

THE HEALTHCARE
LAW REVIEW

THIRD EDITION

Editor
Sarah Ellson

THE LAWREVIEWS

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PREFACE

Welcome to the third edition of *The Healthcare Law Review*. The *Review* now provides an introduction to healthcare economies and their legal frameworks in 17 jurisdictions, with new contributions from Russia and South Africa in this edition. Our expert authors have also reviewed and updated their chapters to reflect the ever evolving situation in the jurisdictions covered in earlier editions. While a hugely diverse area of practice, it is possible to discern common challenges and similar approaches in very different countries.

Increasingly it appears that some aspects of healthcare are being delivered in ways that transcend usual requirements of co-location of the patient and provider, and traditional national boundaries. Regulators and legislative frameworks have struggled to keep pace and to reflect this new reality. In Germany, France and Russia we have seen recent new telehealth laws as countries seek to find a balance between, on the one hand, opening up new provision and meeting patient expectation and, on the other hand, commitments to ensure safety and quality and domestically appropriate regulation.

Every country wants a health system to care for the sick and promote the well-being of its people. Every nation wants to raise the bar to keep up with improving living standards and expectations. However, every economy requires this to be done at an affordable price. Managing the costs of healthcare and workforce shortages, and ensuring a sustainable model of delivery, seem to be key drivers in each of the countries covered in this publication. Integration between health and wider social care continues to be a key area, alongside a recognition of public health and wellness and a desire to relieve pressures by seeking to keep large ageing populations well for longer. Another rapidly developing area is personalised medicine and as countries gather more genomic data, and speed and costs of profiling reduce, payers look to the rapid identification of diseases, their causes and individualised cost-effective treatments. The ways different countries are meeting the demands of healthcare vary enormously and, for the healthcare lawyer or the healthcare provider, alternative destinations provide unique challenges, risks and opportunities. This publication identifies the broad characteristics of healthcare to be found in each jurisdiction. It considers: the role of insurance or public payers; models of commissioning; the interplay (or lack of it) between primary, secondary and social care; and the regulatory and licensing arrangements for healthcare providers and professionals.

These continue to be exciting times for the delivery of healthcare and I anticipate that the year ahead will witness far greater levels of comfort with digital and online involvement

in diagnosis and treatment, continued debates about the democratisation or elitism of new technology and a recognition of the impact of data in the sector. Each chapter describes a country's healthcare ecosystems. I would like to thank the many leading experts for the time and attention they have given to this project, and also the wider team at Law Business Research for their support and organisation.

Sarah Ellson

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Manchester

August 2019

UNITED STATES

Lawrence W Vernaglia and Anna S Ross¹

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’ (initially as a pejorative, but, later, sincerely), 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. However, the ACA has created a number of challenges for the US healthcare system as well, owing to both increased demand driven by newly insured patients and a view by many providers that the rates paid by many payors for healthcare services are inadequate.

Several years into the administration of Donald Trump as US President, the future of the US healthcare system remains uncertain. Trump, a Republican, campaigned on a promise to ‘repeal and replace’ the ACA legislation, and his administration has spearheaded a number of efforts to significantly weaken the programme as envisioned by President Obama, although his efforts to completely repeal the law have not been successful. Still, his efforts have had some impact, most significantly the tax reform legislation passed at the end of 2017 repealed the individual mandate, a cornerstone of the ACA. The Trump administration has also taken other actions to dismantle key components of the legislation, including introducing regulations to provide for short-term health insurance plans, allowing states to impose work requirements for Medicaid, and positioning the Justice Department to undermine the constitutionality of the provisions of the law related to pre-existing conditions.

Thus, although President Obama’s signature domestic achievement remains the law of the land, it has not emerged from these legislative battles completely intact, and indeed now bears a number of scars. Moreover, although the efforts of Trump and congressional Republicans have not yet been able to completely overturn the legislation, many are still determined to further weaken if not destroy the programme. Notably, however, the focus

1 Lawrence W Vernaglia is a partner and Anna S Ross is an associate at Foley & Lardner LLP. 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 article. 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 article to his memory and friendship.

of US politics has shifted to the upcoming 2020 presidential election, in which a number of Democratic challengers to Trump have emerged. The majority of the major Democratic presidential candidates – at the time of writing, a crowded field – have expressed the need to expand healthcare coverage for more Americans, although they are split on how to do it. One of the most dramatic changes in healthcare financing and delivery being considered is the potential expansion of the federal Medicare programme (see Section II.ii) to all Americans: the ‘Medicare for All’ position advocated by the majority of the Democratic presidential candidates in the spring of 2019. At the time of writing this chapter, none of the candidates had articulated a detailed method to pay for a programme of this type, and health economists are divided on whether such a change would cost or save money for the United States.² Legislation such as this would be impossible to pass in the present political climate in the United States, but shows how notions of a national health insurance programme, such as that in the United Kingdom (see Chapter 4), once a fringe consideration in the United States, are now embraced by mainstream candidates.

This dynamic places the US healthcare system in a tenuous position. Trump, running for re-election himself, needs to be able to demonstrate how his administration has been successful in improving the healthcare system, if not in repealing the ACA outright. Yet, nearly 10 years into Obamacare, the programme’s most popular features (including mandatory coverage of pre-existing conditions and expansion of coverage for certain populations) have become firmly entrenched, and it is difficult to imagine a programme succeeding without these aspects. The Democrats’ victories in the 2018 midterm elections further suggests that many Americans value the party’s overall approach towards healthcare.

