LEXOLOGY
Getting The Deal Through

HEALTHCARE REGULATION 2024

Contributing editors
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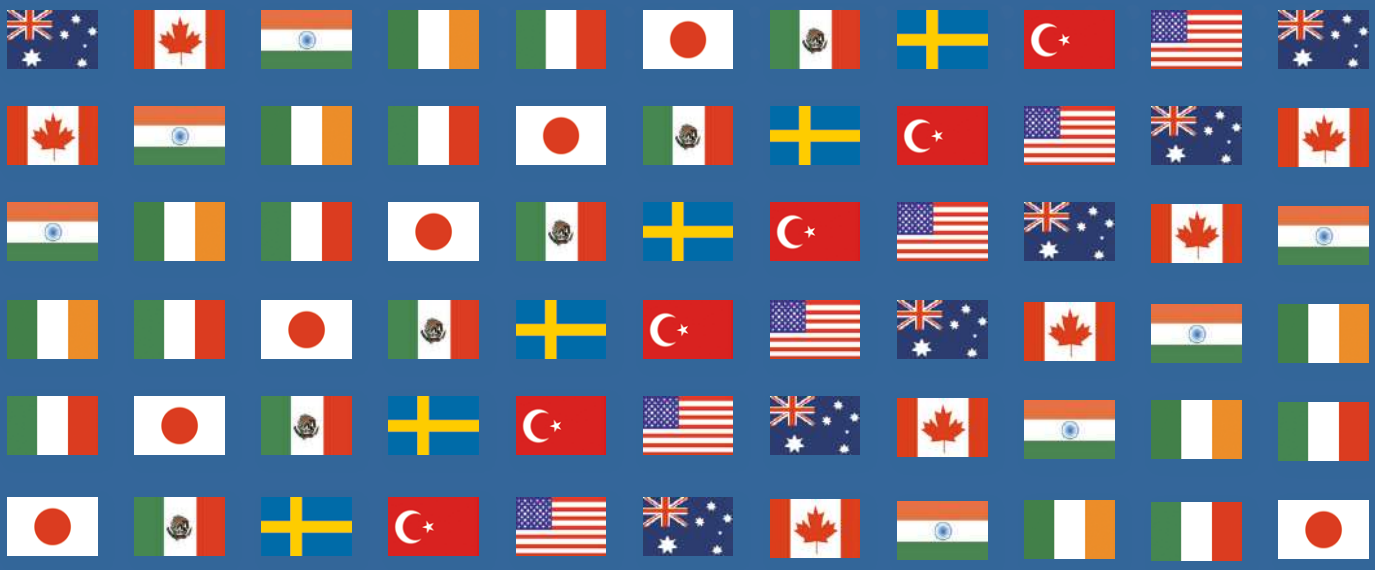

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Global overview

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Healthcare in America is big business. With annual expenditures in 2021 topping US$4.5 trillion, healthcare spending consumes 18.3 per cent of the US gross domestic product. More than half of personal healthcare expenditures in the US are subsidised financially by the public sector, which makes government a key policy actor.

The US healthcare system

The organisation, financing and control of US healthcare is a major policy driver with funding, delivery and access shared among federal, state and local governments and a diversity of private actors, each with overlapping spheres of influence and roles as insurers, financiers, purchasers, providers (ie, hospitals, medical practices, laboratories, post-acute care providers, etc), innovators, researchers and regulators of healthcare.

The US Constitution established a federal system of government where power is distributed between the national (federal) government and states with local governments exercising powers delegated to them by their state. The structure of the healthcare system largely reflects the allocation of government responsibility and facilitates the adaptation of healthcare policy to local preferences and needs.

The US health system is not solely reflective of government structure and interests, but also integrates into it, the private, entrepreneurial nature of corporate financing through investment in new ways to deliver care, innovations through life sciences and technological development and both public and private financing of significant medical research. Market competition plays a strong role in the development of healthcare organisations (eg, physician practices, hospitals, skilled nursing facilities) and the allocation of healthcare resources throughout the US. As a result, this public–private balance (or imbalance) adds to the administrative complexity of the US health system and associated high costs.

Right to healthcare

The US Constitution does not explicitly guarantee the right to healthcare and the US does not have a national health insurance system. Thus, the majority of Americans access healthcare coverage through private commercial plans or public programmes (notably Medicare and Medicaid). Private health insurance coverage continues to be more prevalent than public coverage, at 66 per cent and 36 per cent, respectively. Employer-sponsored commercial health plans are the dominant form of coverage in the US.

How Americans access healthcare coverage

Employer-sponsored health plans

The majority of working-age Americans access health insurance coverage for themselves and their families as a benefit of employment. Such plans provide medical coverage for a range of inpatient, outpatient and ancillary healthcare services for full-time workers and their families. However, the breadth of this coverage is largely uneven, because employers do not pay the full cost of employee health insurance premiums. As a consequence, countless workers contribute to the cost of their employer-based coverage that can result in significant out-of-pocket outlays per year. Further, variability in employer-sponsored insurance coverage is closely associated with employer size. For example, according to the US Bureau of Labor Statistics, 47 per cent of employers with fewer than 50 workers offer health insurance coverage compared to 93 per cent of employers with 50+ workers.

Public programmes

In response to the gaps in coverage produced by healthcare as an extension of the employment relationship, Congress enacted various laws aimed at making healthcare coverage, benefits and services more accessible for certain population groups. According to US census data, government-funded healthcare programmes provided coverage for 36 per cent of the US population for some or all of the year in 2021. Such actions have not, however, achieved universal healthcare coverage, and high out-of-pocket costs continue as a burden for many of the insured.

Medicare

With a total enrollment of some 64 million beneficiaries, Medicare is a federal social health insurance programme that finances the delivery of covered healthcare services for individuals aged 65 and older, certain disabled persons, persons with end-stage renal disease and those with amyotrophic lateral sclerosis (ALS), and provides substantial financial support for medical education, teaching hospitals and safety net hospitals. Medicare covers a wide range of medical services, including care provided in hospitals and skilled nursing facilities, hospice care, home healthcare, physician services, physical and occupational therapy, outpatient prescription drug benefits and other services. The Centers for Medicare and Medicaid Services (CMS), a subagency of the US Department of Health and Human Services (HHS), administers oversight of the Medicare programme that has established a national standard of care for US healthcare facilities and laboratories. Eligible persons enroll in Medicare through the Social Security Administration.

Medicare consists of four parts, with each part covering specific services: Part A, Hospital Insurance [covers inpatient hospital and, skilled nursing facility stays, and hospice and some home healthcare]; Part B, Medical Insurance [covers physicians, outpatient care and other medical services not covered by Part A]; Part C, Medicare Advantage [bundled benefits (typically Parts A, B and usually Part D) provided by a Medicare-approved private managed care plan]; and Part D [voluntary outpatient prescription drug coverage offered by a separate Medicare-approved private plan or included as part of a Medicare Advantage plan].

