



Health Law Diagnosis

Monitoring the Pulse of Health Care and Life Sciences

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 \\$900 Million Settlement Tied to Speaker Bureau Payments to Physicians](#)

On September 26, 2022, the United States Department of Justice (DOJ) [announced](#) a \$900 million settlement with pharmaceutical company Biogen Inc., which arose from alleged violations of the federal False Claims Act (FCA) and Anti-Kickback Statute (AKS) tied to payments from the company to physicians, which were allegedly intended to induce prescription of Biogen's drugs. The matter initiated as a qui tam whistleblower complaint filed by an employee under the FCA. [Read more](#)

[Second Circuit Affirms HHS Rejection of Direct Copayment Assistance Under Anti-Kickback Statute](#)

On July 25, 2022, the U.S. Court of Appeals for the Second Circuit rejected an appeal brought by Pfizer, Inc. in a case that examines whether a "corrupt" intent is required to violate the Anti-Kickback Statute (AKS). The decision addressed a proposed direct copayment assistance program of a pharmaceutical manufacturer which sought to help patients pay for an expensive drug, and whether such a program may be subject to sanctions under the AKS' prohibition on transfers of remuneration inducing referrals of drugs and other items or services reimbursed by federal health care programs. Funding of copayment assistance programs by pharmaceutical manufacturers to increase access to drugs for certain conditions has become a common practice following prior governmental guidance sanctioning the practice as long as certain safeguards are in place, but the Pfizer program posed a distinct issue for the government because the program provided direct assistance to patients looking to purchase Pfizer's own drug. In short, the government has concerns that without sufficient independence and safeguards in place, such assistance programs can become alleged conduits for improper payments from pharmaceutical manufacturers to patients to influence purchase of the manufacturers' drugs. [Read more](#)

[A COVID-19 Laboratory Testing Conviction under EKRA](#)

Mark Schena, the President of Arrayit Corporation, has been found guilty by a jury for violations of the Eliminating Kickbacks in Recovery Act (EKRA), healthcare fraud, wire fraud, and securities fraud. [Read more](#)

[Advisory Opinion 22-16: OIG Declines to Impose Sanctions for Arrangement Involving Provision of Gift Cards to Patients for Completing Learning Program](#)

On August 19, 2022, the Office of Inspector General (OIG) [published](#) Advisory Opinion 22-16 (Advisory Opinion) in which it declined to impose sanctions for an arrangement under which the requestor provides gift cards to patients for completing an online learning program related to surgeries. The OIG concluded that although the arrangement would constitute prohibited remuneration under the federal anti-kickback statute (AKS) and the beneficiary inducement prohibitions of the Civil Monetary Penalties Law (CMP), it is unlikely to impact competition among providers or influence selection of a particular provider and therefore determined that the arrangement did not warrant the imposition of sanctions. [Read more](#)

[OIG Releases Data Brief on Medicare Telehealth Program Integrity Risks During the First Year of the Pandemic](#)

The Department of Health and Human Services Office of Inspector General (OIG) recently [released](#) a Data Brief summarizing the findings of a review of program integrity risks related to telehealth services

reimbursed by Medicare during the first year of the COVID-19 pandemic (the Pandemic).[1] The OIG analyzed Medicare and Medicare Advantage claims data from March 1, 2020, to February 28, 2021, focusing on providers that billed for telehealth services, with an emphasis on identifying providers that posed a high risk to the Medicare program. [Read more](#)

[New Jersey Governor Signs Act Concerning Changes in Control of Health Care Entities](#)

On August 18, 2022, New Jersey Governor Phil Murphy signed [S-315](#), “An Act concerning changes in control of health care entities” (the Act). The Act implements employment protection for healthcare workers when certain licensed health care facilities, staffing registries, and home care services in New Jersey undergo a change in ownership. The Act first requires that former health care entity employers provide the successor health care entity with information pertaining to employees (i.e., employee names, addresses, dates of hire, phone numbers, wage rates, employment classifications) not less than thirty days before a change in control. The Act also requires former health care entity owners to inform eligible employees of the rights provided by the Act and to post a notice of their rights under the Act in a conspicuous location. [Read more](#)

[REMINDER: October 6 Deadline for Information Blocking Rules Approaches](#)

Health care providers subject to the [Information Blocking rules](#) issued under the 21st Century Cures Act, Pub.L. 114–255, are reminded that such Information Blocking rules will apply to an expanded set of information beginning on October 6, 2022. The Information Blocking rules currently apply only to a limited portion of electronic health information (EHI) represented by the specific data elements identified in the United States Core Data for Interoperability version 1 standard (commonly referred to as USCDIv1). Effective October 6, 2022, the Information Blocking rules will apply to all EHI, which is defined as all electronic protected health information (as defined by HIPAA) to the extent that such electronic protected health information is included in a designated record set (also as defined by HIPAA), and excluding psychotherapy notes and information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative proceeding. [Read more](#)

[New Final Rule Under the No Surprises Act Released](#)

On August 19, 2022, the Department of Health and Human Services (HHS), Department of Labor (DOL), and Department of the Treasury (DOT), released “Requirements Related to Surprise Billing: Final Rules” (the Rules). The Rules change and finalize the prior interim final rules concerning the information health insurers must share regarding the qualifying payment amount (QPA) and the independent dispute resolution (IDR) process under the No Surprises Act. The Rules address comments received pertaining to the interim final rules as well as the recent judicial decisions in Texas Medical Association[1] and LifeNet. [2] [Read more](#)

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

[Lisa M. Boyle \(Chair\)](#) | [Nathaniel T. Arden](#) | [Conor O. Duffy](#) | [Kathleen G. Healy](#) | [Leslie J. Levinson](#)

[Danielle H. Tangorre](#) | [Melissa \(Lisa\) Thompson](#) | [Theodore J. Tucci](#) | [Yelena Greenberg](#)

[Erin C. Howard*](#) | [Michael G. Lisitano](#) | [Peter H. Struzzi](#)

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**Erin Howard is a Law Clerk at Robinson+Cole and not yet admitted to practice.*



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