THE HEALTHCARE LAW REVIEW

Seventh Edition

Editor
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URÍA MENÉNDEZ

PREFACE

The seventh edition of *The Healthcare Law Review* covers three new jurisdictions (India, Mexico and Nigeria), summing up to a total of fifteen jurisdictions from countries in Europe, North and South America Asia and – for the first time – Africa. All reports have been provided by leading experts in the field of healthcare law in their countries. The reviews have been prepared by the authors as a practical, business-focused analysis of recent changes and developments, their effects, and a look forward at expected trends. The reviews are intended to provide an overview of legal issues which are of interest for healthcare providers and related businesses.

The global covid-19 pandemic has come to an end this spring. The WHO chief Tedros Ghebreyesus declared the end to covid-19 as a global health emergency on 5 May 2023. According to the reviews from the individual countries, most of the exceptional measures, which had been implemented by the countries to fight the pandemic, have largely been scaled back or totally withdrawn. Therefore, the authors report back to normal in their reviews.

As a major result of the pandemic, many countries have geared their healthcare systems to ensure safe access to healthcare for citizens, even in extraordinary situations, through more digitisation and telemedicine. This is not just about supplementing or replacing face-to-face doctor visits with communication options via telephone or video consultation. Many countries, not only in Europe, have also introduced electronic patient files, regulations for the exchange of health data and other digital communication channels. It seems that it is still a long way to go to implement these innovations successfully in a healthcare reality that is no longer solely determined by a pandemic. A particular challenge in the future will also be to utilise the new digital tools not only within a national healthcare system in a single country, but also across borders.

The European Union is already well on the way with the implementation of a European Health Data Space. Furthermore, the European Commission has published a proposal of a new pharma package, which may have major impact on the healthcare systems in the member states of the European Union in particular.

Germany however, the largest healthcare system in the European Union, still faces many hurdles before implementing electronic prescriptions, electronic patient records or statutes for the secondary use of health data. The authors report from South Korea that the strict measures for telemedicine services are back in force. These examples show that healthcare systems in the individual countries tend to defend the status quo rather than to implement digital and electronic tools with fast speed.

Even if the individual countries solve the problems differently, we all can only benefit from knowing the different approaches to solving the problems and how successful

the respective countries have been with their solutions in each case. I truly hope that the publication of the new edition of *The Healthcare Law Review* will particularly be helpful in that respect.

Like in past years, it has been an extraordinary pleasure to work with this group of exceptional authors of *The Healthcare Law Review* in this edition and in the years to come to provide a practical overview of the healthcare systems of the countries covered. We will continue our efforts to include more countries to be able to give a comprehensive worldwide approach to health issues by each country.

Ulrich Grau
D+B Rechtsanwälte Partnerschaft mbB
Berlin
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Chapter 15

UNITED STATES

Lawrence W Vernaglia, Olivia R K Benjamin, Stephanie J Schwartz and Sheridan Organ[1]

I OVERVIEW

i Overview of the US healthcare system

The US healthcare industry remains at a crossroads. The healthcare reform legislation passed under President Barack Obama in 2010, officially called the Patient Protection and Affordable Care Act (ACA) but widely referred to in the United States as 'Obamacare', resulted in significant changes in the US healthcare system. These changes included a dramatic expansion in the number of insured patients, contributing to increased demand for services. Many of these newly insured are covered by the joint state-federal Medicaid programme, which generally covers low-income patients as an entitlement programme, and reimburses at the lowest rates in most markets.

The prominent partisan debates over the US healthcare system have been further exacerbated by the 2020 coronavirus (covid-19) global pandemic, the greatest challenge the US healthcare system has faced in decades. The US quickly became the covid-19 capital of the world, with the most infected individuals and reported deaths of any country at the time of publication.[2] While many dedicated healthcare providers quickly engaged in covid-19 relief efforts, the federal government failed to contain the pandemic, and left the 50 states to design their own strategies for containing the virus. State responses varied along political lines, with governors aligned with Trump following his lead of downplaying the virus, and those in 'blue states' adopting more restrictive policies of 'social distancing'.

Since Biden began his presidency, there was a significant change in the response to the pandemic. In particular, the nationwide rollout of covid-19 vaccination programmes resulted in decreases in the spread of covid-19 as well as its mortality rate, which allowed states to relax restrictions and the federal government to declare the end of the public health emergency on 11 May 2023.

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1 Lawrence W Vernaglia is a partner and Olivia R K Benjamin and Stephanie J Schwartz are associates at Foley & Lardner LLP. Sheridan Organ served as a summer associate at Foley & Lardner LLP in 2023. The authors would like to acknowledge the significant contributions of their friend and colleague R Michael Scarano for his work on several sections of this chapter. Mr Scarano was a pre-eminent healthcare lawyer in the San Diego office of Foley & Lardner who trained generations of healthcare lawyers and zealously served healthcare provider clients at the highest levels. Mike is sorely missed by his peers, and we dedicate this chapter to his memory and friendship. The authors would also like to thank their colleague Anna S Ross for her material contribution to the prior editions of this chapter.

2 See Johns Hopkins University & Medicine, COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins, "Mortality in the most affected countries," https://coronavirus.jhu.edu/map.html (data stopped being collected 23 March, 2023; last visited 4 July, 2023).

