Healthcare Enforcement & Litigation 2022

Contributing editors
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LEXOLOGY®
Getting The Deal Through

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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.

Lexology Getting The Deal Through titles are published annually in print. Please ensure you are referring to the latest edition or to the online version at www.lexology.com/gtdt.

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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Getting The Deal Through

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Contents

United States

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

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OVERVIEW

Healthcare funding

1 | In general terms, how is healthcare, including access to medicines and medical devices, funded in your jurisdiction? Outline the roles of the public and private sectors.

In the United States, healthcare is funded through a combination of public and private sources. Public sources include health insurance programmes funded by taxpayer dollars and managed by government agencies, at both the federal and state levels. Such public health insurance programmes include Medicare and Medicaid. Medicare is managed by the federal government and provides a variety of different benefits depending on the plan selected by the beneficiary (eg, coverage for inpatient and outpatient care at hospitals and prescription drugs, among many others). Beneficiaries eligible for Medicare coverage generally include people over the age of 65, certain younger people with disabilities and people with End Stage Renal Disease.

Medicaid is a joint state and federal programme. States establish and administer their own Medicaid programmes, using funding from the federal government as well as state financial resources. Federal law requires that states provide Medicaid coverage for certain groups of people (eg, low-income families and qualified pregnant women and children, among others), but also permits states to provide coverage to other groups. Each state determines the amount, type, duration, and scope of services provided, but federal law requires that state Medicaid plans provide certain mandatory benefits (eg, coverage for inpatient and outpatient hospital services, physician services and laboratory services, among many others).

In addition to publicly funded health insurance, private insurance plans fund a large portion of healthcare in the United States. Employers typically provide insurance to their employees, although some people purchase insurance for themselves directly. Private health insurance plans can offer different benefits, but must cover certain mandatory services. In addition to collecting premium payments for the coverage (some or all of which may be paid for by an employer offering the plan), many private health plans also require beneficiaries to engage in some level of cost-sharing, either through deductibles, co-payments or coinsurance amounts.

Delivery

2 | In general terms, how is healthcare delivered in your jurisdiction? Outline the roles of the public and private sectors.

Subject to some limited exceptions, healthcare is delivered in the United States primarily by privately employed practitioners (eg, physicians and nurses) and privately owned and operated facilities (eg, hospitals, clinics and laboratories). For example, New York City is home to the largest public healthcare system in the United States, the NYC Health + Hospitals system, which provides care to over a million people annually. The federal government also operates facilities and employs providers to care for members of the armed forces.

Key legislation

3 | Identify the key legislation governing the delivery of healthcare and establishing the regulatory framework.

Key federal legislation governing the delivery of healthcare and establishing the regulatory framework for the country's healthcare system includes the Social Security Act, the Patient Protection and Affordable Care Act of 2010, the Food Drug and Cosmetic Act (FDCA), and the Health Insurance Portability and Accountability Act of 1996.

In 1965, Congress passed legislation establishing the Medicare and Medicaid programmes as Titles XVIII and XIX, respectively, of the Social Security Act.

The Patient Protection and Affordable Care Act of 2010 (referred to as the Affordable Care Act, the ACA, or Obamacare) was enacted in March 2010. As amended by the Healthcare and Education Reconciliation Act, the ACA mandated comprehensive healthcare reform measures. For example, beginning in 2014, the ACA gave states the authority to expand Medicaid eligibility to individuals under age 65 in families with incomes below 133 per cent of the Federal Poverty Level. The ACA also standardised the rules for determining eligibility and providing benefits through Medicaid, the Children's Health Insurance Programme (which provides federal matching funds to states to provide health coverage to children in families with qualifying financial circumstances), and the health insurance marketplace. In addition, the ACA requires insurance plans to cover people with pre-existing health conditions and allows young people to stay on their parents' health insurance until age 26, among many other requirements.

The FDCA and related regulations authorises the US Food and Drug Administration (FDA) to regulate medical devices, drugs, biologics, radiation-emitting devices and cosmetics, and establish food safety standards. Among other things, the FDCA requires approval for new drugs and devices (based on safety and efficacy) and of the labelling of drugs and devices, and provides the FDA with authority over post-approval marketing and promotion of approved drugs and devices, as well as for enforcement against unapproved drugs and devices.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established comprehensive federal standards for the privacy and security of health information. HIPAA's standards apply to health plans, healthcare clearing houses and healthcare providers that conduct certain healthcare transactions electronically (covered entities). HIPAA also applies to business associates of covered entities that perform services for the covered entities involving the use or disclosure of individually identifiable health information. As amended by the Health Information Technology for Economic and Clinical Health Act

(HITECH) provisions of the American Recovery and Reinvestment Act of 2009, HIPAA includes breach notification requirements for covered entities and business associates. HITECH also expanded and strengthened HIPAA, in part by creating new enforcement targets and by imposing new penalties for non-compliance.

With respect to delivery of healthcare specifically, state law typically governs licensure and operation of healthcare facilities and providers.

Responsible agencies

4 | Which agencies are principally responsible for the enforcement of laws and rules applicable to the delivery of healthcare?