Medicaid

Medicaid is the nation's public health programme for low-income and disabled persons who meet certain income requirements to apply. Administration of the Medicaid programme is left to each state, as long as the program meets certain basic federal guidelines managed by CMS. Participation in Medicaid is voluntary and 100 per cent of states, the District of Columbia (DC) and US territories participate in the programme. Eligible persons may apply for Medicaid coverage through their state of residence and Medicaid enrollees must recertify eligibility and re-enrol in the programme on a semi-annual or annual basis, depending on their state of residence.

Commonly referred to as the 'workhorse' of the nation's healthcare system, Medicaid has evolved into the nation's largest public healthcare insurance programme by total enrollment (76 million). Medicaid covers primary and acute care services and long-term care services and supports for certain low-income adults, children, the elderly and disabled. It also covers nearly 50 per cent of all live births, 60 per cent of persons living in nursing homes and 12 per cent of the disabled. Medicaid is the largest payor for HIV care and the only major source of financial assistance for Alzheimer's. One in three children receives healthcare coverage and benefits through Medicaid.

While states are required to cover certain populations and benefits, they may also cover optional populations and services, and this accounts for the substantial variation in Medicaid programmes across the states. Within parameters set by federal law, states have certain flexibilities to establish their own payment rates for services provided by hospitals, physicians and other medical care providers. These may include payment for benefits directly by the state programme, or through outsourcing the delivery of care and payment to healthcare plans, or both. Although states are required to make additional payments to hospitals that treat a disproportionate share of low-income patients (Medicaid DSH payments), low provider payment rates (and thus, low provider participation rates) remain a perennial Medicaid policy concern.

Children's Health Insurance Program (CHIP)

Jointly funded by the federal government and states, CHIP provides low-cost healthcare for children in families with incomes too high to qualify for Medicaid but too low to afford private insurance coverage. CHIP is a block grant programme that requires periodic reauthorisation and funding. The federal share is subject to an annual cap determined by CMS, and states may limit enrolment and establish programme coverage waiting periods. CMS administers and regulates the federal portion of CHIP. Eligible persons may apply for CHIP coverage through their state of residence.

Affordable Care Act

Enacted in 2010, the Affordable Care Act (ACA) comprehensively reformed the US health insurance market by increasing coverage options for the uninsured. Thus, outside of employment, individuals may purchase comprehensive medical coverage from private plans through the health insurance marketplace established by the ACA, where eligible persons can qualify for premium subsidies. The ACA has been the subject of numerous legal challenges and several decisions by the US Supreme Court. Notably, the Court's June 2012

ruling in National Federation of Independent Business (NFIB) v Sebelius made Medicaid coverage expansion for low-income adults optional for states, 567 U.S. 519 (2012). Currently, 31 states, DC and three US territories (Guam, Puerto Rico and the US Virgin Islands) have expanded Medicaid programmes.

Immigrants with qualified non-citizen status (ie, lawful residents, asylees, refugees, etc) may be eligible for premium tax credits and other savings through the health insurance marketplace established by the ACA, and are generally eligible for coverage through Medicaid and CHIP.

Other public programmes

The federal government also provides comprehensive coverage for healthcare services for active duty service members and families through TRICARE, military veterans through the US Department of Veterans Affairs, and for American Indians and Alaska Natives through the Indian Health Service.

Emergency healthcare and the uninsured

Emergency healthcare

Federal law primarily governs access to emergency services. Medicare-participating hospitals (encompassing almost all hospitals in the US) with dedicated emergency departments must meet the emergency needs of all patients regardless of a patient's ability to pay for the services. The source of this obligation, the Emergency Medical Treatment and Active Labor Act of 1986, requires hospitals to diagnose and stabilise conditions that constitute an 'emergency medical condition', including a patient in active labour.

The uninsured

Currently, 91 per cent of Americans have some form of healthcare coverage although high out-of-pocket costs create barriers to healthcare services for many. While the overall uninsured rate hovers around 9 per cent, it deviates widely across the states. According to recent surveys, the majority of uninsured persons are from low-income families with at least one full-time or part-time worker. Most work for employers that either do not offer healthcare benefits, or the cost of the benefits offered was too high. Recent HHS statistics show the uninsured rate for non-citizens is 30.6 per cent. The federal government publishes and updates an exhaustive resource on coverage options for the uninsured.

The price of healthcare

Healthcare in the US is very expensive with per capita spending the highest in the world, topping out at US$13,000 in 2021. The price of healthcare services varies with the type of insurance coverage. In the commercial insurance market, health plans and providers negotiate pricing for covered items and services that providers agree to accept in exchange for anticipated patient volume. Largely dictated by market conditions, negotiated prices are typically higher than what Medicare, Medicaid and CHIP pay and vary widely within and among geographic areas. By contrast, prices are administratively set for public programmes through laws and regulations. Self-pay and uninsured persons (ie, those without any form of health insurance coverage) typically pay significantly more for healthcare items and services

because they cannot access discounts set by government nor rates negotiated by commercial payors.

How the US finances healthcare

The US healthcare system is generally financed through one, or a combination of individual or employer tax credits or deductions; federal, state or local government revenue; individual or group premiums paid to insurance plans; and individual out-of-pocket expenses.

Employer-sponsored coverage

Employer-sponsored insurance coverage is financed through a combination of employer and employee contributions with the employer's contribution subsidised by federal tax credits. Persons insured by commercial group and individual health plans pay a monthly premium for coverage and the full cost of healthcare up to a yearly deductible for covered medical services and prescription drugs. Costs that routinely count toward the deductible include doctor visits, hospitalisations, surgical procedures, medicines, lab and medical tests. The deductible for in-network services (ie, services by providers that contract with the health plan) is substantially less than for out-of-network services. A fixed amount (copay), or a percentage of the cost (coinsurance), may also be required at the time of service, which may (but not necessarily must) be applied to the annual deductible.

Medicare

Part A (Hospital Insurance) is financed through payroll taxes. Part A benefits are paid out of the federal Medicare Hospital Insurance Trust Fund, which is projected to be fully depleted in 2028. Medicare Part B (Medical Insurance) and Part D (outpatient prescription drug benefit) are financed with beneficiary premiums and general revenue, so insolvency has not been an issue. Medicare Advantage (Part C) plans are funded through a combination of general revenue, beneficiary premiums and payroll taxes.

Medicaid

Medicaid is a means-tested entitlement programme that is jointly funded by the federal government and the states. The federal government's share for most Medicaid expenditures is called the federal medical assistance percentage (FMAP). Determined annually, the FMAP is based on a formula that provides higher reimbursement to states with lower per capita incomes relative to the national average. The formula is intended to reflect states' differing abilities to fund Medicaid from their own state revenues. Medicaid funding is largely dependent on state appropriations and is well known for paying less than the cost of care to providers.