Notwithstanding these challenges, prior to the covid-19 pandemic, the US healthcare system experienced a period of sustained growth of approximately 6 per cent per year over the past several years. The authors expect this pattern to continue. This growth has been coupled with a trend towards consolidation, which has only intensified due to the increasing difficulty for independent hospitals and medical groups to survive. As a result of these trends, healthcare presents an attractive area for investment in the United States. This, along with financial losses by hospitals during the pandemic will further encourage consolidation. The following sections seek to put the larger healthcare services sector in the United States into context, focusing on these and other broad business and regulatory trends, while also understanding the organisational fundamentals.

ii Delivery of healthcare in the United States

Hospitals with inpatient, outpatient and diagnostic capacities are the 'work benches' for the delivery of healthcare in the United States, although the physicians and other professionals who treat patients are critical parts of the care delivery system as well. While physicians are sometimes referred to as the 'captains of the ship' in the hospital context, other non-physician practitioners, such as nurse practitioners, physician assistants and others, are gaining prominence in the institutional and community healthcare setting.

iii Payment for healthcare services

Healthcare services in the United States are paid for primarily by (1) government programmes such as Medicare and Medicaid and (2) private insurance organisations. These public and private organisations are collectively known as 'third-party payers' or simply 'payers'. Most third-party payer arrangements have some element of 'managed care', which means that care is provided subject to utilisation review, such as primary care physicians acting as gatekeepers to specialists. Managed care plans typically enter into contracts with providers to deliver services at a discounted rate, sometimes in exchange for an expectation of increased volume from the payer. Government and private healthcare payers alike in the United States are increasingly focused on the value of services, which has contributed to the rapid expansion of alternative payment models that offer incentives to providers for better care outcomes, and in some cases penalise poor outcomes through reduced payments.

II THE HEALTHCARE ECONOMY

i General

The US healthcare industry is one of the most closely watched and fastest growing sectors of the nation's economy. There are many stakeholders in the US healthcare system, many of which have dramatically differing interests. These include, but are not limited to:

a enterprises that operate hospitals and health systems;
b manufacturers and developers of medical devices, pharmaceuticals and other biotechnology products;
c academic institutions that provide care while training healthcare professionals;
d information technology firms, construction companies and other infrastructure providers;
e insurance companies, self-insured employers and other third-party payers;
f labour unions representing the employees of healthcare organisations;
g medical entrepreneurs and investors (including private equity and venture capital) who finance the healthcare system;

h healthcare trade associations;
i patient advocates and special interest healthcare advocacy organisations; and
j patients and their families.

In addition, there is substantial government involvement in healthcare in the United States, with the government serving as a major payer, as well as a provider and regulator in various parts of the market.

ii The role of health insurance

Most medically necessary healthcare services in the United States are paid for by government or private third-party payers, including insurance companies, self-insured employer plans, health maintenance organisations (HMOs), Medicare and Medicaid, TRICARE, the Veterans Administration and workers' compensation programmes. Most third-party payer arrangements are either managed care indemnity arrangements or involve monthly pre-payments known as 'capitation'. Private third-party payers are heavily regulated by state insurance commissioners, or the United States Department of Labor with respect to employer-sponsored plans, known as ERISA plans (short for the Employee Retirement Income Security Act).

Medicare and Medicaid

The two major government healthcare payment programmes in the United States are Medicare and Medicaid. Medicare is a federal programme that primarily provides coverage for individuals who are age 65 and over, disabled or have end-stage renal disease. Medicare is currently the largest (in total dollars) federal healthcare programme, providing health insurance for the elderly and certain other individuals. Medicare offers several payment arrangements, including traditional indemnity fee-for-service coverage (Traditional Medicare) and Medicare HMOs, known as Medicare Advantage plans. Medicare beneficiaries may choose between the two types of plans.

Under Traditional Medicare, inpatient services for most hospitals (i.e., other than 'excluded hospitals' that have special status under the law because of their specific types of service, such as cancer care) are reimbursed under the Inpatient Prospective Payment System (IPPS). Under the IPPS, hospitals are paid a prospectively determined case rate based on the patient's diagnosis – a diagnosis-related group (DRG) – which may also include certain add-on payments. Provider-based hospital outpatient services under Traditional Medicare are reimbursed under the outpatient prospective payment system (OPPS), which is also based on a prospectively determined case rate. Outpatient services that are not 'provider-based' are reimbursed under the Medicare Physician Fee Schedule or the ambulatory surgical centre (ASC) payment rules, which are less generous than the provider-based rules, discussed further below.

Some outpatient procedures can either be performed (1) outside and independent of a hospital (e.g., in a freestanding clinic or physician's office) and are reimbursed under the Medicare Physician Fee Schedule; or (2) in a hospital-affiliated and hospital-operated site included on the hospital's licence and generally referred to as 'provider-based'. Reimbursement for provider-based facilities under the OPPS methodology is generally higher than comparable rates for the same procedures if performed in a freestanding facility under the Physician Fee Schedule. However, to qualify for provider-based reimbursement, the outpatient site must

meet several requirements, some of which are somewhat onerous.[3] A hospital that operates a surgery centre also has the option of operating that facility as provider-based, thereby permitting use of the OPPS payment structure.