Generally, federal agencies enforce federal laws and regulations, and state agencies enforce state laws and regulations. Nearly every aspect of healthcare is regulated by one or more federal or state agency, or both. At the federal level, three agencies well known for enforcing federal laws and regulations applicable to the delivery of healthcare are the US Department of Health and Human Services, the Centers for Medicare & Medicaid Services, and the US Department of Justice (DOJ). Federal enforcement agencies are typically funded under the federal budget, which is approved by Congress and funded by taxpayer dollars. Federal agency budgets typically do not depend on enforcement activities.

At the state level, healthcare enforcement actions are typically brought by state attorneys general (whose offices typically include consumer fraud protection or Medicaid Fraud Control units, or both, which are also involved in healthcare enforcement) and state Departments of Health, as well as other regulatory and enforcement agencies. These agencies are typically funded under state budgets.

Scope of enforcement

5 | What is the scope of their enforcement and regulatory responsibilities?

The federal authorities investigate and enforce violations of federal statutes but do not have jurisdiction to investigate and enforce violations of state laws. Similarly, each state investigates and enforces violations of its own statutes and does not have the authority to enforce federal laws or the laws of any other state. Accordingly, a healthcare company engaged in business in all 50 states is subject to federal laws and enforcement authorities as well as the laws and enforcement authorities of each state.

Regulation of pharmaceutical products and medical devices

6 | Which agencies are principally responsible for the regulation of pharmaceutical products and medical devices?

The FDA is responsible for regulating pharmaceutical products and medical devices, among many other product categories (eg, foods, tobacco products, biologics and cosmetics). The FDA is funded from two roughly equal sources: federal budget appropriations and industry user fees. FDA funding is not tied to enforcement activity.

Scope of enforcement

7 | What is the scope of their enforcement and regulatory responsibilities?

In addition to regulating pharmaceutical products and medical devices, the FDA has broad regulatory authority over many product categories including but not limited to foods, tobacco products, biologics and cosmetics. The FDA controls approval, classification, labelling, advertising and marketing, and recalls of these products. The FDA also has the power to regulate and inspect manufacturers, laboratories and distributors of FDA-regulated products. The FDA has independent enforcement authority over a wide range of issues, including good manufacturing practices and labelling of drugs and devices. In enforcement actions, the FDA works with DOJ to prosecute violations of criminal or civil federal law in FDA-regulated areas.

Other agencies

8 | Which other agencies (eg, competition or securities regulators, prosecutors) have jurisdiction over healthcare, pharmaceutical and medical device cases?

In addition to DOJ, other federal agencies have jurisdiction to enforce compliance with federal law, including the Federal Trade Commission, which enforces the federal antitrust laws, and the Securities and Exchange Commission, which enforces the federal securities laws applicable to all public companies, including healthcare companies and drug and device manufacturers.

States also have authority and jurisdiction to enforce their laws. In fact, state law is often the primary source of regulation of hospitals, physicians, surgery centres and other healthcare providers. With respect to drug and medical device companies, the FDA is the chief regulatory agency at both the federal and state level because the FDA's comprehensive regulations preclude state regulation on the same topic (referred to as FDA pre-emption).

Simultaneous investigations

9 | Can multiple government agencies simultaneously conduct an investigation of the same subject? Does a completed investigation bar another agency from investigating the same facts and circumstances?

Yes, multiple federal and state government agencies can and do conduct simultaneous and sequential investigations of the same alleged conduct. In fact, DOJ has long encouraged parallel federal civil and criminal investigations in healthcare fraud cases. Other federal agencies may also investigate the same or similar facts and circumstances, with or without coordinating amongst each other. In other words, a completed investigation does not bar another agency from investigating the same facts and circumstances. Agencies do not have authority to preclude each other from investigating the same conduct, and each agency has very specific authority to investigate, bring charges and resolve allegations.

REGULATION OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES

Monitoring powers

10 | What powers do the authorities have to monitor compliance with the rules on drugs and devices?

Federal authorities have authority to approve, authorise or clear drugs and devices for use, and they also have extensive monitoring powers over drugs and devices. Drug-related monitoring covers new drugs, generic drugs, biologics and bio-equivalents. Once a drug is approved, the US Food and Drug Administration (FDA) monitors the manufacturing process to ensure that the drug is produced in compliance with established federal criteria (known as Good Manufacturing Practices). Manufacturers and regulated facilities are subject to site inspections to determine compliance with applicable federal laws and regulations. Federal authorities also have the power to issue warning letters, which provide notice of an alleged violation of federal regulations, and to request documents or records from a regulated entity. Relatedly, drug and device manufacturers are required to maintain various types of

records and must file annual reports with the FDA about their regulated drug or medical device.

In addition, drug and device companies must report certain 'adverse events' associated with a drug or medical device. The FDA also monitors and enforces compliance with strict requirements for the labelling and promotion of drugs and devices. The FDA and US Department of Justice (DOJ) also have authority to enforce laws regarding commercial marketing of unapproved drugs and devices, as well as promotion of drugs and devices that is not consistent with the FDA-approved label for the drug or device.

Investigation time frames

11 | How long do investigations typically take from initiation to completion? How are investigations started?

Criminal and civil federal investigations, including those conducted by DOJ through any of its Criminal, Civil or Antitrust Divisions, or by the Federal Trade Commission may last several years. In contrast, FDA regulatory investigations regarding product labelling and promotion may be initiated and concluded within a one-year time period, and often more quickly if the investigation involves simple and uncontested issues.