CHIP

CHIP is jointly funded by the federal government and states under a formula that is tied to a state's Medicaid FMAP. States have adopted varying thresholds for CHIP eligibility and varying payment structures. The federal share is subject to an annual cap that is determined by CMS, and the states may limit enrolment and establish programme coverage waiting periods. CHIP is almost fully outsourced by states to third-party insurance companies to

administer and payment for services is negotiated largely consistent with private managed care contracts.

The uninsured and underinsured

Non-elderly persons without health insurance coverage and the underinsured, whose healthcare benefits fail to adequately cover all of their medical expenses, are largely left to pay for medical services out-of-pocket, which can quickly leave them with a mounting medical debt they may never be able to pay. As a consequence, unpaid medical expenses are the leading cause of bankruptcies in the US.

Since payment is largely negotiated and subject to competition, and because providers also deliver services that are unreimbursed or underpaid, private commercial contracting and financing is structured to shift costs to employers and commercial payors. And this often leads to lack of transparency in healthcare financing and confusion concerning pricing by consumers of healthcare services.

How the delivery of healthcare is structured in the US

The delivery of healthcare is through private or public hospitals and other healthcare facilities, providers, physicians and clinical practitioners. Each are subject to individual state licensure requirements and, in most cases, Medicare certification standards.

How providers are reimbursed for healthcare services

Both private payors and public programmes purchase healthcare services from providers. Commercial payors reimburse providers under a contracted rate that may vary considerably among other insurers and providers. Although commercial rates are largely unregulated, the Medicare programme substantially influences the benchmarking of commercial payor rates with regard to maximum payment levels, rate modifications and changes in market characteristics. Reimbursement for healthcare services is administratively complex, with determinations based on eligibility, coverage, provider type, facility, geographic area, payor involved and other factors.

Medicare uses different methodologies to reimburse healthcare providers based on the service provided, and Congress has made updates and changes to these payment systems over time. The majority of US hospitals are generally paid according to the Medicare prospective payment system (PPS) formula that reimburses a pre-determined, fixed amount for specific services derived from a classification system that has been developed for that specific site of service in that hospital. Since the implementation of PPS in 1983, a number of similar Medicare classification payment programs have been developed for hospital outpatient, home health agencies, hospice, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals and skilled nursing facility services.

Providers may receive certain supplemental payments from the Medicare and Medicaid programmes if they serve a disproportionate share of uninsured individuals, participate in certain value-based reimbursement models and/or provide graduate medical education.

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Physicians are paid according to a fee schedule of more than 10,000 physician services. Items and services provided in hospital or outpatient settings are typically more expensive than when provided in a physician's office.

Third-party payors have begun to shift to value-based reimbursement, which provides incentives for lowering costs while maintaining or improving quality care through bundled payments and pay-for-performance programmes. Groups of providers are also forming accountable care organisations that accept responsibility for the quality and cost of medical services for specific patient populations.

In conclusion

Widely acknowledged as one of the most complex health systems in the world, US healthcare is a mix of public and private delivery models, where the dual influence of private capital and public goods create a continual shifting and sharing of healthcare roles and responsibilities among government and the private sector. While the organisation and structure of US healthcare produce significant market innovations and improvements in care, nearly 30 million Americans remain uninsured while millions of others are underinsured.

Equally complex is the practice of health law in the US, where health system concerns necessarily involve the expertise of lawyers knowledgeable on the multitude of laws and regulations that govern the US healthcare industry, many of which are addressed in Getting the Deal Through: *Healthcare Regulation 2024*.

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Summary

ORGANISATION, FINANCING AND STRUCTURE OF THE HEALTHCARE SYSTEM

Organisation

1 How is healthcare in your jurisdiction organised? What is the role of government?

The US Constitution established a federal system of government where power is distributed between the national (federal) government and the states with local governments exercising the powers delegated to them by their state. The structure of the healthcare system largely reflects the allocation of government responsibility and facilitates the adaptation of health-care policy to local preferences and needs. It also adds to the administrative complexity of the US healthcare system and associated high costs. Shaped by an abundance of inter-related factors, the organisation, financing and control of US healthcare is divided and shared among federal, state and local government and a diversity of private actors, each with overlapping spheres of influence and roles as underwriters, purchasers, providers and regulators of healthcare.

Key legislation

2 What key legislation governs the provision of healthcare services in your jurisdiction?

The following legislation establishes and defines the statutory rights of certain persons to receive government-financed healthcare coverage, benefits and services.

Medicare (Title XVIII of the Social Security Act) is a federal (national) healthcare programme covering persons aged 65 and older, and those under age 65 with long-term disabilities or end-stage renal disease. 42 U.S.C. § 1395 et seq. The Centers for Medicare & Medicaid Services (CMS), a federal agency within the US Department of Health and Human Services (HHS), administers and regulates the Medicare programme. Eligible persons enrol in Medicare through the Social Security Administration.

Jointly financed by the federal and state governments, Medicaid (Title XIX of the Social Security Act) and CHIP (Title XXI of the Social Security Act) cover persons and families with limited incomes and resources. Medicaid is the nation's public health programme for low-income persons who must meet certain income requirements to apply. 42 U.S.C. § 1396 et seq. CHIP covers uninsured children in families with incomes too high to qualify for Medicaid but too low to afford private health insurance. 42 U.S.C. § 1397 et seq. Participation in Medicaid and CHIP is voluntary and 100 per cent of states, District of Columbia (DC) and US territories participate in both programmes. CMS administers and regulates the federal portion of Medicaid and CHIP and the states have some flexibility in the design and structure of both programmes. Eligible persons may apply for Medicaid and CHIP coverage through

their state of residence and Medicaid enrollees must recertify eligibility and re-enrol in the programme on an annual or semi-annual basis depending on the state of residence.

Enacted in 2010, the Affordable Care Act (ACA) comprehensively reformed the US health insurance market by increasing coverage options for the uninsured, expanding Medicaid coverage for low-income adults, and supporting a number of healthcare service delivery reforms. 42 U.S.C. § 18001 et seq. The ACA has been the subject of numerous legal challenges and several decisions by the US Supreme Court. Notably, the Court's June 2012 ruling in *National Federation of Independent Business (NFIB) v Sebelius* made Medicaid coverage expansion optional for states. 567 U.S. 519 (2012). Currently, 31 states, DC and three US territories (Guam, Puerto Rico and the US Virgin Islands) have expanded Medicaid programmes.

Financing

3 | How is the healthcare system financed in the various patient care sectors?

The US healthcare system is generally financed through one, or a combination of individual or employer tax credits or deductions; federal, state or local government revenue; individual or group premiums paid to insurance plans; and individual out-of-pocket expenses.

Employer-sponsored insurance (ESI) coverage is financed through a combination of employer and employee contributions with the employer's contribution subsidised by federal tax credits. Under the ACA's employer shared responsibility provisions, large employers (businesses with an average of at least 50 employees) must either offer minimum essential coverage that is 'affordable' and that provides 'minimum value' to their full-time employees (and their dependents), or potentially make an employer shared responsibility payment to the IRS. ESI plans provide medical coverage for a range of inpatient, outpatient, and ancillary healthcare services for full-time workers and their families. While the majority of Americans receive healthcare benefits through work, small employers (businesses with fewer than 50 full-time employees) are not mandated to provide ESI coverage. Outside of employment, individuals may purchase comprehensive medical coverage from private plans through the health insurance marketplace established by the Affordable Care Act (ACA), where eligible persons can qualify for premium subsidies.