Medicaid is a joint state and federal programme traditionally for certain impoverished individuals who are aged, blind or disabled, or members of indigent families with dependent children that meet income and resource standards set by the state Medicaid agency. Medicaid today covers more individuals than Medicare, making it the largest single payment system in the United States, in terms of persons served.[4] The federal government contributes roughly half of the reimbursement for the Medicaid programmes, though some US states with struggling economies receive higher reimbursement than others. Although the rates payable by Medicaid in most states are notoriously low (some falling short of the provider's costs), the rates will be increased for a number of years under the ACA, possibly making the programme more attractive for primary care physicians and others who are either in scarce supply or simply do not wish to treat these low-income patients.

Commercial and private insurance

HMOs and preferred provider organisations

Although there remain some 'pure indemnity' arrangements (wherein the beneficiary is reimbursed for all healthcare expenses he or she incurred regardless of the provider who rendered the care), most third-party payer arrangements involve some element of managed care and typically create certain constraints on the beneficiary's choice of provider, usually as a result of network or panel arrangements established by the payer.

There are two primary types of managed care arrangements: HMOs and preferred provider organisations (PPOs). An HMO typically requires the beneficiaries or members to exclusively use providers that have signed a contract with the HMO to receive a discounted or capitated amount for its services. The HMO will not pay for services provided by a non-contracted provider except when the services were performed in an emergency or the HMO does not have a needed specialist in its contracted network.

PPOs are delivery systems wherein the plan assembles a contracted provider network from which the member can receive care on a discounted fee-for-service basis; however, the beneficiary also has the option of going outside the network if he or she is willing to shoulder a greater share of the cost of care, typically in the form of a higher co-payment. There are also 'point-of-service' (POS) plans, which are a hybrid of an HMO and a PPO. Under a POS plan, the member usually receives capitated care but has the option of receiving care from a non-contracted out-of-network provider if he or she is willing to pay a substantial portion of the provider's fee-for-service charges.

iii Funding and payment for specific services

The ACA's overarching objective was to expand coverage to 31 million uninsured Americans, primarily through the individual mandate, employer mandate, expansion of Medicaid and establishment of subsidies (i.e., tax credits) to purchase plans in the health insurance marketplace established by each participating state, or by the federal government. The law

3 42 C.F.R. § 413.65.

4 See The Henry J Kaiser Family Foundation, Medicaid Pocket Primer (updated 9 June 2017; last accessed 6 June 2022), http://files.kff.org/attachment/Fact-Sheet-Medicaid-Pocket-Primer.

establishes a minimum of 10 categories of 'essential health benefits' for plans: (1) ambulatory patient services; (2) emergency services; (3) hospitalisation; (4) maternity and newborn care; (5) mental health and substance use disorder services, including behavioural health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and (10) paediatric services, including oral and vision care. However, other types of healthcare services for adults, such as dental care and vision care, are typically paid for by individuals personally or through other types of private insurance plans that cover such services.

iv Pricing transparency

At the end of the Trump administration, HHS issued a final rule called Transparency in Coverage as part of the federal government's initiative to increase transparency in healthcare pricing. Typically, healthcare prices are negotiated between insurers and providers and not easily accessible, but these new rules require health insurance issuer and group health plans to disclose certain pricing and cost-sharing information and publicly disclose a variety of information about in-network, out-of-network and pharmaceutical prices. Some of these hospital-specific requirements came into effect on 1 January 2021, and CMS has begun sending warning letters, corrective action plan requests and notices of fines to hospitals not in compliance. Similarly, the No Surprises Act, enacted in December of 2020 (and updated on 1 January 2022) by both the HHS and the US Department of Labor and Treasury, was implemented to provide protection from patients incurring surprise costs for healthcare and cost-sharing payment obligations. It requires that consumers have the right to receive a good-faith cost estimate prior to scheduled services, and access to the patient-provider dispute resolution process.

III PRIMARY/FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

i Hospitals and primary care

The Emergency Medical Treatment and Labor Act, a federal law mandating that anyone who arrives at a hospital emergency department must be medically screened and provided stabilising treatment, regardless of their insurance status, has contributed to the use of hospital emergency departments for all types of care. However, the ACA has increased focus on primary care by expanding the number of insured patients and thereby increasing access primary care. As noted above, the ACA has also mandated coverage for certain primary care and preventative services.

ii Electronic health records and privacy

Although many healthcare facilities and providers in the United States have individually adopted use of electronic medical records, there has not yet been a sustained effort to implement a universal electronic medical record.

Healthcare organisations are subject to a plethora of federal and state privacy and security laws pertaining to health information maintained by the organisation. The most comprehensive federal law that applies to healthcare organisations is the Health Information Portability and Accountability Act of 1996 (HIPAA), as modified by the Health Information Technology for Economic and Clinical Health (HITECH) Act. These laws and their implementing regulations provide federal protections for the privacy of individually identifiable health information or protected health information (PHI) held by covered

entities (e.g., health plans, healthcare clearinghouses and most healthcare providers) and give patients an array of rights with respect to such information. The HIPAA Security Rule specifies a series of administrative, physical and technical safeguards that covered entities must implement to ensure the confidentiality, integrity and availability of electronic PHI.