Investigations may commence in a number of ways. First, federal agencies, such as the US Department for Health and Human Services or DOJ, may initiate investigations. DOJ's Civil Division has increasingly used sophisticated data-driven analyses to investigate healthcare fraud. Second, external triggers – such as a news story or public event – may trigger an investigation. Third, private persons (referred to as relators or whistleblowers) may precipitate a federal investigation by invoking the *qui tam* provisions of the federal False Claims Act (31 USC section 3729, et seq) and filing a civil complaint in federal district court on behalf of the United States.

Access to investigation materials

12 | What rights or access does the subject of an investigation have to the government investigation files and materials?

During an investigation, and before criminal charges or a civil complaint is filed, the subject of an investigation has no right to access government investigation files. Once criminal or civil proceedings commence, the targeted company or person typically has extensive rights to obtain documents, depose persons under oath (in a civil proceeding), and obtain certain statements made to the government (in a criminal proceeding). Those rights are determined by the type of proceeding (ie, criminal, civil or administrative) and the rules applicable to that proceeding.

Investigations abroad

13 | If pharmaceutical products or medical devices are made in a foreign country, may the authorities conduct investigations of the manufacturing processes in that other country?

Yes. The FDA has authority over any manufacturer of any active ingredient in a product regulated by the FDA, so long as that product is sold or distributed within the United States (satisfying jurisdictional requirements).

Enforcement proceedings

14 | Through what proceedings do agencies enforce the rules?

Agencies' rules may be enforced through (1) state or federal court proceedings or (2) administrative agency proceedings. Enforcement proceedings in court may be either criminal or civil. For example, DOJ has exclusive authority to bring criminal charges in federal court.

With respect to administrative agency proceedings, various subagencies within the US Department of Health and Human Services, such as the FDA and the Centers for Medicare & Medicaid Services (CMS), have authority to bring civil administrative enforcement and adjudication proceedings. For example, CMS has the power to enforce compliance with enrolment and other requirements relating to the Medicare programme (health insurance for elderly persons) and other agency programmes.

Sanctions

15 | What sanctions and other measures can the authorities impose or seek in enforcement actions against drug and device manufacturers and their distributors?

Available sanctions for a violation of federal law depend in part on the nature of the enforcement proceedings. In criminal cases, sanctions include criminal fines, penalties, restitution and product seizures. In civil cases, damages involve monetary recovery, and parties can also obtain injunctions, which generally prevent certain conduct. Civil damages in the United States can be massive. For example, under the federal False Claims Act (31 USC section 3729, et seq) (FCA), the government can recover treble damages – ie, three times the amount of the government's actual loss – in addition to mandatory statutory penalties. Private citizens (called whistle-blowers or relators) who file FCA claims on behalf of the United States may collect between 15 and 30 per cent of any recovery, plus attorneys' fees.

Agency enforcement proceedings introduce a number of other potential sanctions as well. For example, the Office of Inspector General for the US Department of Health and Human Services has mandatory and permissive (discretionary) authority to exclude individuals and entities from participating in all federal healthcare programmes, based on certain statutorily defined offences. Similarly, the FDA has mandatory and permissive authority to debar or prohibit a corporation or an individual from participating in FDA-regulated activities. Exclusion and debarment effectively amount to a total ban on operating in the healthcare industry.

Actions against employees

16 | Can the authorities pursue actions against employees as well as the company itself?

Yes. Individuals, like companies, are subject to criminal, civil and administrative investigations and proceedings. Individuals are also subject to criminal sentences, financial liability and administrative sanctions, such as exclusion (a bar) from selling products, providing services or treating patients if the conduct involves payments from federal healthcare programmes, such as Medicare.

Defences and appeals

17 | What defences and appeals are available to drug and device company defendants in an enforcement action?

Any defendant in an enforcement action may avail itself of legal, factual, and constitutional defences, as appropriate based on the nature of the specific case. Legal defences include arguments that the alleged conduct did not violate the statute or regulation at issue, as well as procedural defences relating to jurisdiction and notice. Factual defences may include that the allegations are not accurate or did not occur, the defendant did not have the requisite state of mind to violate the legal requirement or that no payment was sought or obtained for the item or service at issue. Finally, all defendants have certain constitutional defences, including the right to due process.

Minimising exposure

18 What strategies should companies adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

The hallmark of mitigating exposure to enforcement actions is an effective corporate compliance programme. Compliance programmes should be tailored to the company and the relevant industry, but some features are nearly universal, including:

- the designation of a compliance officer responsible for implementing and overseeing the compliance programme;
- written policies and procedures documenting appropriate standards of conduct and identifying prohibited conduct;
- periodic training sessions and audits of employees and departments that are subject to the compliance programme; and
- standards for investigating and disciplining violations of the compliance programme or other misconduct.

Once an enforcement action is underway, the company should review its compliance programme, policies and procedures to ensure effectiveness, preserve all records and internally investigate the facts relevant to the alleged conduct. DOJ has policies in place that reward effective compliance programmes, and both DOJ and the Office of Inspector General for the US Department of Health and Human Services publish guidance regarding how to build and maintain one.

Recent enforcement activities

19 What have the authorities focused on in their recent drugs and devices enforcement activity and what sanctions have been imposed?