Medicare comprises four parts (A, B, C, D). The hospital insurance programme (Part A) covers inpatient hospital and, skilled nursing facility stays, and hospice and some home healthcare and is financed through payroll taxes. Part A benefits are paid out of the Medicare Hospital Insurance Trust Fund which is maintained federally and is projected to be fully depleted in 2028. Part B is a voluntary supplemental medical insurance programme covering outpatient care, services by physicians and other healthcare providers, home healthcare, medical equipment and certain preventive services. The voluntary outpatient prescription drug benefit (Part D) is provided by private health plans that contract with Medicare. Parts B and D are financed with beneficiary premiums and general revenue so insolvency has not been an issue. Medicare Advantage (Part C) are private managed care plans covering Parts A and B, and in many instances, Part D benefits. Part C is funded by a combination of general revenue, beneficiary premiums and payroll taxes.

Medicaid is a means-tested entitlement programme jointly funded by federal and state government. The federal government provides matching funds to states through a federal medical assistance percentage (FMAP) formula that is tied to the state's per capita income. Medicaid covers a range of services including primary care, acute care and long-term care for low-income children, adults and the disabled.

CHIP provides low-cost healthcare for children and is jointly funded by the federal government and states under a formula that is tied to the state's Medicaid FMAP. Unlike Medicaid, CHIP is a block grant programme that requires periodic reauthorisation and funding. The federal share is subject to an annual cap determined by CMS, and states may limit enrolment and establish programme coverage waiting periods.

Delivery structures

4 What are the basic structures for the delivery of care to patients in your jurisdiction?

The majority of Americans access coverage through private health plans and public programmes (notably Medicare and Medicaid). Employer-sponsored insurance plans are the principal form of private group health coverage in the US with the majority being regulated by the Employee Retirement Income Security Act (ERISA). 29 U.S.C. § 1001 et seq. In 2010, the ACA established subsidised health insurance coverage for individuals and small employers. 42 U.S.C. § 18001 et seq. Non-ERISA commercial insurance plans are generally regulated by the states. The federal government publishes and updates an exhaustive resource on coverage options for the uninsured.

The delivery of healthcare is largely structured through Medicare, Medicaid, CHIP and the ACA. Healthcare facilities, providers, physicians and clinical practitioners are subject to individual state licensure requirements. States, and to a lesser degree local government, also finance and deliver mental health and personal healthcare services through public hospitals, outpatient health centres (which may be federally subsidised) and local, tax-payer funded special purpose districts.

Access and coverage

5 What rules govern access to treatment and emergency services? Which items and services are covered and which are not covered?

Federal law primarily governs access to emergency services. Medicare-participating hospitals (encompassing almost all hospitals in the US) with dedicated emergency departments must meet the emergency needs of all patients regardless of a patient's ability to pay for the services. The source of this obligation, the Emergency Medical Treatment and Active Labor Act , requires hospitals to diagnose and stabilise conditions that constitute an 'emergency medical condition', including a patient in active labour. 42 U.S.C. § 1395dd.

Exclusions from statutory coverage

6 Are any groups excluded from statutory coverage? Are any groups covered under alternative schemes?

The US Constitution does not explicitly guarantee the right to healthcare with the possible exception of a standard established by the US Supreme Court for incarcerated persons in *Estelle v Gamble*, 429 U.S. 97 (1976). Unique to the US system are the coverage gaps produced by healthcare as an extension of the employment relationship. Congress has enacted various statutes (eg, Medicare, Medicaid, CHIP, ACA) establishing and defining the rights of certain population groups to receive government-financed healthcare through public programmes and subsidies for private group and individual coverage through the tax code. Such actions have not, however, achieved universal coverage.

Gaps in cost coverage

7 Are there any gaps in cost coverage?

Persons insured by commercial group and individual health plans pay a monthly premium for coverage and the full cost of healthcare up to a yearly deductible for covered medical services and prescription drugs. Costs that routinely count toward the deductible include doctor visits, hospitalisations, surgical procedures, medicines, lab and medical tests. The deductible for in-network services (ie, services by providers that contract with the health plan) is substantially less than for out-of-network services. A fixed amount (copay), or a percentage of the cost (coinsurance), may also be required at the time of service which may (but not necessarily must) be applied to the annual deductible. Medicare publishes an annual fact sheet of Medicare Parts A and B premiums and deductibles and the Medicare Part D income-related monthly adjustment amounts. Medicare Advantage plans (Part C) dictate beneficiary out-of-pocket costs, which can differ from Parts A and B.

HEALTHCARE PRICING AND REIMBURSEMENT

Pricing

8 How are prices for healthcare services set and paid for in your jurisdiction? To what extent is the cost of healthcare services governed by law or regulation?

The price of healthcare services varies with the type of insurance coverage. In the commercial insurance market, health plans and providers negotiate pricing for covered items and services that providers agree to accept in exchange for anticipated patient volume. Largely dictated by market conditions, negotiated prices are typically higher than what Medicare, Medicaid and CHIP pay and vary widely within and among geographic areas. By contrast, prices are administratively set for public programmes through laws and regulations. Self-pay and uninsured persons (ie, those without any form of health insurance coverage) pay significantly more for healthcare items and services because they cannot access discounts set by government nor rates negotiated by commercial payors.

Reimbursement

9 How is reimbursement for healthcare services structured?

Providers receive reimbursement for services from a combination of public and private third-party payors, including federal and state government programmes, private insurers, employers, and self-pay patients. While reimbursement for healthcare services varies by payor, the type of payments is largely consistent and often overlap. More than just payment, reimbursement requires consideration of eligibility, coverage, health plan enrolment and payment requirements.

Third-party payors use Medicare as a benchmark for reimbursing medical services. Whether or not an item or service is deemed to be medically necessary by a person's source of coverage determines whether and how it is reimbursed. The majority of US hospitals are generally paid according to a prospective payment system (PPS) formula under the Medicare program that reimburses a pre-determined, fixed amount that is derived from a classification system for that site of service. There are separate PPSs for Medicare reimbursement to acute inpatient hospitals, hospital outpatient, home health agencies, hospice, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals and skilled nursing facilities.

Providers may receive additional reimbursements from the Medicare and Medicaid programmes if they serve a disproportionate share of uninsured individuals, participate in certain value-based reimbursement models or provide graduate medical education.

Physicians are paid according to a fee schedule of more than 10,000 physician services. Items and services provided in hospital or outpatient settings are typically more expensive than when provided in a physician's office.

Third-party payors have begun to shift to value-based reimbursement, which provides incentives for lowering costs while maintaining or improving quality care through bundled payments and pay-for-performance programmes. Groups of providers are also forming accountable care organisations that accept responsibility for the quality and cost of medical services for specific patient populations.

