



Health Law Diagnosis

Monitoring the Pulse of Health Care and Life Sciences

October 2022

The Robinson+Cole Health Law Group is committed to examining and reporting on issues important to the health care and life sciences industries. Below are excerpts from our [Health Law Diagnosis](#) blog, where we post on fraud and abuse, government enforcement, Medicare and Medicaid, reimbursement, hospitals and health systems, pharmaceuticals, medical devices, and other areas of interest. For more updates on news and developments for the health care and life sciences industries, we invite you to [subscribe](#).

[DOJ Announces \\$13 Million Settlement Related to Improper Billing for Lab Tests](#)

On October 17, 2022, the United States Department of Justice (DOJ) [announced](#) a \$13 million settlement with health care services provider Sutter Health, which arose from alleged violations of the federal False Claims Act (FCA). These alleged FCA violations relate to Sutter Health billing the United States for toxicology screening tests performed by other labs. [Read more](#)

[Advisory Opinion 22-17: OIG Declines to Impose Sanctions on a Health System for Forgiveness of Credit Line Note Owed by Clinic](#)

On September 6, 2022, the Office of Inspector General (OIG) published [Advisory Opinion 22-17](#) (Advisory Opinion), in which it declined to impose sanctions against a regional 501(c)(3) not-for-profit health care system that operates four hospitals (Health System) and a clinic that provide services to geographic areas that have been designated as medically-underserved areas and health professional-shortage areas (together, the Requestors). The Health System had supported the establishment of the clinic, which is registered as a Free Clinic and been designated as a Federally Qualified Health Center (FQHC) Look-Alike (Clinic), (but is neither an FQHC nor does it receive funds under Section 330 of the Public Health Service Act). The arrangement involves the forgiveness of a credit line note entered into by the Health System with the Clinic. The OIG concluded that although the arrangement would constitute prohibited remuneration under the federal anti-kickback statute (AKS) if the requisite intent were present, the arrangement and the safeguards in place did not warrant the imposition of sanctions. [Read more](#)

[Supreme Court Denies Certiorari in Three FCA “Particularity” Cases](#)

On October 17, 2022, the U.S. Supreme Court [denied](#) certiorari in three cases asking the court to resolve a circuit split regarding the application of the particularity pleading requirement for allegations of fraud in False Claims Act (FCA) cases, as required under Federal Rule of Civil Procedure 9(b). The cases are: *Johnson, et al. v. Bethany Hospice*, [21-462](#); *U.S., ex rel. Owsley v. Fazzi Associates, Inc., et al.*, [21-936](#); and *Molina Healthcare, et al. v. Prosa*, [21-1145](#). Molina also presented a second question over which circuits had split, regarding the correct interpretation of *Universal Health Services, Inc. v. United States ex rel. Escobar* and whether a request for payment without specific representations can be actionable under an implied false certification theory. ([Petition for Writ of Certiorari](#)). [Read more](#)

[Home Health Company and Two Corporate Officers Settle False Claims Act Allegations for Over \\$30 Million](#)

On October 18, 2022, the Department of Justice (DOJ) announced two settlements with CHC Holdings, LLC, an Oklahoma limited liability company doing business as Carter Healthcare (Carter), and two former senior corporate officers, resolving alleged violations of the federal False Claims Act (FCA), Anti-Kickback Statute (AKS), and Physician Self-Referral Law (commonly referred to as the “Stark Law”). One case [settled](#) claims that Carter had made improper payments to referring physicians in Oklahoma and Texas, while the other case [settled](#) claims that Carter had made false billing claims in Florida. Both matters were initiated by qui tam whistleblower complaints filed under the FCA. Carter agreed to pay more than \$30 million to resolve the allegations. [Read more](#)

[Recent NLRB Decision Requires Union Access to Parts of Asset Purchase Agreement](#)

In a recent decision, the National Labor Relations Board (NLRB) determined that a hospital violated its duty to bargain when it failed to provide the union representing some of its workers with certain documents related to the sale of its parent organization. Specifically, in [Crozer Chester Med. Ctr., 371 NLRB No. 129 \(2022\)](#), the NLRB ordered the hospital to produce portions of an asset purchase agreement (APA) in response to the union's request for information related to the transaction because the NLRB found these documents "potentially" relevant to the union's role as bargaining representative of the unit. [Read more](#)

[Advisory Opinion 22-19: OIG Warns That Proposed Drug Cost Subsidization Arrangement May Warrant Sanctions](#)

On October 5, 2022, the Office of Inspector General (OIG) published [Advisory Opinion 22-19](#) (Advisory Opinion), in which it determined that a proposed oncology drug discount arrangement could constitute grounds for the imposition of sanctions under the federal anti-kickback statute (AKS). The OIG concluded that while beneficiary access to potentially life-saving medications is essential, the provisions of the proposed arrangement "would present more than a minimal risk of fraud and abuse" under the AKS. [Read more](#)

[340B Update: District Court Rejects 2022 Payment Methodology for 340B Hospitals Following Supreme Court Win](#)

We follow up on our [previous blog post](#) concerning the U.S. Supreme Court's unanimous [ruling](#) in favor of 340B hospitals. The Supreme Court previously held that "absent a survey of hospitals' acquisition costs, HHS may not vary the reimbursement rates for 340B hospitals" and therefore, that HHS exceeded its statutory authority by varying the 2018 and 2019 rates for 340B hospitals without first conducting such survey. [Read more](#)

[The DOJ Continues to Prosecute Providers for Fraudulent Telemarketing and Telehealth](#)

A physician in Washington state [pled guilty](#) on September 28, 2022, to a criminal charge of conspiring to accept kickbacks related to fraudulent genetic testing. According to the Department of Justice (DOJ), the physician ordered certain genetic testing for Medicare beneficiaries that he was not treating and with whom a physician-patient relationship was not established as part of the scheme. According to the plea agreement accepted by the physician, the physician would be connected by telemarketers to the beneficiaries for a few minutes, the physician would order the diagnostic test, the labs would then bill for the test, and another company would bill Medicare for the purported telemedicine visit. The physician received almost \$168,000 in kickbacks for ordering the medically-unnecessary testing and other services, which resulted in more than \$18 million being paid by Medicare. [Read more](#)

If you have any questions, please contact any member of Robinson+Cole's [Health Law Group](#).

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