The federal False Claims Act (31 USC section 3729, et seq) is a major enforcement tool used by DOJ in the healthcare industry. In fiscal year 2020, DOJ recovered a total of $1.8 billion under the FCA in healthcare-related settlements and judgments. The largest of those recoveries came from the pharmaceutical industry. Recent DOJ enforcement actions involving pharmaceutical and medical device companies have focused on kickbacks allegedly paid by drug companies to physicians and opioid-related fraud schemes.

In July 2020, Novartis Pharmaceuticals Corporation entered into two civil FCA settlements totalling $642 million. The first settlement resolved allegations that the company provided illegal kickbacks by using three charitable foundations as vehicles to fund Medicare co-payments for patients taking its drugs. The second settlement resolved charges that the company paid kickbacks to physicians through its physician-speaker programmes to induce those physicians to prescribe the company's drugs.

Also in July 2020, Indivior, an opioid marketing company, pleaded guilty to making false statements about the safety of Suboxone Film (an opioid-addiction treatment drug) and the risks of 'accidental' paediatric exposure. The company pleaded guilty to a criminal false statement charge and paid $600 million to resolve criminal and civil charges. Notably, two of the company's executives also pleaded guilty to criminal charges, one of whom was the former Chief Executive Officer and was sentenced to six months in prison under the 'responsible corporate officer' doctrine.

In October 2020 (part of fiscal year 2021), DOJ announced an $8.34 billion settlement and global resolution of criminal and civil investigations into Purdue Pharma and its shareholders, the Sackler family. The resolution included $3.54 billion in criminal penalties, $2 billion in forfeiture, a $2.8 billion civil settlement with Purdue and a separate civil settlement with the Sackler family, who agreed to pay $225 million to resolve their civil FCA liability. These are the largest penalties DOJ has ever recovered from a pharmaceutical manufacturer.

Self-governing bodies

20 Are there self-governing bodies for the companies that sell pharmaceutical products and medical devices? How do those organisations police members' conduct?

Generally, no self-governing bodies have the authority to enforce regulatory requirements against pharmaceutical and medical device companies. Rather, enforcement is conducted by federal and state authorities. That said, some industry groups and trade associations publish voluntary standards of conduct (eg, the AdvaMed Code of Ethics for medical device companies and the PhRMA Code of Interactions with Health Care Professionals for drug manufacturers), but they do not enforce or police the conduct of their members.

RELATIONSHIPS BETWEEN HEALTHCARE PROFESSIONALS AND SUPPLIERS

Relationship rules

21 What are the rules prohibiting or controlling the financial relationships between healthcare professionals and suppliers of products and services?

Two primary federal statutes prohibit or control financial relationships between healthcare professionals and suppliers: the Physician Self-Referral Law (42 USC section 1395nn) (commonly called the Stark Law) and the Anti-Kickback Statute (42 USC section 1320a-7b(b)) (AKS). The Stark Law is a civil statute that prohibits physicians from making referrals for designated health services (DHS) to any entity with which that physician (or the physician's immediate family member) has a financial relationship, including ownership or investment interests and compensation arrangements, where the referred DHS may be paid for by Medicare or Medicaid. The Stark Law also prohibits that entity from billing for DHS referred by physicians with whom it has a financial relationship. Exceptions to the Stark Law may protect certain arrangements, but only if the arrangement meets every element of the exception. Importantly, the Stark Law is a 'strict liability' statute, meaning that no proof of a culpable state of mind is required to establish a violation.

The AKS is a criminal statute. It prohibits, in pertinent part, the knowing and wilful offer, payment, solicitation or receipt of any remuneration (ie, anything of value) to any person (including but not limited to healthcare professionals) to induce that person to purchase or order, or to recommend or arrange for the purchasing or ordering of, any good, service or item that may be paid for in whole or in part by a federal healthcare programme. Like the Stark Law, the AKS has statutory exceptions and regulatory safe harbours that protect certain arrangements and conduct from potential prosecution if all requirements of the safe harbour or exception are met.

In addition to the Stark Law and the AKS, two additional statutes are relevant to enforcement involving financial relationships between healthcare professionals and suppliers: the Eliminating Kickbacks in Recovery Act (18 USC section 220) (EKRA) and the federal False Claims Act (31 USC section 3729 et seq) (FCA). EKRA took effect in late 2018 as part of a broader piece of legislation designed to combat the opioid crisis in the US. As written, this criminal statute is similar to the AKS in that it prohibits the knowing and wilful offer, payment, solicitation or receipt of any remuneration in return for referrals. But the two statutes differ in the scope of arrangements and payors to which they apply, as well as the protections offered by available exceptions. While the AKS applies to any item or service that may be paid for by applicable federal healthcare programmes, EKRA applies to referrals of patients or patronage to a recovery home, clinical treatment facility or laboratory paid for by any health benefit programme (which is defined to include private insurers). In addition, the available EKRA exceptions

are narrower than, and in some cases prohibit conduct protected by, the AKS safe harbours.