Adjudication

10 If applicable, what is the competent body for decisions regarding the pricing and reimbursement of healthcare services?

While the US does not have a centralised authority that sets pricing and reimbursement of healthcare services, third-party payors look to Medicare as a benchmark. Medicare sets the reimbursement used in Parts A and B, and private insurers set the reimbursement used in Parts C and D. Further, Medicare authorises and sets reimbursement for new and/or changing technologies and medical services under nationwide or local coverage determinations. Notably, Centers for Medicare & Medicaid Services (CMS) may use subregulatory guidance (ie, guidance not subject to public notice-and-comment) to 'clarify' Medicare reimbursement standards and requirements.

The US Congress plays a significant role in the pricing and reimbursement of healthcare services for the Medicare programme and has created the Medicare Payment Advisory Commission and the Medicaid and CHIP Payment and Access Commission, as nonpartisan legislative branch agencies for advising Congress and the US Department of Health and Human Services on issues affecting coverage and payment policies, among others.

HEALTHCARE ORGANISATIONS AND BUSINESS STRUCTURES

Legal authorisation

11 What steps are necessary to authorise the provision of healthcare services, and what laws govern this?

A healthcare provider must obtain a patient's express or implied consent to receive a medical treatment. Often special rules apply to obtaining consent for the treatment of minors, incapacitated adults or adults with intellectual disabilities. A provider's failure to inform a patient of the risks associated with a medical treatment (or the failure to receive the medical treatment) can result in medical malpractice liability depending on state law.

The majority of Americans access coverage through private health plans and public programmes (notably Medicare and Medicaid). Limitations on the scope of covered benefits may be established by law (as in the case of public programmes), or through the contractual provisions of private health plans. Pre-authorisation by the insurer may also be required for certain types of non-emergency services.

Legal structures

12 What types of legal entities can offer healthcare services?

Healthcare facilities may be owned and operated by any form of legal entity. According to a survey by the American Hospital Association, 58 per cent of community hospitals are operated by non-profit corporations, 24 per cent are operated by for-profit corporations, and 18 per cent are operated by state and local governments. In order for a non-profit hospital to obtain and maintain exemption from federal income taxation it must satisfy certain organisational and operational requirements, demonstrate community benefit, and satisfy requirements under the Affordable Care Act.

Hospitals and other healthcare providers (eg, ambulatory care facilities, home healthcare agencies, hospices) must be licensed to offer healthcare services by the state in which they operate, and may be required in some states to obtain a certificate of need prior to establishing or expanding a healthcare facility or service. Hospitals will also need to obtain additional licences from state authorities to offer services such as diagnostic imaging services and laboratory services.

With respect to physicians and other clinical practitioners (eg, optometrists, dentists, chiropractors), state law dictates the type of legal entity through which such professionals may offer healthcare services. All states allow physicians to practise medicine through a professional corporation, or association owned by physicians. Many states also allow physicians

to practice medicine through other legal entities, such as corporations or limited liability companies. Certain states require that healthcare professional entities be exclusively owned by healthcare professionals holding the same practice licence. In some states, entities not owned by physicians are prohibited from practising medicine, or employing physicians to provide professional medical services, subject to certain exceptions. The prohibition, known as the 'corporate practise of medicine' doctrine, is memorialised under state statutes, regulations, case law and state government actions and guidance. The corporate practise of medicine prohibition is based on public policy concerns that a physician needs to be able to exercise his or her independent medical judgement without the interference of commercial pressures.

Foreign companies

13 What further steps are necessary for foreign companies to offer healthcare services?

In order to offer healthcare services in the US, a foreign company will need to form a US legal entity either in the state in which healthcare services will be offered, or in another state. If the foreign company desires to offer healthcare services in a state other than the state of incorporation, it may do so by qualifying to do business in the state of its operations. Each state has a process through which a company organised in a different state can register to do business in that state. If the foreign company has foreign government ownership it may be required to make a filing with the Committee on Foreign Investment in the Unites States.

Healthcare arrangements

14 What regulatory and legal issues commonly arise in relation to healthcare arrangements? What are the main rules and principles that apply to extraterritorial participation in these arrangements?

Many state and federal laws are implicated in healthcare mergers and acquisitions and other types of transactions. For licensed healthcare facilities, consent to a change in control of the facility, or to transfer substantially all of the assets of the facility to another owner, requires approval by state healthcare agencies. If a facility's Medicare participation agreement will be transferred from one entity to another, then the Centers for Medicare & Medicaid Services must approve the transfer. Transactions involving multiple healthcare facilities or systems that enjoy substantial market share in a geographic region may be subject to approval from state and federal agencies charged with enforcing antitrust laws. To the extent a party to the transaction is a non-profit corporation, exempt from federal taxation, then the purposes of the transaction and the flow of funds will need to comply with state and federal non-profit tax laws. In addition, the types of joint ventures that a non-profit entity may enter into with a for-profit company are limited by tax laws.

Transactions or ongoing arrangements between providers that make referrals and entities that provide the referred items and services (such as transactions between a physician and a hospital where the physician provides services) are impacted by federal fraud and abuse laws (and state analogues of such laws) that prohibit payment for healthcare-related referrals. Federal and state laws prohibit providers from receiving anything of value as an inducement to make a referral to a particular entity or practitioner. Transactions between

these types of parties are not necessarily prohibited, but federal and state laws establish certain limitations. Thus, any transaction between these types of parties must be carefully reviewed for legal compliance.

COMPETITION, ANTI-CORRUPTION AND TRANSPARENCY RULES

Authority enforcement

15 Are infringements of competition law by healthcare providers pursued by national authorities?

Both the US Federal Trade Commission (FTC) and the US Department of Justice (DOJ) Antitrust Division have jurisdiction to investigate and bring enforcement actions against healthcare providers for violations of US antitrust law. Healthcare providers such as hospital systems and physician groups are primary targets for antitrust litigation and government enforcement actions. Mergers and acquisitions of healthcare providers are subject to section 7 of the Clayton Act (18 U.S.C. § 45), which prohibits transactions the effects of which 'may be substantially to lessen competition, or to tend to create a monopoly'. When reviewing transactions, the US agencies assess whether the transaction may reduce competition through (1) unilateral effects (eg, the elimination of a competitor that increases the merged entity's ability to increase prices); and/or (2) coordinated effects (eg, an increased opportunity for the merged firm to collude with competitors). Certain-sized transactions require government notification under the Hart–Scott–Rodino Act. 15 U.S.C. § 18a. However, the US agencies have jurisdiction to review a transaction whether or not the transaction is reportable under the Hart-Scott-Rodino Act.

In addition to mergers/acquisitions, the US agencies also may review a variety of other types of provider collaborations, including joint ventures (eg, clinical collaborations, joint purchasing arrangements and formation of physician networks), accountable care organisations and information exchanges.