Notwithstanding these challenges, the US healthcare system has continued to experience a period of sustained growth of approximately 6 per cent per year over the past several years. This growth has been coupled with a trend towards consolidation in recent years, which has only intensified since the most recent edition of this publication. One factor that continues to drive consolidation is that it is increasingly difficult for independent hospitals and medical groups to survive. As a result of these factors, healthcare presents an attractive area for investment in the United States. This will further encourage consolidation, along with waning animosity by government towards for-profit healthcare in many markets, and an increasing acceptance of for-profit buyers and investors by state regulators and local communities.

Another major trend in the US healthcare system is a drive towards value-based care and reducing costs in other ways. This has spurred the development of several alternative payment models, which intend to compensate providers based on the outcomes – or value – of the care they provide, rather than the volume of services. Government and private healthcare payors alike are increasingly turning towards these alternative payment models in an effort to reduce the overall costs associated with healthcare while improving the outcomes associated with such care. This trend has also resulted in increased scrutiny on certain aspects of the healthcare system that are some of the biggest cost drivers, such as drugs, and in novel ways of providing care, such as through telehealth services.

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.

2 See Josh Katz, Kevin Quealy and Margot Sanger-Katz, *Would ‘Medicare for All’ Save Billions or Cost Billions?*, The New York Times (10 April 2019), <https://www.nytimes.com/interactive/2019/04/10/upshot/medicare-for-all-bernie-sanders-cost-estimates.html> (last accessed 11 June 2019).

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 there are obviously critical parts of the care delivery system as well. Physicians are also sometimes referred to as the 'captains of the ship' in the hospital context, though other non-physician practitioners are gaining prominence in the institutional and community healthcare setting. Non-physician practitioners, sometimes called mid-level practitioners, include nurse practitioners, physician assistants, certified registered nurse anaesthetists, nurse midwives and others. These practitioners are licensed in their respective states by the state professional board, such as the medical board or the nursing board. Sometimes these practitioners are licensed by the state department of health or another agency within the government.

To help ensure that patients are adequately protected from substandard care provided by deficient practitioners, hospitals and other healthcare facilities in the United States are required by law to perform 'peer review' and 'quality assurance' activities. Compliance with specific procedures required by these laws qualifies the organisation and its physicians who participate in peer review for immunity from liability under antitrust and certain other laws. Physicians and other practitioners who are disciplined and do not prevail in their hearings are listed on a nationwide databank that warns other institutions and prospective employers regarding a practitioner's professional shortcomings.

However, there is a growing trend towards services provided in other care settings, coupled with a drive towards lower costs. This has spurred on the presence and success of telehealth services, which may offer increased efficiency and also lower the total cost of care.

iii Payment for healthcare services

Healthcare services in the United States are paid for primarily by (1) governmental programmes such as Medicare and Medicaid and (2) private insurance organisations. These public and private organisations are collectively known as 'third-party payors' or simply 'payors'. Most third-party payor 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 provide services at a discounted rate, sometimes in exchange for an expectation of increased volume from the payor. Governmental and private healthcare payors 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.

iv Regulation of healthcare

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 a number of 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 Department of Health and Human Services (HHS), which has a separate enforcement arm – the Office of Inspector General (OIG). The OIG helps to fight fraud, abuse and other forms of waste in government healthcare programmes. The OIG provides oversight by carrying out audits, investigations, and

evaluations and develops resources for the healthcare industry. The Trump administration proposed a restructuring of the federal government in June 2018. In a 132-page document, entitled ‘Delivering Government Solutions in the 21st Century’, the administration offered several changes to the regulation of healthcare, including renaming the HHS the Department of Health and Public Welfare and consolidating several functions within the agency.³ As of the time of publication, this proposal had yet to be implemented.

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 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 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 payors;
- 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 governmental involvement in healthcare in the United States, with the government serving as a major payor, 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 governmental or private third-party payors, including insurance companies, self-insured employer plans, health maintenance organisations (HMOs), Medicare and Medicaid, Tri-Care, the Veterans Administration and workers’ compensation programmes. Most third-party payor arrangements are either managed care indemnity arrangements or involve monthly pre-payments known as

3 See Executive Office of the President of the United States, *Delivering Government Solutions in the 21st Century: Reform Plan and Reorganization Recommendations*, <https://www.performance.gov/GovReform/Reform-and-Reorg-Plan-Final.pdf> (last accessed 11 June 2019).

'capitation'. Private third-party payors 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 governmental 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 a number of 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). There are certain add-on payments to the DRG, such as 'outlier' cases, where the patient requires medically necessary hospital services for a longer time than is normally the case. 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 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 a number of requirements, some of which are somewhat onerous. 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.

A significant change in Medicare policy affecting outpatient services was implemented through Section 603 of the Bipartisan Budget Act of 2015, capping the ability of hospitals to add new off-campus outpatient departments and have them reimbursed under the favourable OPPS rates. Unless grandfathered or meeting limited exception, these new off-campus facilities are reimbursed at lower, freestanding rates. CMS decreased the outpatient hospital rates subject to Section 603 to 40 per cent per cent of the current OPPS rates, a major hardship for land-locked hospitals or those in communities with changing demographics and geographies, and further expanded 'site neutrality' rate cuts for all off-campus hospital departments. At the time of writing, litigation opposing a CMS regulatory expansion of site neutrality was pending, which, if successful, would limit the financial impact on hospitals. Site neutrality has also been embraced by private payors and state Medicaid programmes and is expected to be expanded to other services and payors.