The FCA is a civil statute that imposes treble damages as well as per-claim penalties for the submission of false claims for payment to the United States, among other conduct. Although the application of the FCA is not limited to healthcare providers and companies, this statute is frequently used by the United States, as well as private plaintiffs on the government's behalf (relators or whistle-blowers), to bring claims against entities in the healthcare industry. Notably, if a claim for payment to federal healthcare programmes (eg, Medicare) results from a violation of the AKS, such claims are deemed to be false for the purposes of the FCA. Courts have taken the same position with respect to claims resulting from Stark Law violations.

Many states have state law equivalents of the AKS, the Stark Law and the FCA, which may or may not mirror their federal counterparts.

Enforcement

22 | How are the rules enforced?

The US Department of Justice (DOJ), along with its US Attorneys' Offices (USAOs) across the country, is primarily responsible for enforcement of the FCA. An FCA investigation is usually triggered by the filing of *qui tam* complaint in federal court by a whistle-blower, but DOJ also can initiate an FCA investigation on its accord. The latter type of investigation has become more common in recent years and such investigations often arise as a result of data analysis.

FCA investigations commonly involve allegations that the defendant filed false claims (or caused such claims to be filed) because the claims were 'tainted' by underlying violations of the AKS or the Stark Law, or both. For example, a whistle-blower may allege that a hospital violated the AKS and the Stark Law and thus the FCA if a hospital provided free office space to a physician group that refers to the hospital and then filed claims for the services ordered by the physicians.

An FCA investigation may be criminal or civil or both (the latter type of investigation is often referred to as a 'parallel' investigation) and it typically begins with service of a subpoena or civil investigative demand. DOJ may seek large volumes of documents, request interrogatory responses, conduct voluntary interviews or seek testimony on the record. Upon concluding the investigation, DOJ will decide whether to pursue the matter. The parties may enter into a settlement or DOJ may move forward with court proceedings.

Reporting requirements

23 | What are the reporting requirements on such financial relationships? Is the reported information publicly available?

The Open Payments Program, which implements a law commonly referred to as the 'Sunshine Act', is a national transparency programme intended to highlight the financial relationships between physicians, teaching hospitals, and drug and device manufacturers. Under the Program, drug and medical device companies must report to the Centers for Medicare & Medicaid Services (CMS) payments or transfers of value they make to certain healthcare providers and teaching hospitals for research, meals, travel, gifts, speaking fees and more. Reports must be submitted to CMS annually and include all payments of $10 or more made to any physician or teaching hospital. These reports must also include information about the nature of the payment, whether the payment was related to marketing, education or research specific to a drug or medical device, as well as the date, amount and form of the payment, and the recipient's name. This information is reported in the Open Payments section of CMS's website.

REGULATION OF HEALTHCARE DELIVERY

Authority powers

24 | What powers do the authorities have to monitor compliance with the rules on delivery of healthcare?

Federal and state authorities have extensive monitoring powers over the delivery of healthcare. With respect to drugs and medical devices, the US Food and Drug Administration (FDA) monitors new drugs, generic drugs, biologics and bio-equivalents. Manufacturers and regulated facilities are subject to site inspections to determine compliance with applicable federal laws and regulations. Federal authorities also have the power to issue warning letters, which provide notice of an alleged violation of federal regulations, and to request documents or records from a regulated entity. Relatedly, drug and device manufacturers are required to maintain various types of records and must file annual reports with the FDA about their regulated drug or medical device. The FDA and US Department of Justice (DOJ) also have authority to enforce laws regarding commercial marketing of unapproved drugs and devices, as well as the promotion of drugs and devices that is not consistent with the FDA-approved label for the drug or device.

Federal investigations focused on compliance with rules relating to healthcare delivery also often examine (1) whether remuneration given to a healthcare provider induced that provider to use or order a given product or service and thus affected clinical decision-making), (2) whether a provider billed an insurer for a service that was not provided or not medically necessary, or (3) whether services provided to patients and billed to insurers were so deficient that they were equivalent to providing no services at all (ie, worthless services).

With respect to state-level regulation of healthcare delivery, each of the 50 states has licensing authorities and regulatory bodies that govern the delivery of healthcare by healthcare facilities and providers. These entities interpret and enforce a variety of regulatory provisions that set forth, for example, licensure requirements for healthcare providers and facilities, and structural requirements for medical facilities, among many other examples.

Investigation time frames

25 | How long do investigations of healthcare providers typically take from initiation to completion? How are investigations started?

Depending on the circumstances, investigations of healthcare providers can take years. Investigations commence in many ways, including initiation by federal agencies through their own investigations or by private plaintiffs referred to as whistle-blowers or relators.

Access to investigation materials

26 | What rights or access does the subject of an investigation have to the government investigation files and materials?

During an investigation, and before criminal charges or a civil complaint is filed, the subject of an investigation has no right to access government investigation files. Once proceedings are commenced, the targeted company or person typically has extensive rights to obtain documents, depose persons under oath (in a civil proceeding) and obtain certain statements made to the government (in a criminal proceeding). Those rights are determined by the type of proceeding (ie, criminal, civil or administrative) and the rules applicable to that proceeding.

Enforcement agencies

27 | Through what proceedings do agencies enforce the rules?

Agencies' rules may be enforced through (1) proceedings in a federal or state court, or (2) administrative agency proceedings. Enforcement proceedings in court may be either criminal or civil. For example, DOJ has exclusive authority to bring criminal charges in federal court.