In addition to transactions, the US agencies can review provider conduct such as staffing of healthcare facilities and patient referrals, insurer contracting, exclusive service arrangements, anti-steering provisions (contracts terms that prohibit the insurer from encouraging patients to seek services from a hospital's competitor) and non-competition agreements (contracts which restrict an individual from practising in a certain geographic area or soliciting patients from a previous employer).

Private enforcement

16 Is follow-on private antitrust litigation against healthcare providers possible?

The US federal antitrust laws for the most part may be enforced by US enforcement agencies (the FTC and DOJ Antitrust Division) and by private parties. One primary exception is that section 5 of the Federal Trade Commission Act, which prohibits 'unfair or deceptive acts or practices in or affecting commerce', can only be enforced by the FTC. This is an important distinction because the FTC may bring an action under section 5 that addresses conduct that is not considered unlawful under other federal antitrust statutes. For example, the FTC

has brought actions under a theory of 'invitation to collude', which is not actionable under any other federal antitrust statute.

Although either the FTC or the DOJ brings most actions to enjoin a transaction under section 7 of the Clayton Act (18 U.S.C. § 45), which prohibits transactions the effects of which 'may be substantially to lessen competition, or to tend to create a monopoly', private parties may also bring such actions. Similarly, an aggrieved party that has sustained injury as a result of anticompetitive conduct may bring an action against a healthcare provider seeking damages whether or not the FTC or DOJ has brought an enforcement action concerning the same conduct. It is common, for example, for private plaintiffs to commence follow-on private litigation after a DOJ criminal investigation for price fixing or other criminal conduct.

In short, private parties are not prohibited from commencing private follow-on litigation even if the FTC or DOJ have commenced an enforcement or criminal action for the same or similar conduct.

Anti-corruption and transparency

17 What are the main anti-corruption and transparency rules applicable to healthcare providers?

The federal Foreign Corrupt Practices Act (FCPA) prohibits the payment of bribes (including money or anything of value) by certain persons and entities to foreign government officials to influence the official in obtaining business. Healthcare providers and other US corporations and individuals are subject to the FCPA. 15 U.S.C. §§ 78dd-1, et seq.

The National Physician Payment Transparency Program: Open Payments Rule, promulgated by the Centers for Medicare & Medicaid Services (CMS), requires manufacturers of drugs, devices, biologicals and medical supplies covered by Medicare, Medicaid or CHIP to report payments or other transfers of value they make to physicians, teaching hospitals and certain non-physicians to CMS, which posts the data to a public website. 42 C.F.R. § 403.902.

Federal and state fraud and abuse laws establish rules applicable to healthcare providers and impose civil, criminal and administrative penalties on healthcare providers that violate such laws, including the healthcare fraud statute (18 U.S.C. § 1347), the federal Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)); physician self-referral law or 'Stark law' (42 U.S.C. § 1395nn); False Claims Act (31 U.S.C. §§ 3729-3733); Exclusion statute (42 U.S.C. § 1320a-7); and Civil Monetary Penalties Law (42 U.S.C. § 1320a-7a). Many states have companion versions of these laws that can be grounds for imposing additional sanctions, and penalties.

The Hospital Price Transparency Rule sets forth requirements for complying with Section 2718(e) of the Public Health Services Act that compels US hospitals to make public their standard charges, described as 'the regular rate established by the hospital for an item or service provided to a specific group of paying patients' 45 C.F.R. Part 180.

The No Surprises Act seeks to protect consumers from surprise medical bills arising from certain out-of-network emergency care. Pub. L. 116-260. CMS maintains a website for the implementing rules and guidance.

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The US government at all levels has 'Sunshine laws' that require public access to, and disclosure of the meetings and records of government agencies (which may include hospitals owned or operated by governmental bodies), as well as Freedom of Information Acts that require government agencies to make their records available upon request. See FOIA.gov for an overview of the rules applicable to federal agencies.

REGULATION OF HEALTHCARE SERVICES

Licensing authority and process

18 Which authorities are charged with licensing and regulating patient care facilities and healthcare professionals? What licensing processes apply?

Most US patient care facilities are licensed by a state agency in the state where they are located. Every state has an agency that issues licences for patient care facilities, including hospitals, skilled nursing facilities, ambulatory surgery centres and other facilities. Each agency has its own licensing process. Some states also may require hospitals to obtain a certificate of need from a designated state authority prior to opening a new hospital or undertaking a significant expansion. Local jurisdictions may also require certain permits or approvals (eg, building codes).

The federal government requires certification that Medicare and Medicaid participating patient care facilities meet certain health and safety standards known as Conditions of Participation (CoPs) or Conditions for Coverage (CfCs) by means of a state survey conducted on behalf of the federal government, or from a Centers for Medicare & Medicaid Services (CMS)-approved national accrediting organisation, such as The Joint Commission.

Healthcare professionals (physicians, nurses, dentists, chiropractors, optometrists, podiatrists, physical therapists, etc) are licensed and regulated by specific state agencies in the state where they will practise. Every healthcare professional must be licensed in each state where they will practise with certain exceptions.

Cross-border regulation

19 What requirements and restrictions govern the mobility of licensed health professionals across borders?

Healthcare professionals who provide clinical services are licensed and regulated by specific state agencies. This includes physicians, dentists, chiropractors, optometrists, nurses and other practitioners. Every healthcare professional must be licensed in each state in which they will practise. In some professions, such as nursing, there are interstate compacts between states that permit a professional licensed in one state to be recognised in another. Specific enquiry must be made under each state's law as to whether this applies, and the requirements.

Collaboration between healthcare professionals

20 What authorisations are required for collaboration between healthcare professionals? How is this regulated?

Physicians, dentists, chiropractors and optometrists are authorised to practise independently, and are not required to collaborate with other healthcare professionals. Registered nurses generally practise under the supervision of a physician, both in physician office (clinic) settings, and in hospitals and other patient care facilities.

Most states recognise advanced categories of nurse training and specialisation, generally described as advanced practice nurses or nurse practitioners (collectively, APNs). In some states, APNs can practise independently, while in other states they must practise under the supervision and direction of a physician, generally governed by a collaborative practice agreement between the APN and a physician.

Physician assistant is a separate licensed category authorised to provide patient care services under the direction and supervision of a physician. Most states limit the number of physician assistants who can be supervised by an individual physician (generally between two and six). State law governs the scope of practice for APNs and physician assistants.

Collaboration between patient care facilities and healthcare professionals

21 What authorisations are required for collaboration between patient care facilities and healthcare professionals? How is this regulated?

Most collaborations between patient care facilities and healthcare professionals are governed by employment or contractual arrangements. In general, no specific authorisation is required for such collaborations. Nevertheless, there are rules and protocols governing certain collaborations, particularly in hospital settings.

Under state law and accreditation requirements, hospitals are responsible for maintaining and overseeing a medical staff of physicians. The physicians govern and operate the medical staff, with certain actions being subject to approval by the board of directors of the hospital. The medical staff is responsible for granting medical staff membership and privileges to physicians, and for overseeing patient care quality and safety. To practise medicine within a hospital, a physician must obtain privileges for specific procedures and the scope of practice of the physician.