Medicaid is a joint state and federal programme traditionally for certain indigent or 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 much higher reimbursement than others. Although the rates payable by Medicaid in most states are notoriously low (and in many cases fall far short of the provider's costs), the rates will be increased for a number of years under the ACA, hopefully 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.

Under the ACA, the rules governing Medicaid eligibility were substantially relaxed, thereby making it possible for millions of additional Americans to qualify for the programme even though they do not meet these traditional criteria. However, recent changes under the Trump administration may roll back some of these protections, as the HHS announced a new policy in January 2018 to promote work among Medicaid beneficiaries, allowing states to pursue demonstration projects that impose work requirements as part of their Medicaid plan. At the time of this update, 12 states had either received or were in the final stages of seeking federal approval to advance a work requirement. Notably, such requirements have been challenged in court in at least one state, with opponents of the work incentive demonstration projects arguing that no evidence exists to indicate that imposing such requirements will strengthen the health insurance system and that such work incentives will destroy Medicaid's purpose as a safety net for some of the most vulnerable Americans.

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 payor arrangements involve some element of managed care, meaning that the healthcare services are provided subject to utilisation review procedures such as a primary care physician serving as a 'gatekeeper' for specialists, and typically create certain constraints on the beneficiary's choice of provider, usually as a result of network or panel arrangements established by the payor.

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

⁴ See The Henry J Kaiser Family Foundation, *Medicaid Pocket Primer* (updated 9 June 2017; last accessed 11 June 2019), <http://files.kff.org/attachment/Fact-Sheet-Medicaid-Pocket-Primer>.

'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.

Consumer-driven health plans

An increasingly popular type of insurance arrangement combines a 'high deductible health plan' with a 'health savings account' (HSA). The HSA is similar to an individual retirement account in that it permits individuals to save, on a tax-sheltered basis, through the establishment of a special account. The member funds the HSA with up to the maximum permitted by law (US\$3,450 for an individual and US\$6,900 for a family in 2018). Those funds can only be used to pay for healthcare items and services that would be deductible under federal tax rules if incurred by a taxpayer, as well as to pay down the deductible, until the funds in the HSA are exhausted. The beneficiary must exhaust the high deductible in the health plan and spend down the HSA, before receiving the full benefit of the health plan's coverage. Once the HSA is exhausted and the deductible is met, the plan pays most or all the beneficiaries' remaining charges. These are sometimes called consumer-driven health plans because the beneficiary controls the expenditure of his or her healthcare dollars to a much greater extent than under a traditional plan. If the funds deposited in the HSA at the beginning of the year are not all used during the benefit year (which is the calendar year), the individual gets to carry the remaining amount in the HSA forward to the next year. The funds also earn interest or investment income until they are spent. The combination of HSAs and high deductibles essentially gives the individual what Americans call 'skin in the game', namely an incentive to find and use cost-effective providers. To the extent that those providers include domestic or overseas providers, these consumer-driven plans may be a catalyst for the growth of overseas medicine in the United States. Patient advocates are concerned that high deductible plans, coupled with insufficiently funded HSAs, have caused a spike in consumer bankruptcy filings. Indeed, many view medical debt as one of the leading causes of personal bankruptcy in the United States.

iii Funding and payment for specific services

Healthcare reform, including the ACA and any new healthcare legislation that may ultimately be passed under the Trump administration, has and will continue to have a major impact on healthcare delivery and expenditures. The ACA's overarching objective was to expand coverage to 31 million currently 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 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 individuals personally or through other types of private insurance plans that cover such services.

However, with the passage of the Tax Cuts and Jobs Act, which was signed into law by Trump on 22 December 2017, the individual mandate has been repealed effective in 2019. The mandate, which subjects individuals without health insurance coverage to steep tax penalties (US\$695 or 2.5 per cent of household income, whichever is greater), has long been seen as a cornerstone of the ACA, as the expanded coverage provisions of the programme are subsidised by requiring all individuals to pay into the system. Given the delay in the implementation of change, it may take some time before the effects of the repeal are fully borne out. Early projections by the nonpartisan Congressional Budget Office (CBO) indicate that elimination of the mandate will cause 4 million people to drop health insurance coverage in 2019, with 13 million more becoming uninsured by 2027. The CBO's estimate projects savings to the government in the range of US\$300 billion, stemming from fewer people receiving subsidies or Medicaid, though it also anticipates a 10 per cent rise in the cost of insurance premiums following repeal of the individual mandate.