With respect to administrative agency proceedings, various subagencies within US Department of Health and Human Services, such as the FDA and the Centers for Medicare & Medicaid Services (CMS), have authority to bring civil administrative enforcement and adjudication proceedings. For example, CMS has the power to enforce compliance with enrolment and other requirements relating to the Medicare programme (health insurance for elderly persons) and other agency programmes.

Sanctions

28 | What sanctions and other measures can the authorities impose or seek in enforcement actions against healthcare providers?

Available sanctions for a violation of federal law depend in part on the nature of the enforcement proceedings. In criminal cases, sanctions include criminal fines, penalties, restitution and product seizures. In civil cases, damages involve monetary recovery, and parties can also obtain injunctions, which generally prevent certain conduct. Civil damages in the United States can be massive. For example, under the federal False Claims Act (31 USC section 3729, et seq) (FCA), the government can recover treble damages – ie, three times the amount of the government's actual loss – in addition to mandatory statutory penalties. Private citizens (called whistle-blowers or relators) who file FCA claims may collect between 15 and 30 per cent of any recovery, plus attorneys' fees.

Agency enforcement proceedings can also result in other potential sanctions. For example, the Office of Inspector General for the US Department of Health and Human Services has mandatory and permissive authority to exclude individuals and entities from participating in all federal healthcare programmes, based on certain statutorily defined offences. Similarly, the FDA has mandatory and permissive authority to debar or prohibit a corporation or an individual from participating in FDA-regulated activities. Exclusion or debarment effectively amount to a total ban on operating in the healthcare industry.

Defences and appeals

29 | What defences and appeals are available to healthcare providers in an enforcement action?

Any defendant in an enforcement action may avail itself of legal, factual and constitutional defences, as appropriate based on the nature of the specific case. Legal defences include arguments that the alleged conduct did not violate the statute or regulation at issue, as well as procedural defences relating to jurisdiction and notice. Factual defences may include that the allegations are not accurate or did not occur, the defendant did not have the requisite state of mind to violate the legal requirement or that no payment was sought or obtained for the item or service at issue. Finally, all defendants have certain constitutional defences, including the right to due process.

Minimising exposure

30 | What strategies should healthcare providers adopt to minimise their exposure to enforcement actions and reduce their liability once an enforcement action is under way?

The hallmark of mitigating exposure to enforcement actions is an effective corporate compliance program. Compliance programmes should be tailored to the company and the relevant industry, but some features are nearly universal, including:

- the designation of a compliance officer responsible for implementing and overseeing the compliance programme;
- written policies and procedures documenting appropriate standards of conduct and identifying prohibited conduct;
- periodic training sessions and audits of employees and departments that are subject to the compliance programme; and
- standards for investigating and disciplining violations of the compliance programme or other misconduct.

Once an enforcement action is underway, the company should review its compliance programme, policies and procedures to ensure effectiveness, preserve all records and internally investigate the facts relevant to the alleged conduct. DOJ has policies in place that reward effective compliance programmes, and both DOJ and the Office of Inspector General for the US Department of Health and Human Services publish guidance regarding how to build and maintain one.

Recent enforcement activities

31 | What have the authorities focused on in their recent enforcement activity and what sanctions have been imposed on healthcare providers?

In 2020, enforcement activity involving healthcare providers covered a variety of different provider types and theories. For example, DOJ and other enforcement authorities prioritised opioid-related fraud cases again in 2020 and seemed to increase their efforts to prosecute individual providers who allegedly overprescribed opioids or otherwise contributed to the opioid crisis.

DOJ also continued to focus on telemedicine fraud that allegedly resulted in the ordering of medically unnecessary laboratory testing, durable medical equipment and pain medication, either after a short phone call between the physician and the patient or no interaction at all. Ordering providers allegedly received kickbacks in exchange for these referrals, which resulted in false claims submitted to federal healthcare programmes.

Sanctions imposed in criminal enforcement matters included significant fines or jail time, or both. Further, any provider convicted of a felony is subject to exclusion from the federal healthcare programmes by the Office of Inspector General for the US Department of Health and Human Services and loss of professional licensure.

Self-governing bodies

32 | Are there self-governing bodies for healthcare providers? How do those organisations police members' conduct?

Generally, there are no self-governing bodies that have the authority to enforce regulatory requirements against healthcare providers. Rather, enforcement is conducted by federal and state authorities. That said, some industry groups and professional associations (eg, the American Medical Association and the American Nurses Association) operate chapters at the national, state and local levels and provide guidance on various topics, but they do not engage in enforcement or police members' conduct.

Remedies for poor performance

33 | What remedies for poor performance does the government typically include in its contracts with healthcare providers?

Healthcare providers do not typically have contracts with the government. Poor performance is generally addressed through surveys and inspections conducted by the Centers for Medicare & Medicaid Services or state licensure agencies.

PRIVATE ENFORCEMENT

Causes of action

34 | What private causes of action may citizens or other private bodies bring to enforce a healthcare regulation or law?