In the US, physicians may practise medicine at hospitals either as employees of the hospital or as independent professionals. In either case, their privileges and quality of care are subject to oversight under the medical staff processes.

Other licensed healthcare professionals in the hospital setting are generally employed by the hospital. Such professionals include registered nurses, nurse assistants, equipment technicians, pharmacists and others.

Collaboration at other patient care facilities is generally governed by employment and contractual relationships. At ambulatory surgery centres, for example, physicians provide

services and medical direction, either as employees or under contractual arrangements. Other healthcare professionals, such as nurses, provide services as employees of the surgery centre or as employees of the physicians.

Training of healthcare professionals

22 What educational and training requirements must physicians and healthcare professionals satisfy to obtain the right to practise in your jurisdiction?

The path to becoming a physician in the US typically includes four years of attendance at a college or university with receipt of a 'bachelor's degree' upon graduation, followed by attendance at medical school. US medical schools are also traditionally four years and may confer a doctor of medicine (MD) degree, or a doctor of osteopathic medicine (DO) degree upon completion.

As explained by the Association of American Medical Colleges, many medical schools, regardless of the type of degree offered, organise medical student training into two years of classroom or pre-clinical education followed by two years of clinical education.

In addition to attending medical school, medical students studying to practise medicine in the US take certain licensing examinations: the United States Medical Licensing Examination (USMLE) for MD students, and/or the Comprehensive Osteopathic Medical Licensing Examination of the United States for DO students. After medical school, graduates must complete additional training in an accredited 'residency' programme in order to obtain an unrestricted licence. The length of postgraduate training or residency varies by medical speciality, from three years to five years; however, the period of postgraduate education required to obtain an initial licence to practise medicine may be of a shorter duration, and varies by state.

The pathway to obtaining a licence and practising other forms of healthcare, including as a registered nurse, advanced nurse practitioner, physical or occupational therapist, physician assistant, audiologist, optometrist or psychologist is highly variable and dependant not only on the degree and licence sought, but the state where the licensee will practise. Most healthcare providers are required to attend schools accredited as offering a curriculum and education in the healthcare speciality and will engage in clinical training. Information on the education and training required for a specific form of healthcare practise is available from the individual state's regulatory agencies conferring the specific licence and/or through national organisations, including, for example, the American Nurses Association, American Physical Therapy Association and American Occupational Therapy Association.

Discipline and enforcement

23 What civil, administrative or criminal sanctions, penalties, corrective measures and related tools may be imposed on patient care facilities and healthcare professionals for regulatory non-compliance?

Federal and state licensure, operational, administrative, and fraud and abuse laws provide grounds for imposing civil, criminal and administrative penalties on healthcare providers that run afoul of statutory and regulatory requirements.

Healthcare organisations must meet certain health and safety standards, known as Conditions of Participation (CoPs) or Conditions for Coverage (CfCs), in order to participate in Medicare and Medicaid. Failure to operate in compliance with the CoPs/CfCs can result in sanction, recoupment of reimbursements, and suspension or termination from the programmes.

Healthcare providers are subject to a number of fraud and abuse laws including the healthcare fraud statute (18 U.S.C. § 1347); federal Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)); physician self-referral law, or 'Stark law' (42 U.S.C. § 1395nn); False Claims Act (31 U.S.C. §§ 3729-3733); Exclusion statute (42 U.S.C. § 1320a-7); and Civil Monetary Penalties Law (42 U.S.C. § 1320a-7a). Many states have companion versions of these laws that can be grounds for the imposition of additional sanctions and penalties.

Healthcare providers must also comply with federal and state privacy and security laws. The Health Insurance Portability and Accountability Act (HIPAA) (Pub. L. 104-191) established national standards for the privacy and security of protected health information. Implementing regulations are found via the Privacy Rule and the Security Rule (45 C.F.R. Part 160; Subparts A, C, and E of Part 164). The Health Information Technology for Economic and Clinical Health (HITECH) Act also created requirements relating to breach notification (Pub. L. 111-5; 45 C.F.R. §§ 164.402-164.412). HIPAA is considered the floor of healthcare privacy requirements and many states have implemented their own, more stringent, healthcare data privacy laws.

Patient complaints

24 | How are patient complaints processed and adjudicated?

The CMS requires hospitals and other providers participating in the Medicare and Medicaid programmes to have an established process for receiving and responding to patient grievances. Failure to adequately respond to a grievance can place a provider's continued participation in Medicare and Medicaid at risk. Patient complaints against licensed professionals may be filed with the applicable state licensing board governing the professional. Patients may also pursue complaints against providers in state civil courts.

The National Practitioner Data Bank maintains a database on medical malpractice payments and certain adverse actions related to healthcare practitioners, providers and suppliers (eg, adverse licensure and clinical privileges actions, and exclusions from federal healthcare programmes). Healthcare entities granting clinical privileges or employment to a practitioner may query the database for any information reported about such practitioner.

Complaints relating to a patient's protected health information may be reported to the Office for Civil Rights (OCR), a federal agency within the US Department of Health and Human Services. If OCR finds that a patient's protected health information was disclosed or misused, the responsible provider will have a period of time to correct the violation. OCR also may initiate enforcement proceedings and impose civil monetary penalties.

DATA PROTECTION, PRIVACY AND DIGITAL HEALTH

Responsible authorities and applicable legislation

25 Which authorities are responsible for compliance with data protection and privacy, and what is the applicable legislation?

The federal and state governments are primarily responsible for compliance with data protection and privacy. On the federal level, the key laws that govern healthcare data are the Health Insurance Portability and Accountability Act (HIPAA) privacy, security and enforcement rules. 45 C.F.R Parts 160 and 164. The Office for Civil Rights is the federal agency that enforces HIPAA.

States also may have laws protecting data. HIPAA pre-empts state laws to the extent they are contrary to or less protective than HIPAA. HIPAA does not pre-empt more stringent state laws, however, that provide greater privacy protections than HIPAA.

Other federal data protection laws include the Gramm-Leach-Bliley Act, which protects the privacy of consumers' financial information, and the Children's Online Privacy Protection Act and associated rule that protect the online privacy of minors under age 13.

Requirements

26 What basic requirements are placed on healthcare providers when it comes to data protection and privacy? Is there a regular need for qualified personnel?

The HIPAA Privacy Rule creates limits on use and disclosure of protected health information (PHI), establishes safeguards for the protection of such information, and provides individuals with certain rights to control and access their health information. 45 C.F.R. Part 160 and Subparts A and E of Part 164. To protect the confidentiality of and access to health information, the HIPAA Security Rule creates standards for the implementation of administrative, physical and technical safeguards. 45 C.F.R. Part 160 and Subparts A and C of Part 164.