Another important development includes the introduction of alternative healthcare plans into the US healthcare market. As background, the ACA amends the prior law to prohibit a health plan from establishing limits on the dollar value of these essential health benefits. It requires the plans to provide coverage for and to all individuals, and prohibits cost-sharing requirements for certain preventive services and immunisations. Further, it requires health plans that provide independent coverage of children to extend that coverage to adult children up to the age of 26. It establishes a minimum payment for primary care Medicaid services. The ACA further looks to novel healthcare delivery models to reimburse providers based on improved health outcomes, prevent preventable hospital readmissions, improve patient safety and reduce medical errors, as well as promote wellness. Health plans are prohibited from imposing pre-existing condition exclusions or discriminating on the basis of any health status-related factor, including genetic factors.⁵

The trend toward alternative payment models has strengthened in recent years, with recent data demonstrating that US healthcare payments associated with alternative payment models are steadily increasing.⁶ However, despite the appeal of certain alternative payment models (also known as value-based payment models), particularly those offering higher payments to providers who demonstrate a higher quality of care, providers have been reluctant to participate in programmes imposing full capitated risk. As a result, CMS has announced several new initiatives, including mandatory bundled payment models for certain clinical areas and a new direction for the Medicare Shared Savings Program, pushing accountable care organisations (the most popular type of alternative payment model, involving a group of providers that takes responsibility for the total cost and quality of care in exchange for a portion of the savings) into a two-sided risk model more quickly than before. Other laws passed in recent years, including the Medicare Access and CHIP Reauthorisation Act of 2015, have established new ways of paying for care that focus on value instead of volume.

Despite these requirements of the programme and other initiatives, changes to the ACA introduced under the Trump Administration have cut away at other features of the

5 For more information about the ACA, see the CMS Center for Consumer Information & Insurance Oversight, Patient's Bill of Rights, <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/Patients-Bill-of-Rights.html> (last accessed 11 June 2019).

6 Health Care Payment Learning & Action Network, *Measuring Progress: Adoption of Alternative Payment Models in Commercial, Medicaid, Medicare Advantage, and Medicare Fee-for-Service Programs* (22 October 2018).

ACA. For instance, in February 2018, HHS proposed regulations allowing for alternative health plans in the form of short-term plans lasting just under one year (under the previous administration, the duration of short-term plans was limited to 90 days, making them exceptionally unattractive to potential consumers). Such short-term plans are likely to create a competitive, lower-priced alternative to the plans available under Obamacare because they are not subject to the same requirements as full-scale health plans.

Critically, the short-term plans may exclude people with pre-existing conditions, undercutting one of the most popular (and expensive) protections of the ACA. The short-term plans are also not required to offer the same comprehensive coverage as other plans under the ACA, and indeed typically do not provide benefits such as free preventive care, maternity care, prescription coverage and mental health services. Further, the short-term plans may impose annual or lifetime limits, meaning that policyholders will be responsible for the cost of care beyond these caps (typically around US\$1 million), and are not required to cap consumers' cost-sharing burdens.

Another recent change introduced by the Trump administration in June 2018 is the option for 'association health plans', which permits small businesses to join forces to purchase the types of coverage available to large employers. The new rule allows such businesses to band together based on common geography or industry, and collectively purchase health insurance as a much larger employer might. Although the association health plans would not be able to discriminate based on an employee's health status or any 'health factor', they may be able to offer health insurance that does not include all the essential health benefits required by the ACA. While proponents of this new measure say it will allow small businesses to provide care that is more affordable and more tailored to their employees' needs, and help 'level the playing field' between large and small businesses, critics of the rule warn that it will roll back the protections of the ACA, opening the door to 'junk health insurance' and allowing association health plans to write their membership rules in such a way that discriminates against or avoids high-cost areas or high-risk professions.

Although these reforms to the ACA have created a number of different options for consumers (albeit with increased risks), there nonetheless remains a widespread perception that the US healthcare system will continue to be inefficient and burdened with unnecessary administrative expenses and inflated prices. Problems with the healthcare infrastructure in the United States may continue to be a substantial drag on the nation's economic growth and development, notwithstanding the ACA and other reform measures. Indeed, early implementation problems, including but not limited to the serious defects in the ACA's enrolment website, have contributed to the view that the United States lacks the competence to reform its healthcare system.

These concerns, along with a view shared by the Trump administration and the Republican congressional majority that espouses a fundamentally different role for government in the healthcare sector, have contributed to calls for further reform. However, despite Republicans' current control of both houses of Congress, efforts to repeal and replace Obamacare have been generally unsuccessful, partly because of the popularity of many of Obamacare's requirements related to exclusions and discrimination. There is thus an inherent tension between conservatives' desire to limit the role that government plays in healthcare with the more popular features of the law, one that is likely to lead to further legislative battles in the coming years.

III PRIMARY / FAMILY MEDICINE, HOSPITALS AND SOCIAL CARE

i Hospitals and primary care

As noted above, hospitals are the work benches for the delivery of healthcare in the United States. Further, the Emergency Medical Treatment and Labor Act, a federal law mandating that anyone who arrives at a hospital emergency department must be stabilised and treated, regardless of their insurance status, has contributed to the use of hospital emergency departments for all types of care. However, there has been an increased focus on primary care, particularly under the ACA. Not only has the ACA expanded the number of insured patients, thereby increasing the number of patients able to access primary care, but provisions of the law have also specifically addressed the types of primary care and other preventive services that must be covered by insurance and have set minimum payment rates for primary-care Medicaid services.

Further, under most types of third-party payment arrangements, there is an element of managed care, meaning that the healthcare services are provided subject to utilisation review procedures such as a primary care physician serving as a gatekeeper for specialists. Such care arrangements typically place restrictions on the beneficiary's choice of provider, usually as a result of network or panel arrangements established by the payor. Thus, although it is possible to have direct access to different healthcare providers, for many insureds, access to a specialist is only possible through a referral by that individual's primary care provider.