HIPAA imposes liability on healthcare organisations for technical violations of the required privacy protections and security safeguards, and for any unauthorised access, use or disclosure (i.e., breach) of confidential health or medical information. If a healthcare organisation violates HIPAA, the Secretary of HHS may impose civil monetary penalties or corrective action plans on a covered entity and the business associates with which it contracts. The secretary may also refer criminal violations to the Department of Justice (DOJ). State attorneys general also have a right to bring a cause of action on behalf of residents of their states under HIPAA. State laws vary considerably, but in some states, a healthcare organisation is also subject to state civil penalties and damages in any action brought by an individual whose privacy was compromised as the result of a violation of state privacy law. In addition to any potential liability for their own actions, healthcare organisations may also bear liability for the actions of their subcontractors for violations of state privacy laws.[5]

Since the 2018 passage of the European Union General Data Protection Regulation (GDPR) imposing rigorous requirements on companies that monitor or process the personal data of European citizens, some US states have passed similarly stringent privacy laws, leading to many healthcare providers adjusting their business practices in efforts to comply. One of the more comprehensive of these laws is the California Consumer Privacy Act of 2018, which provides California residents with similar rights to those that GDPR provides to EU citizens, including the right to access personal data an organisation has collected and the right to have that personal data deleted.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

Because the government spends so much on Medicare, Medicaid and other programmes, it has taken aim at fraud and abuse and made concerted efforts to reduce provider misconduct and to recover funds inappropriately paid by these programmes. This regulation is carried out by several regulatory bodies. At the federal level, most laws affecting the structure and payment of healthcare are promulgated by the Centers for Medicare and Medicaid Services (CMS). The CMS is a division of the US Department of Health and Human Services (HHS), which has a separate oversight arm – the Office of Inspector General (OIG). (Many state and federal agencies have inspectors general to oversee the operations and fight fraud within the agencies).[6] The OIG fights fraud, abuse and other forms of waste in government healthcare programmes and provides oversight by carrying out audits, investigations and evaluations and develops resources for the healthcare industry.

At the state level, state government agencies oversee issues such as Medicaid rules and payment requirements along with provider licensing, and often also enforce state-level

5 See US Department of Health & Human Services, Notification of Enforcement Discretion under HIPAA to Allow Uses and Disclosures of Protected Health Information by Business Associates for Public Health and Health Oversight Activities in Response to covid-19 (16 June 2021), https://www.hhs.gov/sites/default/files/notification-enforcement-discretion-hipaa.pdf.

6 See Inspector General Act of 1978, 92 Stat. 1101 (1978).

versions of some of the major federal compliance rules and regulations. This two-tiered structure creates a complicated patchwork of healthcare laws, often with significant variations among the 50 states and the District of Columbia.

ii Institutional healthcare providers

Licensure

The licensing of hospitals and other healthcare facilities is regulated at the state level, resulting in at least 51 different sets of licensure requirements for institutional healthcare providers. Notably, even the types of healthcare facilities that require a licence to operate vary from state to state, which can become particularly challenging as more healthcare providers move towards consolidation. In general, states will require licensure of hospitals, nursing homes, ambulatory surgical centres, healthcare clinics, pharmacies and other similar healthcare facilities.

For hospitals and other health facilities, the licensure laws typically cover issues such as staffing; physical plant requirements; required clinical services; and administrative capabilities. In most states, in addition to hospital licensure, full-service hospitals require other licences and permits, such as laboratory permits, hazardous wastes permits, food service permits and transportation licences for hospital-affiliated ambulances. Other residential healthcare facilities, such as nursing homes or behavioural health homes, are typically subject to similar requirements.

States generally impose sanctions on facilities for providing healthcare services without a licence. State licensure authorities have individualised procedures for the issuance, suspension or termination of a facility licence, which typically provides for an opportunity to appeal a refused, suspended or terminated licence. As described in Section X, many state governments waived certain facility licensure and operational requirements during the covid-19 public health emergency.

Certification and accreditation

In addition to state licensure requirements, Medicare, Medicaid and other government reimbursement programmes rely on the 'power of the purse' in regulating healthcare providers in their delivery of services. These programmes impose 'conditions of participation' and 'conditions of payment', which essentially mandate providers' compliance with specified standards to be reimbursed. The process of determining compliance by a hospital or other healthcare provider with the programme's rules is known as 'certification'. Certification is a right to participate in the government payment systems distinct from state 'licensure' and private 'accreditation'. In most cases, hospitals will possess all three: certification, licensure and accreditation, although there are hospitals that do not.

Although they are ultimately responsible for granting certification, the Medicare and Medicaid programmes delegate much of this responsibility to private accreditation agencies and state 'survey agencies'. The two primary private accreditation bodies in the United States are the Joint Commission (TJC) (previously referred to as the Joint Commission on Accreditation of Health Care Organisations, or JCAHO), which surveys most hospitals and other healthcare institutions, and the American Osteopathic Association (AOA), which surveys osteopathic hospitals. Compliance with TJC or AOA standards affords a hospital 'deemed status', meaning that a hospital has complied with Medicare, and usually Medicaid, requirements. Accreditation also confers deemed status for state licensure purposes in some jurisdictions.

Hospitals are not required to seek private accreditation. The process of seeking accreditation is lengthy and expensive. Some smaller organisations seeking to reduce their expenses forego accreditation and rely on the surveys by the state survey agencies. The federal Medicare programme has contracted with the state healthcare agency in every state to be the official state survey agency for the CMS.

iii Healthcare professionals

Health practitioners are subject to licensure by their respective state boards. These typically include the medical board for physicians, the nursing board for nurses, and others. These boards establish and enforce the criteria for initial and ongoing licensure, as well as a process for revoking such licensure or taking other disciplinary action.

Although each state issues its own licences, some states permit reciprocity by honouring each other's licences, for example, the Nursing License Compact (NLC) under which 35 member states recognise the nursing licences granted by all the other member states.