The three types of entities covered under HIPAA, referred to as 'covered entities', are health plans, healthcare clearinghouses and healthcare providers that conduct standard healthcare transactions electronically. HIPAA further governs business associates of covered entities and their subcontractors. Covered entities and their business associates are required to implement reasonable and appropriate policies and procedures to comply with the Privacy and Security Rules. Such policies address aspects of data privacy including when a covered entity can disclose PHI without patient authorisation, notifications of privacy or security breaches, individual requests to restrict disclosure of or amend information, a person's right to access their PHI, patient authorisations, security incidents, workforce training and non-compliance.

Covered entities must have both a privacy official and security official who is responsible for developing and implementing the policies and procedures. The workforce must be trained on the policies and procedures, and covered entities are expected to have appropriate disciplinary procedures in place for employees who fail to comply with these policies and procedures.

Regulatory guidance

27 Have the authorities issued specific guidance or rules for data protection and privacy in the healthcare sector?

The HIPAA Privacy Rule creates national standards for the protection of individually identifiable health information. 45 C.F.R. Part 160 and Subparts A and E of Part 164. The HIPAA Security Rule requires covered entities to implement appropriate administrative, physical and technical safeguards to ensure the confidentiality, integrity and security of electronic PHI. 45 C.F.R. Part 160 and Subparts A and C of Part 164. The HIPAA Enforcement Rule, which was subsequently strengthened by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. § 139w-4(0)(2)), creates a civil and criminal enforcement framework for violations of HIPAA. 45 C.F.R. Part 160, Subparts C, D and E. See also, HIPAA Basics for Providers: Privacy, Security, & Breach Notification Rules.

Common infringements

28 What are the most common data protection and privacy infringements committed by healthcare providers?

A common type of data privacy infringement would include ordinary course errant communications in which patient information is included. These communications include healthcare correspondence addressed to the incorrect recipient in either hard copy or email form. To the extent that patient information is received by an unintended recipient, the healthcare provider must determine whether the nature of the disclosure, identity of the recipient and other factors suggest that the health information contained in the communication has been compromised. To the extent circumstances suggest that the errant communication was actually viewed by an unintended recipient, a data privacy infringement or breach, is understood to have occurred.

Another form of ordinary course communication that may result in a data privacy infringement is the use of unencrypted electronic communications containing health information. To the extent that an unencrypted communication may result in access to that information by a third party, a data breach may result. If a healthcare provider becomes aware that unencrypted communications have occurred and may have resulted in third-party access, that provider must evaluate the probability that the health information contained in the communication has been compromised.

Other forms of common data privacy infringements include impermissible access by a third-party actor with unlawful intent. These instances are traditionally considered to be a data breach, and may include impermissible access in either physical or electronic form. Physical breaches may include stolen laptops, lost smartphones and impermissible viewing of hard-copy data files. Electronic breaches may include instances of malware use, phishing, ransomware, or traditional hacking, either alone or in combination. Where a healthcare provider understands that it may be a target of any of the above, it has an obligation to investigate and not only determine the source of the potential data breach, but to mitigate against the harmful effects of the same.

Digital health services

29 Which authorities regulate the provision of digital health services and what is the applicable legislation? What basic requirements are placed on healthcare providers when it comes to digital health services?

The provision of healthcare services by providers through telehealth/telemedicine was a growing trend in the US that greatly accelerated during the covid-19 pandemic. As individual states govern the licensing of healthcare providers and the provision of healthcare services within their state, each state has also created its own telehealth legal scheme to govern the provision of such services by a provider. Generally, a provider must be licensed to provide care in the state in which the patient receiving telehealth services resides (which can create legal hurdles to the interstate practice of telehealth). With respect to payment for telehealth services, public (Medicare/Medicaid) and private insurers set standards that must be met under their respective programmes before they will reimburse a provider for telehealth services.

Digital health tools that are used in the provision of healthcare are also greatly expanding. Remote patient monitoring devices, robotics, and other consumer devices are typically regulated by the Federal Food, Drug and Cosmetic Act (FD&C Act); such laws are enforced by the Food and Drug Administration, U.S.C. Title 21. On the other hand, digital health services provided through consumer devices such as 'smart watches' or apps on a consumer's phone are typically regulated by the US Federal Trade Commission and/or the US Department of Health and Human Services. The agencies have issued joint guidance regarding online data collection. HIPAA compliance is also implicated by telehealth services. Regardless of the mode of service delivery, healthcare providers, insurers and certain other entities must maintain the privacy and security of patient information held and transacted.

UPDATE AND TRENDS

Key developments

30 Are there any current or foreseeable legislative initiatives, court cases, laws or other rules that affect the regulation of healthcare? What has recently changed (or will likely change), and what steps need to be taken in preparation?

The implementation of healthcare policy via agency regulations is often subject to challenge using the Administrative Procedure Act (5 U.S.C. §§ 551-559). The US Supreme Court will hear *Loper Bright Enterprises v Raimondo* during its 2023-24 term, which could have wide-ranging implications for health law and policy. Specifically, the Court will consider whether to overturn the 1984 decision *Chevron U.S.A., Inc. v Natural Resources Defense Council, Inc.* (467 U.S. 837). *Chevron* held that where a statute's language is ambiguous, courts must give deference to a federal agency's interpretation of the statute. If the Court overturns *Chevron*, it will have a significant impact on the ability for federal agencies to implement and regulate healthcare policy.

Price transparency policies continue to receive support at both the federal and state level as a means to empower healthcare consumers and lower the cost of care. The Affordable Care Act requires each hospital operating in the US to establish and make public its standard

charges for items and services. The Price Transparency Requirements for Hospitals to Make Standard Charges Public final rule requires hospitals to also make public their payor-specific negotiated rates, minimum and maximum negotiated rates, and cash price for all items and services, including individual items and services and service packages. The Centers for Medicare & Medicaid Services has begun to take enforcement actions against hospitals for non-compliance with the price transparency requirements and has updated its enforcement process to shorten the average time by which hospitals must come into compliance with these requirements.

Congress passed the No Surprises Act (NSA) to address costly surprise medical bills for out-of-network healthcare. Pub. L. 116-260. Consequently, the NSA compels health plans to hold patients harmless from surprise medical bills. Providers and payers enter a 30-day negotiation period to settle disputed out-of-network claims. If the parties are unable to reach a settlement, either party may initiate an independent dispute resolution process that has been subject to legal challenges since the NSA became law. The NSA further requires health plans to make publicly available, online up-to-date directories of their in-network providers, and to provide a price comparison tool for enrolees.

An emerging issue in the digital health field is the prohibition of 'geofencing' around healthcare facilities. Geofencing is a tool that advertisers use to collect data on individuals by tracking their physical location, such as sending consumers a coupon when they are near a particular restaurant. With respect to healthcare, tracking data could be used for other purposes, such as targeted ads or to identify what types of health services individuals have likely received. To help protect patients' privacy, thus far, New York, Connecticut, Nevada and Washington have adopted bans on the use of geofencing to track individuals' healthcare data. Other states are likely to follow.

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