There have recently been other developments in this area as well, as innovators from other sectors of the economy become more involved in the delivery of healthcare. For instance, there has been a growing movement towards telemedicine, whereby providers and patients interface virtually rather than through an in-person office visit. Capitalising on improvements in technology in this way can present opportunities to help offer increased access to primary care services, particularly in areas where providers are scarce or patients are not easily able to travel to provider offices. Another example is the announcement by business leaders Jeff Bezos of Amazon, Jamie Dimon of JPMorgan Chase, and investor Warren Buffett of a new health venture that aims to transform the delivery of healthcare to be headquartered in Boston, Massachusetts with noted author and physician, Atul Gawande as the chief executive officer, but with a promise of no profit motive.

ii Electronic health records and privacy

Although many healthcare facilities and providers in the United States are individually moving towards 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 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, along with other federal and state privacy and security laws, 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 Health and Human Services 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. 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.

In 2018, US companies (both healthcare and non-health-related) devoted significant efforts to meeting the requirements of the European Union General Data Protection Regulation (GDPR), applicable to companies that monitor or process the personal data of European citizens. Many US companies rushed to meet the GDPR's strict requirements as to how such personal data is collected, stored and maintained. Most US healthcare providers (e.g., hospitals, physicians and skilled nursing facilities) determined that they are not subject to GDPR and have not voluntarily adopted a compliant position. A small minority of providers that advertise in the EU have complied with GDPR.

IV THE LICENSING OF HEALTHCARE PROVIDERS AND PROFESSIONALS

i Regulators

Licensure of healthcare providers and professionals is primarily regulated at the state level, typically by the state departments of health, departments of public health, or similarly titled agencies. Such agencies serve as the primary agency that promulgates and enforces licensure requirements for healthcare facilities and individual providers, including physicians, nurses, physician assistants, pharmacists and other healthcare professionals. In some states, accreditation by a private accreditation agency, discussed below, creates 'deemed' compliance status for the provider. Regulatory boards, usually made up of other licensed practitioners, guard the 'scope of practice', often fighting to exclude new, competing professionals, like new categories of non-physician practitioners (referred to above).

Usually, licences are limited to a specified period (e.g., one to three years) and must be renewed on a periodic basis. Each type of healthcare facility and provider has its own set of licensure requirements, although there are some types of requirements that are common to all.

ii Institutional healthcare providers

Licensure

As indicated above, the licensing of hospitals and other types of 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 and more healthcare providers move towards consolidation. In general, states will require licensure of

hospitals (both general and specialty), nursing homes, ambulatory surgical centres, healthcare clinics (though the specific types of licensure and restricted activities can vary widely from state to state), pharmacies and other similar healthcare facilities.

For hospitals and other health facilities, the licensure laws typically cover issues such as professional and non-professional staffing; physical plant requirements; required clinical services; administrative capabilities; and a vast array of other requirements. In most states, in addition to hospital licensure, full-service hospitals require other licences and permits, such as laboratory permits, permits related to hazardous wastes, 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 also generally impose sanctions for the provision of healthcare services without a licence by a facility, which often include penalties per violation or per day in operation without a licence. State licensure authorities also have individualised procedures for the issuance, suspension or termination of a facility licence, which typically provide for an appeal by a provider that is refused a licence or has its licence suspended or terminated.

Certificate of need laws

There are also a number of other healthcare-related restrictions that may preclude the construction of a hospital or other health facility. In this regard, many states have certificate of need (CON) (sometimes called determination of need) laws that 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.

A federal law enacted in 1974 provided for the establishment of CONs by the states. That law was repealed in 1986 and, since that time, a number of other states have repealed their CON laws or dialled back the types of healthcare facilities required a CON. However, despite the gradual fading of CONs during the 1990s and 2000s, as states seek to find ways to contain costs as Medicaid and private employer spending on healthcare becomes a serious budgetary concern, some states are revisiting their CON laws.

Certification and accreditation

In addition to the licensure requirements administered by the states, Medicare, Medicaid and other governmental 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 compliance with specified standards set out in the government programme’s regulations and policies. The process of Medicare, Medicaid and other government reimbursement programmes 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 governmental payment systems; it is distinct from state ‘licensure’ and private ‘accreditation’. In most cases, hospitals will possess all three: certification, licensure and accreditation, although there are examples of 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. Foreign healthcare organisations may be most familiar with Joint Commission International, or JCI, affiliated with TJC. Compliance with TJC or AOA standards affords a hospital 'deemed status' as a certified provider under the Medicare programme, as well as the Medicaid programme, in most states. This means that a hospital is deemed to comply with the Medicare, and usually the Medicaid, requirements, if it complies with the applicable accreditation standards. Accreditation expires no later than three years from the date of the most recent survey of the hospital. The accreditation agencies can also resurvey hospitals on an unannounced basis. As noted above, 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. The accrediting bodies charge considerable fees for the survey process, and also sell a variety of consulting services to accredited hospitals. These fees will often run into hundreds of thousands of dollars per year. 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 (usually the Department of Public Health) to be the official state survey agency for the CMS. These state survey agencies will visit and approve the certification in the Medicare programme and do not charge the hospital, other than nominal licensing fees.