The federal False Claims Act (31 USC section 3729, et seq) (FCA) and state law equivalents allow a private citizen (called a relator or whistle-blower) to file suit on behalf of the United States. FCA claims typically allege that another person or entity has submitted false claims to the federal government (or state government, if the suit is filed under a state false claims provision). These suits are referred to as *qui tam* actions. In FCA *qui tam* cases, the federal government, represented by the US Department of Justice (DOJ), may decide to take over (or intervene in) the suit or decline to intervene. In the latter circumstance, the whistle-blower may still proceed to litigate the suit on behalf of the United States. In addition to intervening or declining to intervene, the United States can also move to dismiss *qui tam* cases. The United States may elect to dismiss a matter, for example, where it believes that a *qui tam* action has the potential to create undesirable legal precedent.

Framework for claims

35 | What is the framework for claims of clinical negligence against healthcare providers?

There are no federal laws that establish the framework for a clinical negligence claim. Such claims are typically filed under state law. Each state, in turn, has its own legal framework for negligence claims, but such claims typically include the following elements: (1) the provider owed a professional duty to the patient; (2) the provider breached that duty; (3) the breach caused an injury to the patient; and (4) resulting damages. If a plaintiff is successful in a negligence claim, the amount of damages to be awarded is decided by the finder of fact (often a jury), but legal limits may apply. Providers, in turn, typically carry malpractice insurance to help pay for the cost of defending (and, if applicable, losing) such claims.

Seeking recourse

36 | How and on what grounds may purchasers or users of pharmaceuticals or devices seek recourse for regulatory and legal infringements?

A private individual who purchases or uses a drug or device and wants to seek recourse for regulatory or legal infringements can file a complaint or report relating to the product (eg, an adverse event report) or its labelling (eg, regulatory misconduct report) with the US Food and Drug Administration (FDA), a state regulatory agency or attorney general. A private individual (sometimes referred to as a whistle-blower or relator) may also file a *qui tam* suit under the federal False Claims Act (31 USC section 3729, et seq.), asserting claims on behalf of the United States. Healthcare providers that purchase and use drugs or devices on patients may also report adverse events or regulatory misconduct to the FDA.

Compensation

37 | Are there any compensation schemes in place?

DOJ administers three compensation programmes, each applicable in very specific circumstances and created by different pieces of legislation: the National Childhood Vaccine Injury Act of 1986, the Radiation Exposure Compensation Act and the James Zadroga 9/11 Health and Compensation Act of 2010.

Class and collective actions

38 | Are class actions or other collective claims available in cases related to drugs, devices and provision of care?

Class actions are not used in governmental enforcement proceedings but may be pursued by private parties (called plaintiffs). To proceed on behalf of a class, a plaintiff must show that the case turns on common issues of fact and law that affect numerous similarly situated claimants, but can be resolved for all claimants through common proof, without requiring individualised findings. Examples of drug, device or healthcare class actions include patient claims that the cost of drugs or care was improperly inflated due to regulatory violations, or shareholder claims that non-disclosure of regulatory violations inflated share prices. Insurers and patients often bring antitrust class actions claiming that wrongful enforcement of pharmaceutical patent rights excludes competitors and inflates drug prices. Conversely, claims alleging harm from defective drugs or devices typically require patient-specific proof of injury and are not pursued as class actions.

Review

39 | Are acts, omissions or decisions of public and private institutions active in the healthcare sphere subject to judicial or administrative review following a complaint from interested parties?

Not applicable.

Whistle-blowers

40 | Are there any legal protections for whistle-blowers?

The federal False Claims Act (31 USC section 3729, et seq) includes a provision that protects whistle-blowers (also called relators) who are employees, contractors or agents of the entity against which they have filed a *qui tam* action from retaliation by that entity. The Dodd-Frank Wall Street Reform and Consumer Act and the Sarbanes-Oxley Act also protect whistle-blowers who report potential wrongdoing by public companies. State law equivalents, which vary by jurisdiction, may include similar provisions.

41 | Does the country have a reward mechanism for whistle-blowers?

The federal False Claims Act (31 USC section 3729, et seq) awards whistle-blowers (also called relators) a percentage of amounts recovered by the United States as a result of the *qui tam* action. If the United States declines to take over (or intervene in) the suit, the whistle-blower may still proceed with the suit on behalf of the United States, and, in such cases, is entitled to between 25 and 30 percent of any recovery. If the United States does intervene, the whistle-blower's share is between 15 and 25 per cent. State law equivalents to the federal False Claims Act may include similar provisions. The Dodd-Frank Wall Street Reform and Consumer Act also provides awards to whistle-blowers.

42 | Are mechanisms allowing whistle-blowers to report infringements required?

Generally speaking, healthcare companies and providers are not required by law to provide mechanisms that allow whistle-blowers to report infringements. It is nevertheless considered to be best practice from a compliance perspective (and it is strongly recommended by relevant regulatory agencies) that healthcare companies and providers establish hotlines or other mechanisms that allow employees or other whistle-blowers to anonymously report compliance concerns or violations.

CROSS-BORDER ENFORCEMENT AND EXTRATERRITORIALITY

Cooperation with foreign counterparts

43 | Do prosecutors and law enforcement authorities in your country cooperate with their foreign counterparts in healthcare cases?