In addition to government licensing and certification requirements, 'credentialling' of individual professionals occurs at the facility level. Compliance with standards and requirements established by individual health facilities permits individual licentiates to perform services within those facilities. Health plans, professional associations and licensed outpatient facilities usually also impose credentialling requirements.

State and federal statutes applicable to physicians and certain other licentiates provide hearing and appeals rights when a state agency denies or revokes licensure or certification. Similarly, hospitals, health plans and certain other providers or professional organisations are required by state and federal law to have formal peer review and quality assurance or quality improvement procedures in place whereby they determine whether to permit a new practitioner to provide services to their patients. These procedures also govern any adverse disciplinary actions against practitioners, such as the revocation or restriction of their clinical privileges. Under a federal law called the Health Care Quality Improvement Act (HCQIA), and under state laws in many jurisdictions, these organisations must follow specified procedures in making adverse decisions affecting a practitioner's privileges. In most states, practitioners must go through or 'exhaust' these administrative appeal procedures before they can challenge the denial or revocation of privileges or other adverse action in court. Because failure to follow these rules can result in liability to the organisation, it is incumbent on hospitals and other healthcare organisations that are subject to these rules to have a compliant peer review and appeals process in place prior to commencing operations.

iv Negligence liability

Professional liability ('medical malpractice') is a characteristic of the US healthcare system that many believe contributes to its high cost. Under the US professional liability system, any patient who believes he or she has been hurt or injured by the professional negligence or wilful misconduct of a healthcare provider is entitled to damages if they demonstrate that it is more likely than not that the misconduct caused the patient's injury. As a result, in a practice called 'defensive medicine', physicians may order tests that are not medically indicated out of fear that the theory or failure to order the test will be second-guessed if the patient has a bad outcome.

In addition to provider liability, medical devices and pharmaceuticals companies experience liability for patient injuries, most notably 'products liability'.

A recent study by Johns Hopkins University found that, despite some calls for reform (code for reducing the ability of injured patients to seek compensation), more than 250,000 patient deaths per year in the United States are a result of medical error, making these types of errors a leading cause of death in the country.[7]

V OWNERSHIP OF HEALTHCARE BUSINESSES

i Types of ownership and management

The trend toward consolidation of the healthcare industry in the United States has created several different ownership and management models. Entities entering the healthcare market typically acquire a healthcare business through an asset acquisition, a stock or limited liability company acquisition, a merger, or a true consolidation that forms a new entity.

Increasingly, government hospitals are entering into management agreements with private parties, with the private entity managing the assets and personnel of the government hospital. These public–private partnerships raise complex issues under the special laws that apply to government agencies. These include laws that: require most governing body meetings to be public; require public disclosure of most of the agency's documents; provide special liability protections for the entity and its employees; and protect the assets of the government entity from exploitation by private parties, and prevent 'gifts of public funds' or the 'lending of the government entity's credit'.

ii Restrictions on ownership

Several states prohibit 'corporate practise of medicine' (CPOM), which is generally defined as the operation of a medical practice, or the employment of physicians (or other licensed practitioners of the healing arts), by lay corporations and entities that are not themselves licensed to practise medicine. The US states have wildly divergent degrees of CPOM regulation, with states such as California having the strictest prohibition on physician employment, and Florida having, perhaps, the most lax.

The CPOM is typically articulated in state statutes and regulations, case law, attorneys' general opinions and medical board guidance. There are usually limited exceptions to the CPOM in those states that enforce the prohibition. The rationale for the CPOM is that commercial business issues (revenue generation, profit and loss, etc.) should not be permitted to intrude on the physician–patient relationship. Depending on the state, violations of the CPOM can result in injunctive relief, civil penalties and criminal enforcement. Despite CPOM prohibitions, the need to access capital and innovate in the delivery of medical services has introduced private equity, venture capital and publicly traded investors into the medical marketplace. Two strategies are generally deployed in the US to comply with CPOM while permitting lay investment: seeking state licensure as a healthcare facility or designing a management company and contractually tied-in professional corporation (a 'friendly PC').

7 Vanessa McMains, Johns Hopkins University HUB, 'Johns Hopkins study suggests medical errors are third-leading cause of death in US' (3 May 2016), available at https://hub.jhu.edu/2016/05/03/medical-errors-third-leading-cause-of-death/ (last accessed 6 June 2022).

VI MARKETING AND PROMOTION OF SERVICES

Several laws restrict the promotion and advertising of healthcare services and business. For example, advertising of prescription drugs is limited to their Food and Drug Administration-approved purpose. Although providers may prescribe drugs for any purpose that they deem medically appropriate and necessary, pharmaceutical companies are limited to marketing only for those purposes for which the drug has been approved. Additional restrictions are relevant to arrangements that implicate 'remuneration' in exchange for a referral for particular types of healthcare services. In general, remuneration means the payment or transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

i The Federal Anti-Kickback Statute

The Anti-Kickback Statute (AKS) prohibits any person from 'knowingly and wilfully' paying, offering, soliciting or receiving any remuneration in exchange for or to induce the referral of, any item or service covered by a federal healthcare programme, or in exchange for arranging for or recommending purchasing, leasing or ordering any good, facility, service or item covered by a federal healthcare programme, including Medicare and Medicaid. Violation of the AKS is punishable by a US$100,000 fine, imprisonment for up to 10 years or both, and may subject a violator to civil monetary penalties as well. Moreover, violation of the AKS is grounds for exclusion from participation in Medicare, Medicaid and other federal healthcare programmes. The ACA amended the AKS to provide that items or services resulting from a violation of the AKS can constitute false claims for the purposes of the False Claims Act (FCA), discussed below. Thus, violations of the AKS can also lead to substantial civil liability under the FCA. Several US states have 'all payer' anti-kickback statutes, punishing similar activities when commercial payers are involved.