The OIG has criticised the relationship between TJC and hospitals as being too collegial,⁷ and a reaction has been somewhat harsher TJC surveys. Consequently, more hospitals are considering relying on the state survey rather than TJC accreditation status to achieve Medicare certification.

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 other boards for other types of licentiates. In some states, the state department of health performs this function for some professional categories. 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, such as the imposition of probation.

Although each state issues its own licence, some states permit reciprocity by honouring each other's licences. For example, there is a National Nursing Compact, under which 24 member states recognise the nursing licences granted by all the other member states. In addition, some states honour each other's medical licences or permit physicians who are licensed in another jurisdiction to practise medicine across their state lines using telemedicine.

In addition to governmental 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 such requirements.

⁷ See 'The External Review of Hospital Quality: A Call for Greater Accountability', (July 1999 OEI-01-97-00050) ('As the system increasingly tilts toward the collegial mode, however, it could result in insufficient attention to investigatory efforts intended to protect patients from questionable providers and substandard practices.').

State and federal statutes applicable to physicians and certain other licentiates provide hearing and appeals rights when a state agency denies, or proposes to deny or revoke, 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.

Pursuant to the reporting provisions of the HCQIA, practitioners who either do not challenge adverse actions or who are unsuccessful in their challenges are identified on the National Practitioner Data Bank so that other prospective employers or hospitals become aware of any competence or conduct issues before permitting such practitioners to join their staffs. The HCQIA also confers immunity on hospitals and certain other organisations that perform peer review and on the individuals who participate in that process. To qualify for immunity under the HCQIA, certain conditions must have been met, including adequate notice and an opportunity for the affected practitioner to be heard that meets certain criteria. The peer review action must also have been taken with the reasonable belief that the action was warranted based on the facts known.

As is the case with health facilities, individual healthcare licentiates enroll in Medicare and other government payment programmes if they want to participate in these programmes. They must also meet specified requirements, such as licensure under state law.

V NEGLIGENCE LIABILITY

One characteristic of the US healthcare system that is viewed by many as contributing to its exorbitant cost is professional liability ('medical malpractice'). Under the US professional liability system, any patient who believes he or she has been damaged by the professional negligence or wilful misconduct of a healthcare provider is entitled to damages if he or she demonstrates that it is more likely than not that the negligence or wilful misconduct caused the patient's damages.

It is believed by many providers and politicians on the right that fear of liability drives up the cost of US medicine because physicians order tests that are not medically necessary out of fear that the theory or failure to order the test will be second-guessed if the patient has a bad outcome. This is sometimes referred to as practising 'defensive medicine'.

In addition, professional liability can arise from failure to obtain appropriate informed consent. If a practitioner fails to do so, the patient may argue that he or she would not have undertaken the procedure and its inherent risks had he or she been notified of those risks.

There are some basic steps providers can take to help reduce their risk of liability. These include careful documentation; obtaining consent from patients; using validated protocols, when available; and following up with patients after they receive their treatment. Some states,

including California, have enacted caps on non-economic damages in professional liability cases. This reduces the exposure that practitioners face when performing medical services. Fortunately, most states in the United States also have ‘good Samaritan’ laws that permit physicians and other healthcare practitioners to render aid at the scene of an emergency, or to assist in the rescue of an individual, without incurring liability.

In addition to provider liability, medical devices and pharmaceuticals experience liability for patient injuries on some different theories, most notably ‘products liability’.

Despite some calls for reform, medical malpractice suits continue to be a frequent presence, based in part on real concerns regarding medical errors. A recent study by Johns Hopkins University found that more than 250,000 patient deaths per year in the United States are a result of medical error, making such errors the third leading cause of death in the country.⁸

VI OWNERSHIP OF HEALTHCARE BUSINESSES

i Types of ownership and management

The trend toward consolidation of the healthcare industry in the United States has created a number of 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.

In addition to the foregoing organisational changes, control of a hospital can be transferred or shared through the formation of a joint venture or the establishment of a management or co-management relationship. Joint ventures are a common vehicle for extending the reach of an existing hospital into new neighbourhoods and markets, or for leveraging the assets of multiple (usually two) existing market participants to enhance the collective ability of those participants to serve their combined communities. Another vehicle for entering the marketplace, potentially with minimal assets, is a management agreement. Under the terms of a typical management agreement, one party with special expertise in the operation and management of a hospital will essentially assume control of the assets and personnel of an existing facility.

It has also become increasingly common over the past two decades for governmental hospitals to enter into management agreements with private parties with the private entity managing the governmental hospital. These ‘public-private partnerships’ raise complex issues under the special laws that apply to governmental 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, similar to the laws protecting the assets of tax-exempt organisations, protect the assets of the governmental entity from exploitation by private parties, and prevent ‘gifts of public funds’ or the ‘lending of the government entity’s credit’.

Hospitals seeking to lawfully partner with their physicians may also enter into ‘co-management agreements’. These are contractual arrangements under which certain physicians in a particular specialty (e.g., cardiology, oncology, gastroenterology) agree

8 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 11 June 2019).

to provide certain management services to a service line of a hospital. The purpose of the agreements is to develop and manage the service line collaboratively, and to improve its quality and efficiency of delivery.