US Department of Justice (DOJ) attorneys routinely cooperate with their counterparts in foreign countries in cases with international components, including healthcare cases. One of these areas is Foreign Corrupt Practices Act (FCPA) enforcement. The FCPA makes it illegal to corruptly offer or provide money (or anything of value) to foreign officials, with an intent to obtain or retain business. The FCPA applies to US companies that have securities registered in the US or are otherwise required to file periodic reports with the Securities Exchange Commission. The FCPA also applies to any individual who is a citizen, national or resident of the United States, including certain business entities with a principal place of business in the United States. Accordingly, US corporations and nationals can be held liable for any bribes paid to foreign officials even if no actions or decisions take place within the United States. DOJ interprets the FCPA to confer jurisdiction if a foreign company or national (or an agent of either) causes an act to be done within the United States. Due to these provisions, FCPA enforcement often necessitates cooperating with foreign officials.

Additionally, DOJ's Office of International Affairs has personnel stationed at embassies across the globe to serve as liaisons between domestic DOJ prosecutors and foreign authorities.

Triggering investigations

44 | In what circumstances will enforcement activities by foreign authorities trigger an investigation in your country?

A foreign investigation rarely prompts enforcement activities by DOJ. Requests for assistance from foreign authorities are handled by DOJ's Office of International Affairs (OIA). These requests may be made by foreign authorities pursuant to treaties, letters rogatory, letters of request or other channels. Individual DOJ prosecutors do not have authority to institute legal process in aid of the request without statutory authorisation from OIA. Accordingly, in the uncommon event where foreign activities may lead to enforcement by DOJ, such matters are handled through OIA.

Pursuing foreign entities for infringement

45 | In what circumstances will foreign companies and foreign nationals be pursued for infringements of your country's healthcare laws?

Foreign companies and foreign individuals are subject to the same healthcare laws and regulations as domestic companies and US citizens. Investigations and enforcement actions against foreign healthcare companies are commonplace, provided those companies are subject to jurisdiction in the United States. While the Foreign Corrupt Practices Act reaches a wide swath of foreign conduct, many other laws and statutes regulating healthcare companies do not. So, foreign companies or individuals must bear a sufficient jurisdictional connection to the United States for enforcement of any non-extraterritorial healthcare laws.

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UPDATE AND TRENDS

Key developments of the past year

46 | What are the authorities' enforcement priorities likely to be in the coming year? Are there any noteworthy cases pending? Are there any current developments or emerging policy or enforcement trends that should be noted?

While covid-19 temporarily diverted the attention of the US Department of Justice (DOJ), enforcement activity has largely returned to normal in the US. DOJ continues to actively pursue federal False Claims Act (31 USC section 3729, et seq) (FCA) investigations, whether stemming from *qui tam* cases filed by private parties (known as whistle-blowers or relators) or from DOJ's own investigative activities. In addition, 2021 brought a new president and attorney general. While both major US political parties typically support healthcare fraud enforcement, the Biden administration is expected to increase regulatory and enforcement activity.

The US has faced a public health crisis resulting from opioid addiction for many years now, and the federal government has sought to address those perceived to be bad actors through criminal and civil enforcement activities. Opioid-related enforcement thus will likely remain a key area of focus for enforcement authorities in 2021. Targets are likely to include individuals and companies that have allegedly contributed to the opioid epidemic, opioid manufacturers and marketers, physicians accused of improperly prescribing opioids, pharmacies and other entities in the drug supply chain. In 2020, DOJ used the responsible corporate officer doctrine to hold company executives responsible in opioid-related enforcement matters and may seek to do so again in 2021.

Covid-19 will also undoubtedly generate substantial enforcement activity in 2021, as it did in 2020. The large amount of covid-19 relief funding disbursed to healthcare providers and suppliers by the federal government likely will receive close scrutiny. The pandemic also put nursing homes under the spotlight. DOJ and state attorneys general may escalate enforcement against nursing homes, building upon DOJ's 2020 National Nursing Home Initiative. DOJ will vigorously pursue wide-ranging allegations of deficient care, substandard services and billing for unnecessary services.

With the dramatic acceleration of the adoption of telemedicine during the pandemic, telemedicine is expected to remain embedded in the healthcare delivery system and will likely remain a target of enforcement authorities. These enforcement efforts will likely be directed at countless healthcare providers and suppliers who provide testing, drugs, durable medical equipment and other products and services.

Coronavirus

47 What emergency legislation, relief programmes and other initiatives specific to your practice area has your state implemented to address the the pandemic? Have any existing government programmes, laws or regulations been amended to address these concerns? What best practices are advisable for clients?

During the covid-19 pandemic, emergency legislation, relief programmes and other initiatives were implemented at both the state and federal level. At the federal level, various pieces of legislation were passed to provide relief to states and individuals, including the CARES Act and the Families First Coronavirus Response Act. In addition, federal agencies such as the Centers for Medicare & Medicaid Services (CMS) implemented a variety of waivers and took many other actions to provide the healthcare industry the flexibility needed to continue to operate during the public health emergency. Among other things, CMS relaxed the Medicare programme's strict coverage requirements for telemedicine services in an effort to broaden access to telehealth services, and many states followed suit. In addition, the US Food and Drug Administration issued Emergency Use Authorizations for covid-19 testing and vaccines and thus permitted these products and services to be offered without going through the full approval or clearance process. At the state level, state leaders issued executive orders establishing states of emergency and introducing mask mandates. States also implemented various pieces of legislation designed to increase availability of covid-19 testing and vaccines. The landscape of these varying executive orders, emergency legislation and relief programmes remains in flux as the parameters of the pandemic continue to change.

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