

**OIG Announces Large 12 Year Fraud Settlement:** The U.S. Attorney for the Southern District of New York on March 1, 2017 announced criminal and civil actions relating to an alleged 12 year scheme to defraud Medicare, Medicaid and other private health insurance companies of more than \$50 million. The defendants named in the indictment include City Medical Associates, P.C., a cardiologist, a neurologist and numerous other individuals. According to the announcement, the multi-faceted scheme included, among other things:

- (1) Making false representations to insurance providers, including providers paid through Medicaid and Medicare, about medical condition of patients in order to obtain prior authorization for medical tests and procedures;
- (2) Submitting false claims to insurance providers for tests and procedures that were not performed and/or medically unnecessary, as well as for drug items not used or provided;
- (3) Paying kickbacks to local primary care medical offices in exchange for referrals from these offices; and
- (4) Accessing, without authorization, electronic health records of patients at a particular hospital based on Long Island, in violation of HIPAA, in order to identify patients to be recruited to CMA.

The U.S. Attorney stated that numerous state and federal agencies were involved in the investigation, including the FBI, HHS-OIG, the NYPD, and the NYS Department of Financial Services.

**Advocate, NorthShore Drop Merger Plans:** In last month's *StatLaw® New York*, we reported that Aetna and Humana had ended their \$34 billion merger deal due to the court's January 23, 2017 decision in *United States of America v. Aetna, Inc.*, Civil Action No. 2016-1494. It now appears more stringent scrutiny of healthcare mergers may indeed be a new trend. In similar fashion, a court ruling has caused Advocate Health Care and NorthShore University HealthSystem to abandon their plans to merge. The merger, first proposed in September, 2014, was challenged in court by the Federal Trade Commission ("FTC") in 2015. In *Federal Trade Commission v. Advocate Health Care Network*, Civil Action No. 15 C 11473, the FTC contended the merger would result in anticompetitive effects in the systems' geographic market, with the merged system being able to force price increases on insurers, while the hospital systems contended the FTC had defined the market too narrowly, omitting competitors such as Rush University Medical Center and Northwestern Memorial Hospital. The United States District Court for the Northern District of Illinois initially declined to enjoin the merger, but the FTC appealed the denial of the requested injunction to the United States Court of Appeals for the 7th Circuit, and the District Court approved a temporary injunction blocking the merger pending the appeal. On October 31, 2016, the 7th Circuit reversed the District Court's decision refusing to enjoin the merger and remanded the case. On March 7, 2017, United States District Judge Jorge Alonso granted the FTC's application for a preliminary injunction to block the merger. As a result of the Court's decision, the parties cancelled their plans to merge.

**President Trump Nominates Scott Gottlieb, M.D. to Head FDA:** On March 10th, the White House announced that President Donald J. Trump had nominated Scott Gottlieb, M.D. to head the Food and Drug Administration ("FDA"). Dr. Gottlieb had previously served as a deputy commissioner of the FDA under President George W. Bush, and before that had served as a senior advisor to the CMS administrator and is a resident fellow at the American Enterprise Institute. He has previously said that he believes excessive regulation hampers competition in the pharmaceutical market, and many commentators have stated he is a friend of the pharmaceutical industry. Since leaving the FDA, Dr. Gottlieb has served as a board member or advisor for some nine drug or device manufacturers. President Trump has stated he would like to streamline what he calls the "slow and burdensome" approval process for drugs and medical devices, and Dr. Gottlieb's attitude appears to coincide with the President's expressed wishes. In the past, Dr. Gottlieb has supported relaxing the FDA's oversight of wearable devices and smart watches. Reaction to Dr. Gottlieb's nomination from the pharmaceutical and medical device industry has been almost uniformly favorable. Scott Whitaker, CEO of the Advanced Medical Technology Association, has congratulated Dr. Gottlieb on his nomination, stating that he is a "strong choice" due to his prior experience with the FDA and CMS. "Our industry applauds Dr. Gottlieb's commitment to innovation in medical technology and his recognition of its important role in providing the best care possible for patients," said Mr. Whitaker. "Specifically, we look forward to working with Dr. Gottlieb and his team on the medical device user fee reauthorization in the coming weeks and months in our mutual pledge to continued patient access to life-changing technologies." The nomination will now go before the United States Senate for possible confirmation.

For more information on the above items, contact Kern Augustine, P.C. at 1-800-445-0954 or via email at [info@DrLaw.com](mailto:info@DrLaw.com)



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