

Healthcare Enforcement & Litigation 2022

Contributing editors

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Samantha Kingsbury and Karen Lovitch**

Mintz

Lexology Getting The Deal Through is delighted to publish the seventh edition of *Healthcare Enforcement and Litigation*, which is available in print and online at www.lexology.com/gtdt.

Lexology Getting The Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique Lexology Getting The Deal Through format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes a new chapter on European Union.

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Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Lexology Getting The Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to the contributing editors, Grady Campion, Laurence Freedman, Caitlin Hill, Samantha Kingsbury and Karen Lovitch of Mintz for their assistance with this volume.



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Global overview

Grady Campion, Laurence Freedman, Caitlin Hill, Samantha Kingsbury and Karen Lovitch
Mintz

Like our healthcare delivery, payment and regulatory systems, healthcare enforcement and litigation are complex. Healthcare is delivered through a disjointed nationwide assemblage of private healthcare providers, suppliers and institutions, and healthcare items and services are generally reimbursed through a complicated system of public and private funding sources. Healthcare delivery and payment are subject to both state and federal legal requirements, which may vary depending on the type of healthcare provider at issue, the source of payment and the jurisdiction (state or federal) where the enforcement is taking place. Despite the many sources of enforcement authority and responsible agencies, trends in enforcement priorities develop over time, particularly in the context of federal enforcement and litigation. Below, we discuss some of those trends because they highlight how enforcement agencies interpret and apply relevant laws, as well as the kinds of conduct that enforcement agencies prioritise.

Federal civil and criminal enforcement

In 2020, the US Department of Justice (DOJ), one of the primary federal agencies responsible for healthcare enforcement, continued to focus in certain areas that have resulted in enforcement actions over the past few years (eg, opioids) and also developed some new enforcement priorities as well (eg, covid-19 related fraud).

Despite its broad authority to enforce criminal and civil federal laws, DOJ tends to bring healthcare enforcement actions under a handful of civil and criminal statutes. Perhaps the most well-known civil enforcement statute is the federal False Claims Act (FCA) (31 USC section 3729 et seq) because violations can result in significant per-claim statutory penalties, in addition to treble damages awards. Although DOJ can directly file an FCA claim against a defendant, private whistleblowers (referred to in the statute as relators) may also file FCA claims on behalf of the United States. A case filed by a whistle-blower under the FCA is called a *qui tam* action, and it is filed under seal (ie, filed in secret). The seal remains in place until the United States either decides to intervene in the case and proceed with the litigation or declines to intervene. In the latter scenario, the whistle-blower may still proceed with the litigation. Regardless of the United States' intervention decision, the whistle-blower is entitled to between 15 and 30 per cent of any recovery in the case (but the percentage depends in part on whether the United States intervenes).

Each year, DOJ releases data about its FCA enforcement activities. For example, in 2020, DOJ reported a total of 922 new FCA matters, 672 of which were filed by whistle-blowers under the FCA. Although the FCA is not a healthcare-specific statute and applies to any claim for payment submitted to the federal government, the vast majority of FCA cases filed every year are healthcare-related. Of the \$2.2 billion recovered by DOJ under the FCA in 2020, \$1.8 billion came from healthcare cases.

The types of healthcare entities that are the targets of FCA claims vary from year to year, but in 2020, DOJ reported that hospitals and physicians were the subject of the greatest number of such claims. Former employees are the most frequent type of whistle-blowers, but current employees, contractors, competitors and customers commonly file such cases as well.

In addition to civil FCA enforcement, DOJ uses criminal statutes to prosecute healthcare fraud committed by both companies and individuals. One of the criminal statutes upon which DOJ most often relies is the Anti-Kickback Statute (42 USC section 1320a-7b(b)) (AKS). The AKS, in pertinent part, prohibits the offer, payment, solicitation or receipt of anything of value (including but not limited to money) to a person in return for that person ordering or recommending or arranging for the ordering of, items or services for which payment may be made under applicable federal healthcare programmes (eg, Medicare and Medicaid). Unless an AKS safe harbour or exception applies, the federal government interprets the AKS to mean that if even one purpose of an otherwise seemingly legitimate payment (or the provision of other remuneration) is to induce referrals of items or services payable by federal healthcare programmes, such a payment could violate the AKS.

DOJ, with the assistance of other federal investigative and enforcement agencies such as the Federal Bureau of Investigation and the Office of Inspector General for the US Department Health and Human Services, uses these statutory tools to target conduct and arrangements that are part of its enforcement priorities.

Federal enforcement priorities in 2020

Opioid enforcement

Given the ongoing opioid addiction epidemic that has plagued the United States for many years, DOJ has long been investigating and prosecuting companies and individuals it believes have contributed to this crisis. DOJ remained intensely focused in 2020 on opioid-related enforcement activity, prosecuting both corporations and individuals. Opioid manufacturers, distributors and prescribers all continued to be targets of DOJ, but DOJ expanded its enforcement efforts to include companies engaged in marketing opioids, as well as pharmacies. A few of the more notable opioid-related resolutions in 2020 are discussed below.