As the proposed US\$69 billion merger between health insurance giant Aetna and pharmacy chain CVS indicates, other areas of the healthcare industry have also been swept up in the move toward greater consolidation. Under the terms of the proposed merger, Aetna would become a subsidiary of CVS, which the companies argue would provide for better coordination and continuity of care by helping patients to adhere to their medication regimens. Given the size of the deal, the merger requires federal approval, and a number of antitrust experts and other groups – including, most recently, the American Medical Association, the largest provider association in the country – have spoken out against it. They argue that the combination would lessen competition and increase insurance premiums.

ii Restrictions on ownership

A number of 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 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. In theory, the corporate practice prohibition ensures that physicians are able to put the medical interests of their patients above all other concerns, unfettered by the demands of a corporate entity employer. Depending on the state, violations of the CPOM can result in injunctive relief, civil penalties and criminal enforcement.

VII COMMISSIONING AND PROCUREMENT

Because most hospitals are private (whether for-profit or not-for-profit), procurement and purchasing is handled on a local level, with each hospital (or other healthcare provider) making 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 governmental 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 (e.g., 3 per cent) and then negotiate large contracts of multiple hospitals. The GPOs retain significant influence in the healthcare industry, though commenters note that physicians’ preference for expensive technologies continues to drive needless expense and waste in the industry.

VIII MARKETING AND PROMOTION OF SERVICES

There are a number of laws that restrict the promotion and advertising of healthcare services and business, particularly to the extent that any arrangements of this kind involve

‘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 prohibits any person from ‘knowingly and wilfully’ paying, offering, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, 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 Anti-Kickback Statute is punishable by a US\$25,000 fine, imprisonment for up to five years or both, and may subject a violator to civil monetary penalties as well. Moreover, violation of the Anti-Kickback Statute is also grounds for exclusion from participation in the Medicare and Medicaid programmes and other federal healthcare programmes. The ACA amended the Anti-Kickback Statute to provide that items or services resulting from a violation of the Anti-Kickback Statute can constitute false claims for the purposes of the False Claims Act (FCA), discussed below. Thus, violations of the Anti-Kickback Statute can also lead to substantial civil liability under the FCA. Several US states have ‘all payor’ anti-kickback statutes, punishing similar activities when commercial payors are involved.

The Anti-Kickback Statute 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 Anti-Kickback Statute contains several exceptions. Given the breadth of the Anti-Kickback Statute, Congress authorised HHS to promulgate regulatory safe harbours that would provide additional guidance regarding arrangements that are not subject to the Anti-Kickback Statute. There are a number of regulatory safe harbours, covering arrangements such as recruitments, electronic health records subsidies, discounts and certain investment interests.

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, taking into account the facts of the particular arrangement.

Thus, unlike the Stark Law (discussed below), the failure to comply with an Anti-Kickback Statute exception or regulatory safe harbour does not necessarily mean that an arrangement violates the statute. The absence of a bright-line rule regarding failure to comply with the Anti-Kickback Statute exceptions can make it particularly difficult to analyse whether certain arrangements comply with the law. If an arrangement does not comply with each and every requirement of an Anti-Kickback Statute exception or safe harbour, the exception or safe harbour will not apply to the arrangement. However, as noted, the arrangement does not automatically violate the statute simply because an exception or safe harbour does not apply.

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

The Federal Physician Self-Referral Law (commonly referred to as the Stark Law, after Congressman Fortney ‘Pete’ Stark, who introduced the legislation) prohibits a physician from referring Medicare beneficiaries for ‘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 defines 'physician' as a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry or a chiropractor. Violations of the Stark Law may result in penalties that include denial of payment, civil monetary penalties of up to US\$15,000 per service (and US\$100,000 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 hospital and physicians. There are several exceptions, covering arrangements such as space leases, bona fide employment relationships, isolated transactions, and recruitment arrangements. In addition, there are 23 regulatory exceptions. Although each exception is 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 Anti-Kickback Statute, the Stark Law is 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. Because of its broad scope, the Stark Law can implicate many financial arrangements that may seem relatively innocuous. A number of practices present risk under the Stark Law (and potentially under the federal Anti-Kickback Statute, as well), and have been the source of government investigations, enforcement actions and settlements. Such practices as the giving of free items and services, undocumented arrangements, failure to adhere to contract terms, and lack of fair market value are all subject to a high degree of scrutiny.

Free items and services

Under the Stark Law, compensation is broadly defined to include 'any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind'. 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. For example, if a hospital administrator provides a physician with free football tickets, the physician is deemed to receive compensation because the free items and services have an independent value to the physician. 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\$398 (in 2017) in the aggregate over the course of a year, this amount is relatively easy to exceed.

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 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.

The future of the Stark rules?

