THE HEALTHCARE LAW REVIEW

Editor
Sarah Ellson

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CONTENTS

Chapter 16

UNITED STATES

Lawrence W Vernaglia and Anna S Ross[1]

I OVERVIEW

i Overview of the US healthcare system

The US healthcare industry is 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. 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.

Further, even greater changes to the US healthcare system may be on the horizon, as Congress currently considers legislation that would create sweeping reforms to the programme and the US healthcare system as a whole. The dramatic turn of events in the 2016 US presidential election, with the surprise victory of Republican candidate Donald Trump over Hillary Clinton (a recognised defender of the policies embodied by the ACA), plus the Republican control of both houses of Congress, calls into question the long-term survival of the ACA and its benefits. Republican legislators have promised to 'repeal and replace' the ACA, and multiple bills have been presented. However, as of the completion of this Article, neither the 'repeal' nor the 'replace' legislation has been finalised, and defections from both the Republican right and more moderate factions appear to have doomed any immediate hopes of those driven to dismantle President Obama's signature domestic achievement. The following discussion, therefore, addresses the ACA as it stands today. The significance of overturning such legislation is apparent. These changes would affect the many stakeholders in the US system, including providers, patients, vendors, private payors, as well as the government agencies that are involved in healthcare – Medicare, Medicaid and others that serve as both as payors and regulators.

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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 preeminent 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.

Notwithstanding these challenges, the US healthcare system has experienced 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. One factor driving 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 continue to drive 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.

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 (US Health Care 101).

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.

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.

iv Regulation of healthcare

Since 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. Such 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). CMS is a division of the Department of Health and Human Services, 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. 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, 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 '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, like 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 of 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. Proposed payment policies for 2018 would cap those rates at 25 per cent of the current OPPS rates, a major hardship for land-locked hospitals or those in communities with changing demographics and geographies.

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.[2] The federal government contributes roughly half of the reimbursement for the Medicaid programmes, though some

2 See The Henry J. Kaiser Family Foundation, Medicaid Pocket Primer (updated June 9, 2017; last accessed 19 July 2017), www.kff.org/medicaid/fact-sheet/medicaid-pocket-primer/. See also The Henry J. Kaiser

US states with struggling economies receive much higher reimbursement than others. Under the ACA, the rules governing Medicaid eligibility have been 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. 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.

Commercial/private insurance

HMOs and PPOs

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: health maintenance organisations (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 of 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' or 'POS' plans which are a hybrid between 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 so-called '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$3,400 for an individual and US$6,750 for a family in 2017). 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

Family Foundation, Total Number of Medicare Beneficiaries (Timeframe: 2015), www.kff.org/medicare/state-indicator/total-medicare-beneficiaries/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

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 of 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', i.e., 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 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 is 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.

The ACA also 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.[3]

3 For more information about the ACA, see www.hhs.gov/healthcare/rights/law/index.html and www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/Patients-Bill-of-Rights.html.

Despite these refinements, there is 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 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. Congressional Republicans, who were in the minority when the ACA was passed in 2010 but now enjoy majorities in both houses of Congress, have called for 'repeal and replace' of Obamacare for the past several years, and now are in a position to do so. However, there is widespread public support for many of the reforms created by the ACA, particularly the prohibition related to exclusions or discrimination based on pre-existing conditions, and such provisions may prove difficult to overturn.

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.

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, impose 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.

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 of time (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 centers, 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 CON 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 forth 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 Organizations, 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 (JCI), affiliated with TJC. Compliance with the 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 last 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 the 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 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,[4] 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 of 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, 'credentialing' of individual professionals occurs at the facility level. Compliance with standards and requirements established by individual health facilities permit individual licentiates to perform services within those facilities. Health plans, professional associations and licensed outpatient facilities usually also impose such requirements.

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

4 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.').

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 so-called '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.[5]

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 though 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 in order 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. Such '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 so-called 'co-management agreements'. These are contractual arrangements under which certain physicians in a particular specialty (e.g., cardiology, oncology, gastroenterology) agree 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.

5 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/.

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 like 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, like 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 such arrangements 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.

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 the US Department of Health and Human Services 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 harbor 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.

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 such 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 of 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 to provided to patients present one example of potential risk under the CMPL's patient inducement prohibition. Although such items or services can be structured to comply with an exception to the CMPL's prohibition on patient inducements, such arrangements 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 has long been a target for many congressional Republicans, who are against the law's 'individual mandate' – the requirement that each individual purchase or otherwise maintain healthcare coverage, or pay a tax penalty. Republicans have supported a number of

legislative and legal challenges to the ACA since it was first enacted, including several votes to repeal the act between 2011 and 2015 and lawsuits challenging the constitutionality of the law.

To date, these efforts at 'repeal and replace' have not succeeded. However, with the 2016 election of President Trump, a major critic of the ACA, along with Republican majorities in both the Senate and the House, the right is now poised to implement significant reform. In May 2017, the House narrowly voted in favour of the American Health Care Act, which would eliminate tax penalties for people who go without insurance, roll back state expansions of Medicaid, and offer tax credits to aid the purchase of healthcare insurance instead of the government-subsidised insurance policies created by the ACA.

As of this writing, the Senate has released its own version of a healthcare reform bill, the Better Care Reconciliation Act, which also would eliminate the mandate, while allowing insurers to sell lower-cost healthcare plans with fewer benefits and expanding the use of tax-favoured health savings accounts. Like the House bill, it would also severely curtail spending on Medicaid, both by phasing out money provided by the federal government to expand Medicaid eligibility in the states and by placing limits on spending for the entire programme. However, the Senate bill faces a steep uphill climb, with several Republican senators indicating that they will not vote for the bill.

One challenge is that the bills considered by both the House and Senate have had low public approval ratings, with criticism being lobbied against the Senate bill in particular for being crafted mostly out of public view. The issue of pre-existing conditions has also drawn significant public concern and comment, since many voters favour the ACA's prohibition on exclusion or discrimination based on pre-existing conditions. The House and Senate bills have taken different approaches to this issue. The House bill provides for waivers that permit states to allow insurers to charge people with pre-existing conditions higher premiums if the states meet certain conditions, such as setting up high-risk insurance pools. The Senate bill, on the other hand, does not permit states to use waivers to change federal regulations related to pre-existing conditions, but some critics have pointed out that under the proposed law, insurers could nonetheless use other loosened regulations to design policies that indirectly discriminate against those with pre-existing conditions.

Another sticking point for healthcare reform has been the proposed reductions to Medicaid. The House bill gradually eliminates the Medicaid expansion created by the ACA, and goes one step further to turn Medicaid into a programme providing a block grant to states to cover total spending, rather than providing guaranteed matching funds. Although Republicans have argued that these reforms will drive efficiencies in care, opponents have voiced concern that fewer funds will result in reduced eligibility, diminished provider payments and fewer benefits.

Not being able to carry out their promise to repeal and replace the ACA while in the majority would deal a significant blow to congressional Republicans, many of whom campaigned on a promise to overturn the law. However, following the setback of the Senate bill, President Trump issued a call to Republicans to simply repeal Obamacare and then work on replacement from a 'clean slate'. The fate of the ACA thus remains to be seen, although there will almost certainly be significant changes to the law in one form or another.

Probably the single largest challenge of the US healthcare system is 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. 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.

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 that may be on the horizon, as the Republican majority attempts to 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, change of one type or another appears inevitable.

Both the ACA and the legislation proposed to replace 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 like 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 in to 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.

Appendix 1

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