OIG expects recoveries of more than $5.66 billion, 844 criminal actions and 708 civil actions (which include false claims act and civil monetary penalty cases).
- For FY 2016, 3,635 individuals or entities have been excluded from participation in the Federal health care programs.
- During the six-month period, 350 OIG agents participated in the Health Care Fraud Strike Force's largest national health care fraud takedown, which involved approximately $900 million in false claims billings and charges against 301 individuals, many of whom were home and community-based services (*"HCBS"*) providers.
- Over half of all spending on Medicaid long-term services and supports is now for HCBS, exceeding Medicaid spending on institutional services. OIG's examination of HCBS programs have revealed gaps in polices and controls to protect patients.