The AKS is an intent-based statute. Consequently, whether an arrangement violates the statute depends on the facts and circumstances of a particular arrangement and, more specifically, whether the parties entered into the arrangement with the intent to induce referrals. Further, the AKS contains several statutory exceptions. Given the potential breadth of the AKS, Congress authorised HHS to promulgate regulatory safe harbours that would provide additional guidance regarding arrangements that are not subject to the AKS. These include recruitments, electronic health records subsidies, discounts, certain investment interests, care coordination and value-based arrangements.[8]

Importantly, the OIG has stated that the failure of an arrangement to fit squarely inside a safe harbour does not mean that the arrangement is illegal; it means only that the arrangement does not have guaranteed protection and must therefore be evaluated on a case-by-case basis.

Thus, unlike the Stark Law (discussed below), the failure to comply with an AKS exception or regulatory safe harbour does not necessarily mean that an arrangement violates the statute.

8 See 42 C.F.R. §§ 1001.952(ee), (ff) and (gg); see also 85 Fed. Reg. 77,684 (20 December 2020).

ii The Federal Physician Self-Referral Law (the Stark Law)

The Federal Physician Self-Referral Law (commonly referred to as the Stark Law, after the late Congressman Fortney 'Pete' Stark, who introduced the legislation) prohibits a physician from referring Medicare[9] beneficiaries for certain 'designated health services', including all inpatient and outpatient hospital services, to entities with which the physician has a financial relationship (and prohibits billing for services provided pursuant to such a referral), unless an exception applies. The Stark Law is a Medicare billing rule, and if claims are paid without an available exception, they are overpaid and must be refunded or risk FCA liability, in addition to potential penalties that include denial of payment, civil monetary penalties of up to US$27,750 per service (and US$185,009 for schemes that are designed to circumvent the Stark Law) and exclusion from the Medicare and Medicaid programmes.

A financial relationship under the Stark Law can be created through a direct or indirect ownership or compensation arrangement between a healthcare entity and physicians. There are several exceptions, covering arrangements such as space leases, bona fide employment relationships, isolated transactions, recruitment and value-based arrangements. Although requirements for each exception are different, most of the 'compensation arrangement' exceptions require that the arrangement be: (1) in writing; (2) signed by the parties; (3) commercially reasonable without regard to referrals; and (4) at fair market value.

Unlike the AKS, the Stark Law is often viewed as a strict liability law (i.e., the intent of the parties is irrelevant). If the elements of the Stark Law are met, namely that a financial relationship exists between a physician and a healthcare entity pursuant to which the physician makes referrals of designated health services that are payable by Medicare, then an exception must be met to avoid penalties.

Free items and services

Free items and services provided to physicians are generally treated as compensation to physicians, and, therefore, must meet a Stark Law exception to avoid compliance issues. Although the Stark Law contains a 'non-monetary compensation' exception that permits gifts of non-monetary items (e.g., meals and theatre tickets) valued at up to US$489 (in 2023) per physician per year.

Lack of fair market value

An important requirement of many Stark Law exceptions is that payments under an arrangement constitute fair market value payment for goods or services. Fair market value in this context generally means the price that an asset would bring, or the compensation that would be included in a service agreement, as the result of bona fide bargaining between well-informed parties to an agreement who are not otherwise in a position to generate business for the other parties on the date of acquisition of the asset or at the time of the service agreement. If a healthcare entity undercharges or overpays a physician, then the healthcare entity bestows a financial benefit on the physician that the government could view as being in exchange for patient referrals. Thus, it is very important that financial

9 There is a related Medicaid Stark provision, but it has rarely been enforced against healthcare providers.

arrangements between a healthcare entity and a physician (e.g., space leases, professional services agreements, equipment leases and employment agreements) contain compensation that is fair market value.

iii The Eliminating Kickbacks in Recovery Act of 2018

The Eliminating Kickbacks in Recovery Act of 2018 (EKRA), which became law in October 2018, is a criminal statute passed as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act). EKRA prohibits recovery homes, clinical treatment facilities, and laboratories from knowingly and wilfully paying kickbacks in exchange for referrals. EKRA violations result in a fine not exceeding US$200,000, a prison sentence not exceeding 10 years, or both, for each occurrence. EKRA does provide for certain exceptions, including bona fide employment relationships and certain discounts, provided those discounts are disclosed. Due to a likely drafting error, the provisions of EKRA appear to extend to laboratories irrespective of whether they are processing tests for substance use identification, leading some laboratories to have to make changes to employee compensation programmes relating to sales and marketing efforts.

iv Penalties

The Civil Monetary Penalty Law

The Civil Monetary Penalty Law (CMPL) is a civil statute that prohibits various forms of inappropriate activities, such as the submission of false claims, contracting with an individual who has been excluded from federal or state healthcare programmes, violating the AKS, denying access to the OIG during an audit, or failing to return any overpayment.