In June 2018, the CMS published a Request for Information (RFI) seeking ‘input from the public on how to address any undue regulatory impact and burden of the physician self-referral law’. It appears that the CMS is particularly concerned with ‘removing unnecessary government obstacles to care coordination’ and is especially interested in responses that address ‘the structure of arrangements between parties that participate in alternative payment models or other novel financial arrangements’, but more wide-ranging responses from the industry are expected in response to the RFI. This move by the agency is consistent with the Trump administration’s overall push toward deregulation. The budget proposed by Donald Trump for fiscal year 2019 also included a legislative proposal to establish a new exception to the Stark Law for arrangements that arise because of providers’ participation in alternative payment models, so change to the Stark Law may be multifaceted.

iii 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 Anti-Kickback Statute, 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 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. Remuneration is defined to include (among other things) the waiver of co-payments and deductible amounts. Violation of the CMPL is punishable by a monetary penalty of US\$10,000 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 Anti-Kickback Statute, there are several exceptions to the CMPL that, if met, protect the arrangement. Advertising and other promotional materials provided to patients present one example of potential risk under the CMPL’s patient inducement prohibition. Although these items or services can be structured to comply with an exception to the CMPL’s prohibition on patient inducements, arrangements of this kind warrant particular attention from a compliance standpoint.

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 through a variety of methods, including 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\$11,000 to US\$22,000 per claim, plus three times the amount of damages to the government. These penalties were most recently half as large, before a little-known federal agency, the Railroad Retirement Board (the Board), which administers retirement-survivor and unemployment-sickness benefit programmes for railroad workers, published an interim final rule on 2 May 2016, nearly doubling the amounts of penalties ‘under the Board’s jurisdiction’ including the FCA.

Under recent changes in the law, 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. In addition to potential FCA liability, failure to report and return overpayments within this timeline can result in civil monetary penalties of no more than US\$10,000 for each item, plus three times the amount of damages to the government. This is a significant new source of liability and is considered a ‘reverse false claim’.

IX FUTURE OUTLOOK AND NEW OPPORTUNITIES

Although the ACA has brought about a number of important reforms to the US healthcare system, the law continues to be a target for Trump and many congressional Republicans, despite their numerous failures to completely overturn the law and challenge its constitutionality. Their current strategy has been to chip away at the specific features of the law on a piece-by-piece basis. As discussed above, this slow dismantling of Obamacare has taken place in several parts since the inception of Trump’s administration, with the repeal of the individual mandate through the 2017 tax reform legislation representing the biggest blow.

The cumulative effect of these efforts remains to be seen, although early projections indicate that by stripping out several of the ACA’s most important provisions, millions of Americans will be without healthcare coverage. What is not yet clear is whether the healthcare system designed by the law can withstand these reforms, as the requirement for all individuals to maintain coverage was intended to underpin the expanded access to care and protections offered by Obamacare. Further, some of the other changes introduced by Donald Trump, such as the short-term health plans and association health plans, may also affect the overall structure of the system if increasing numbers of Americans opt for limited, less expensive coverage of this kind. Importantly, diminished access to care affects not only patients but providers as well, particularly if growing numbers of patients are not able to afford care or delay preventive care, exacerbating other health conditions.

Healthcare finance is shaping up to be a major policy debate in the US 2020 elections, with the Republican incumbent Trump facing an increasingly left-leaning field of dozens of Democratic candidates, many of whom endorse a radical change to the US healthcare system.

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*. 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, bricks-and-mortar hospitals, achievements in high-end diagnostics, and expensive pharmaceuticals. Other causes are more uniquely American, such

as the notion of the patient as an individual entitled to the best possible cure for disease and prolongation of life, as opposed to more communitarian notions that might look to the overall public health as the ultimate goal of the healthcare system. But whatever the cause, the result has been a materially more expensive system that has an arguably (questionably) superior outcome across the board. Thus, when the ACA was being debated, a 'triple aim' was proposed as a goal: reduced cost, increased access and improvement of the patient experience. The ACA addressed the patient access issue, but cost containment, and likely patient experience improvements, remain elusive, and it is not yet clear whether the reforms to the system under the Trump administration will improve these features of the healthcare 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.

A number of initiatives have tried to address concerns about cost in different ways. Most notably, the expansion of alternative payment models that reward volume over value have proliferated and matured, with many payors – 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. There have been numerous efforts, including at the state level, to tamp down the cost of drugs, such as by establishing upper payment limits. Although relatively few changes have actually been made to date, drug pricing will certainly be an area to watch in the coming years.

X CONCLUSIONS

The US healthcare system is made up of a complex set of provider types and payor types, and is set against a backdrop of overlapping federal and state laws. Further complicating the system are significant changes introduced by the Republican majority despite repeated failures to completely overturn the ACA, a law passed by the then-President Obama that ushered in sweeping reforms both to access to insurance and the delivery of care. Although the repeal and replace efforts have not yet been successful, the full impact of the changes brought about in the new administration under Donald Trump has not yet been realised.

Both the ACA and the recent reforms to it address access to healthcare, through the type of insurance plans available and the type of benefits provided by such plans. Currently, insured Americans typically receive care either through the government – such as through a programme such as Medicare or Medicaid – or through a private insurance plan.

Another important trend in the US healthcare industry is the move towards greater consolidation, with more and more facilities and medical groups coming into common control. This movement has created a number of interesting types of ownership and management structures.

Relatedly, rising healthcare costs remain a significant issue for the US healthcare system. This has driven in part a number of laws targeting fraud and abuse in the provision

of healthcare, particularly related to referral practices. The Anti-Kickback Statute and the Stark Law, and the related penalty provisions, can be difficult for providers to navigate when structuring financial arrangements. Nevertheless, given the complex causes for cost increases, the United States will likely need to look to innovators, disruptors, or other investor-backed initiatives to address rising costs in the healthcare system.

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