Purdue Pharma

This matter was the largest opioid-related enforcement resolution in 2020. Purdue Pharma, which manufactures OxyContin, reached a global resolution with DOJ to settle a criminal and civil investigation of both the company and its individual shareholders, the Sackler family. The company pled guilty to criminal charges, including that it (1) violated the AKS by paying two physicians (through sham speaker arrangements) to write more opioid prescriptions and (2) made criminal false statements by lying to the Drug Enforcement Agency for over a decade, falsely representing that it maintained an anti-drug diversion programme when in fact the company marketed opioids to providers that the company had reason to believe were illegally diverting opioids. The total settlement included \$8.34 billion in criminal penalties, forfeitures and civil settlement amounts, as well as the unusual requirement that the company reorganise as a public benefit company. The purpose of this public benefit company will be to try to prevent future patient harm by safely distributing opioids, subsidising overdose rescue drugs and funding opioid abatement. These measures reflect DOJ's continued

emphasis on preventing and remediating patient harm stemming from abuse of opioids. Also as part of this resolution, the Sackler family agreed to pay \$225 million to resolve liability under the FCA for their role in the company's wrongdoing. Notably, the company's global resolution with DOJ did not prohibit the government from seeking future criminal or civil penalties against company executives or employees, so it is possible that enforcement actions against individuals will follow this resolution with the company.

Indivior Solutions

In July 2020, DOJ announced the resolution of criminal and civil charges against Indivior Solutions, which markets Suboxone, an opioid-addiction treatment drug. The company's settlement included a \$600 million payment, as well as a guilty plea to making criminal false statements to a state Medicaid programme when marketing and promoting a Suboxone product's purported safety. Two former executives also pled guilty to charges stemming from the same conduct, one of whom (the former Chief Executive Officer) was sentenced to a six-month term of imprisonment.

Pharmacies

Pharmacies appear to be the next in line for opioid-related DOJ enforcement efforts. For example, in 2020, two pharmacies resolved civil charges relating to high-volume opioid prescriptions. One of these pharmacies and its owner agreed to a \$600,000 civil penalty and a permanent prohibition on dispensing opioids and other controlled substances. The other such pharmacy and its owner agreed to pay over \$1 million in civil penalties and to cease dispensing controlled substances. In both cases, the defendants allegedly ignored 'red flags' of drug diversion and drug-seeking behaviour in filling prescriptions.

State Attorneys General

State Attorneys General (AGs) have also been bringing opioid enforcement actions and continued doing so in 2020. For example, the Missouri AG, along with many other state AGs, announced a \$1.6 billion settlement of claims against a generic opioid manufacturer that was based in Missouri.

2021 is likely to see a similar level of opioid-related enforcement, perhaps with a shift in the types of entities under scrutiny to include more marketing companies and pharmacies, as discussed above.

Covid-19 related enforcement

The covid-19 pandemic and measures taken by federal and state governments to provide support and aid to individuals and businesses seem to have created many opportunities for fraud schemes. In 2020, DOJ took swift and serious criminal and civil action against alleged perpetrators. DOJ's general attention appeared to be on allegedly fraudulent products, as well as individuals and small businesses accused of alleged misuse of relief funds, such as those provided under the federal

Paycheck Protection Program (PPP), a loan forgiveness programme created by federal law for businesses suffering covid-19 related losses.

More specifically, covid-19 related enforcement efforts in 2020 included:

- criminal prosecution of marketing schemes regarding allegedly fraudulent covid-19 products, such as ineffective ozone therapies, a fake vaccine and industrial-strength bleach (marketed as a cure for covid-19);
- criminal prosecution of and civil enforcement against covid-19 testing schemes, such as promoting (and billing insurers for) medically unnecessary tests in addition to covid-19 testing or using (and billing insurers for) test kits that failed to meet applicable standards for safety and effectiveness; and
- criminal prosecution of individuals and small businesses making false statements in connection with applications to covid-19 financial relief programmes (eg, the PPP).

Going forward in 2021, DOJ is likely to continue to concentrate investigative and enforcement attention on companies that accepted covid-19 relief funds through other federal programmes beyond the PPP. One such programme is the Provider Relief Fund. Through this programme, the federal government gave billions of dollars in aid to qualifying hospitals and healthcare providers that treated patients with covid-19 and incurred healthcare-related expenses or lost revenue due to the covid-19 pandemic. DOJ made this enforcement priority clear in May 2021 when the US Attorney General directed the establishment of the COVID-19 Fraud Enforcement Task Force, through which DOJ and other federal agencies will collaborate and use available criminal, civil and administrative tools to prosecute and eliminate covid-19-related fraud.

Nursing homes and elder care

For years, DOJ and other federal agencies have targeted their enforcement efforts on nursing homes and providers of related services, and 2020 was no different. In March 2020, DOJ launched a National Nursing Home Initiative, which coordinates civil and criminal enforcement efforts against nursing homes suspected of providing wholly deficient care to residents (eg, failure to adhere to basic hygiene and infection control protocols). DOJ representatives have also commented publicly that DOJ intends to use the FCA to combat schemes to take advantage of the elderly and indicated a particular focus on nursing homes and rehabilitation contractors as possible enforcement targets.

The topics discussed above are just a small sample of the many different types of conduct and entities that are subject to healthcare enforcement efforts in the United States, but they provide helpful insight into how federal enforcement agencies in particular interpret and apply the laws they are charged with enforcing.

We hope that this edition of *Healthcare Enforcement & Litigation* is a helpful introduction to the unique and complex landscape of healthcare enforcement in the United States.

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