One particular area of concern related to the CMPL is the prohibition on patient or beneficiary inducements. The CMPL prohibits the offering or transferring of remuneration to any individual eligible for benefits under Medicare or Medicaid that the offeror 'knows or should know' is likely to influence that individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under Medicare or Medicaid. Advertising and other promotional materials provided to patients, unless structured to comply with an exception, present one example of potential risk under the CMPL's patient inducement prohibition. Violation of the CMPL is punishable by a monetary penalty of US$22,427 per item or service, damages of up to three times the amount claimed for the item or service, and potential exclusion from Medicare. Similar to the AKS, there are several exceptions to the CMPL that, if met, protect the arrangement.

The False Claims Act

The FCA prohibits a variety of fraudulent conduct with respect to federal programmes, purchases or contracts. A person or entity can violate the FCA by knowingly: (1) submitting a false claim for payment; (2) making or using a false record or statement to obtain payment for a false claim; (3) conspiring to make a false claim or get one paid; or (4) making or using a false record material to an obligation to pay the government, or concealing or avoiding such an obligation. Either the attorney general or a private person through a private whistleblower action can bring a lawsuit for violation of the FCA. The FCA imposes penalties of US$13,508 to US$27,018 per claim, plus treble damages to the government.

Providers also have an obligation under the FCA to refund and report Medicare and Medicaid overpayments by 60 days after the overpayment is identified or the date the corresponding cost report is due. This is a significant new source of liability and wrongful retention of overpayments is considered a 'reverse false claim'.

VII PROCUREMENT OF SERVICES AND GOODS

Unlike many countries included in this Review, the United States does not have a healthcare commissioning system. Instead, some US states limit their healthcare by requiring hospitals and other healthcare facilities to complete a certificate of need (CON) (sometimes called 'determination of need'). CON laws regulate the construction and licensing of new hospitals and other types of healthcare facilities and the addition of new beds to existing facilities. These laws are aimed at avoiding excess capacity and inefficiencies in the delivery of healthcare. While only a few states have CON laws, they are a way for states to contain Medicaid and private employer-based insurance costs.

While large-scale decisions about hospital construction and capacity may require state-level approval, most hospitals make purchasing decisions individually with the manufacturers and distributors of medical supplies and products. The large federal systems, such as the Veterans Administration hospitals, purchase through government procurement contracts.

To address the disparity of bargaining power by private hospitals, many hospitals have banded together in 'group purchasing organisations' (GPOs) that retain a percentage of the total spent and then negotiate large contracts of multiple hospitals.

VIII REIMBURSEMENT OF SERVICES AND GOODS

As discussed in Section II.ii, most medically necessary healthcare services in the United States are paid for by government or private third-party payers, including insurance companies, self-insured employer plans, health maintenance organisations, Medicare and Medicaid, TRICARE, the Veterans Administration and workers' compensation programmes. Most of these third-party payer arrangements have some element of managed care that subjects providers to utilisation review in order to qualify for reimbursement. Apart from utilisation review, entities that are reimbursed by Medicare, Medicaid and other government programmes must abide by 'conditions of participation' and 'conditions of payment' in order to be reimbursed for their services. These conditions establish standards for high-quality and safe healthcare.

If a healthcare service is not paid for by a third-party payer, it may be paid out-of-pocket by the recipient or by the state through charity care and financial assistance programmes. As a last resort, hospitals and other health care facilities may on occasion go unpaid for their medical services and absorb the debt.

IX DIGITAL HEALTH DEVELOPMENTS

Some of the most monumental shifts in digital health policy in the United States have happened because of the covid-19 pandemic. For instance, federal and state actions in response to the pandemic have advanced telehealth and could signal a new status quo for healthcare delivery in the US. Many of the telehealth measures, including payment parity

between in-person and telehealth visits, mandatory coverage of telehealth services and expansion of permissible telehealth modalities, represent important advancements in the US healthcare system's capacity to serve patients in vulnerable populations, rural communities and high-risk settings.

X CORONAVIRUS

The covid-19 pandemic profoundly tested the strength of the US healthcare system.[10] To assist healthcare providers and essential workers on the frontline of the disease, Congress and federal executive agencies passed relief measures and waived regulatory barriers. State governments also enacted significant changes to existing healthcare laws in order to provide local systems and providers with needed flexibility to address covid-19. The United States had over 103 million reported cases of covid-19 and over 1.2 million reported deaths as of 10 March 2023.[11]

The financial impact of the covid-19 pandemic has been extreme. The American Hospital Association estimated a total financial impact of at least US$323 billion in losses resulting from covid-19 expenses and lost revenue for hospitals and health systems in 2020. A similar analysis projected an additional US$53 to US$122 billion decrease in hospital and health systems' revenue in 2021.[12] For hospitals, much of the loss was caused by the cessation of elective, often outpatient, hospital procedures to prevent exposure of patients to covid-19. These elective procedures are often the more financially positive services offered by hospitals, cross-subsidising other money-losing services.

i Federal legislative measures and regulatory waivers

The US Congress passed several measures to aid healthcare systems and providers during the public health emergency. Congress appropriated approximately US$2.6 trillion via the Families First Coronavirus Response Act (FFCRA), Coronavirus Aid, Relief, and Economic Security (CARES) Act, the Paycheck Protection Program and Health Care Enhancement Act and the Coronavirus Preparedness and Response Supplemental Appropriations Act 2020, a portion of which went directly to healthcare providers, and much to other industries and individuals.[13] The FFCRA also required health insurers, including Medicare, Medicaid and private payers, to cover covid-19 testing at no cost to consumers and prohibited some payers from requiring patient cost sharing for covid-19 testing.

10 See Johns Hopkins University & Medicine, COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins, https://coronavirus.jhu.edu/map.html (last visited 6 June 2022).

11 See COVID-19: Opportunities to Improve Federal Response and Recovery Efforts, Report to Congress, GAO-20-625 (25 June 2020) [hereinafter June 2020 GAO report]; see Johns Hopkins University & Medicine, COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins, https://coronavirus.jhu.edu/map.html (last visited 22 June 2023).

12 See Hospitals Face Continued Financial Challenges On Year into the COVID-19 Pandemic, American Hospital Assn. (March 2021).

13 See June 2020 GAO Report.

In addition to legislative measures, numerous federal agencies waived regulations that could encumber rapid response to the covid-19 pandemic. For instance, CMS issued 'blanket waivers' that eased Medicare enrolment, expanded the ability for facilities to provide long-term care services, and enhanced the ability for Medicare providers to utilise telehealth.[14]

Additionally, the US Food & Drug Administration (FDA), an agency within HHS, issued numerous emergency use authorisations (EUAs) to vaccine manufacturers that allowed for the country's relatively fast roll out of vaccines against covid-19.[15]

ii End of the public health emergency

On 11 May 2023, the federal government officially ended the public health emergency (PHE). The declared PHE afforded the federal government flexibility and speed in passing emergency regulations. Many of the regulatory waivers and legislative measures described above, including expanded coverage under Medicaid, expired automatically upon the end of the PHE. However, other regulatory waivers, such as increased telehealth flexibilities, have been made permanent.

XI FUTURE OUTLOOK AND NEW OPPORTUNITIES

Much is uncertain for the future of the US healthcare system because of the monumental impact of the covid-19 pandemic. As was outlined in Section IX, covid-19 has significantly shifted the way healthcare is delivered by creating opportunities for expansion of telehealth services. Further, the pandemic highlighted the racial disparities in healthcare delivery in the United States.

Covid-19 disparately affected people of colour, with American Indian, Alaskan Native, African American, Hispanic and Latino communities especially impacted. While these communities suffered from huge numbers of infection and death, there is hope that their disproportionate suffering will spark necessary change.

Probably the single largest challenge of the US healthcare system continues to be the management of cost. While beyond the scope of this chapter, it is well accepted that the cost per capita in the United States is significantly higher than in the other Western democracies and other countries discussed in *The Healthcare Law Review*.[16] The causes for that cost increase are many and complex, and often attributed to the core structural issues discussed above, such as the dependence on high-cost, brick-and-mortar hospitals, achievements in high-end diagnostics, and expensive pharmaceuticals sold in the US at prices many times those offered to other countries. But whatever the cause, the result has been a materially more expensive

14 See Centers for Medicare and Medicaid Services, COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers (25 June 2020), https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf.

15 16 See US Food & Drug Administration, Ventilators and Ventilator Accessories EUAs (29 June 2020), https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/ventilators-and-ventilator-accessories-euas; see also US Food & Drug Administration, Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised), Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff (11 May 2020), https://www.fda.gov/media/135659/download.

16 See, e.g., Institute for Healthcare Improvement, The IHI Triple Aim, http://www.ihi.org/Engage/Initiatives/TripleAim/Pages/default.aspx (last viewed 6 June 2022).

system. Innovators, disruptors or other investor-backed initiatives seeking to address cost are likely the most important frontier for new healthcare service businesses in the United States for the foreseeable future.

Several initiatives have tried to address concerns about cost in different ways. Most notably, the expansion of alternative payment models that reward value over volume have proliferated and matured, with many payers – especially CMS – increasingly focused on getting providers to accept downside risk in addition to the opportunity for shared savings. Another result has been a focus on care settings and options to provide care in lower-cost settings, particularly through telehealth services. And in some cases, there has been increased scrutiny on the prices themselves, particularly for high-cost items such as expensive pharmaceuticals. For example, the Inflation Reduction Act of 2022, significantly limits cost-sharing for insulin and covered adult vaccines for Medicare participants and allows the federal government to negotiate prices for a subset of Medicare-covered drugs.[17] Cost sharing provisions will become effective in 2023 while drug price negotiations will not begin until 2026.

Finally, access to both abortion and gender affirming care has been significantly reduced in many states because of partisan state legislation. After the United States Supreme Court overruled *Roe v. Wade*, returning the right to regulate abortion to each state independently, as of June 2023, 14 states imposed complete bans on abortion while many others imposed restrictions. Abortion and gender-affirming care will continue to be contested as states legislate in reaction to partisan debate.

XII CONCLUSIONS

Although the covid-19 public health emergency has officially ended, the pandemic continues to have an enormous impact on the delivery and regulation of health care in the United States. Many of the priorities that emerged throughout the pandemic, such as expanding access to care through telehealth and reducing cost through value-based payment models, continue to be the focus of innovators and regulators. We expect that these innovations and others that improve efficiency of health care delivery will continue to be prioritised in years to come. We are also expecting a wave of enforcement activities as the OIG and DOJ seek to recoup improperly paid amounts of covid-related benefits from providers and other employers during the pandemic.

17 H.R.5376 Inflation Reduction Act of 2022 (117th Cong.).