

HEALTHCARE FINANCING AND REIMBURSEMENT: A GLOBAL REVIEW OF MAJOR TOPICS AND TRENDS

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LAWS AND REGULATIONS ON HEALTHCARE FINANCING AND REIMBURSEMENT

1. Please provide a bird's eye view on the healthcare economy, indicating, in general terms, the role of the government (public healthcare) and private actors (private healthcare).

The United States healthcare system is regulated by the federal, state, and local governments. The federal government is generally responsible for setting payment and coverage policies, rules, and regulations related to government-funded health plans. Individual states also play a large role in regulating private insurers and may also choose to *expand* federal initiatives beyond the 'floor' set by the US Congress and federal agencies. Under federal law, most residents and their dependents are required to have either public or private health insurance coverage, however, there is no longer a tax penalty at the federal level for non-compliance. Several states (for example, California, New Jersey, and Massachusetts) have enacted secondary mandates through which non-exempt individuals may incur monetary penalties.

Healthcare is financed by both governmental programs and private actors, including (1) Medicare, a federal health insurance plan for individuals 65 or older and those with certain disabilities or conditions, which offers 'Original Medicare' (Medicare Part A and Part B) and a managed care option through Medicare Advantage (Medicare Part C), (2) Medicaid, a joint federal-state program that helps to cover medical expenses for eligible populations, including persons with limited income and assets, (3) 'commercial insurance' offered through private health insurance companies, engaged either directly by individuals or indirectly through their employer, and (4) individuals privately paying for healthcare. Nearly all healthcare providers in the United States are private and voluntarily agree to accept reimbursement from private commercial insurers, Medicare, and Medicaid at their discretion.

For both public (Medicare or Medicaid) or commercial insurance, individuals typically contribute to the cost of their healthcare via monthly premiums and/or co-payments (for certain services, supplies and equipment, and medications). As noted above, employers may sponsor health insurance for their employees, with the employer often paying a portion of the cost of commercial insurance. Employer-sponsored health insurance is a leading source of coverage for non-Medicare-eligible individuals, and the quality of coverage varies greatly across workplaces.

2. Please provide a high-level overview of the legal framework regarding healthcare financing and reimbursement.

At the federal level, healthcare financing and reimbursement is primarily impacted by statutes (and related regulations) under the Social Security Act (SSA) and other federal laws, including

the Anti-Kickback Statute (AKS) and Stark Law, the Affordable Care Act (ACA), the False Claims Act (FCA), and the Employee Retirement Income Security Act (ERISA).

The AKS is an especially broad criminal statute meant to avoid financial influences that can impact clinical decisions and affect patient care, healthcare costs, and market competition. In particular, the statute prohibits any entity (ie, including patients) from soliciting or receiving remuneration for the (1) referral or order of, (2) purchase or use of, and (3) arrangement for or recommendation of, healthcare items and services reimbursed by a federal health care program (eg, Medicare and Medicaid), outside of enumerated safe harbors. Sanctions can be severe and may include felony convictions, including prison time, civil, and administrative penalties, such as excluding convicted providers from reimbursement through federal health care programmes. As a result, the statute, in part, helps to preserve the integrity and quality of healthcare and federal funds by curbing overutilisation.

In contrast, the Stark Law is a much narrower civil statute that generally prohibits physicians (and immediate family members) from making referrals to entities with which they have a financial relationship, for ‘designated health services’. In turn, referee entities are also prohibited from billing individuals and third-party payors for such services. Unlike the AKS, the Stark Law only applies to certain providers (eg, MD/DOs, DDSs, and chiropractors). Nurse practitioners and physician assistants, for example, are excluded. The FCA is another major civil statute that prevents entities from submitting false or fraudulent claims to Medicare or Medicaid for reimbursement. The FCA works in conjunction with the AKS and Stark Law, such that claims resulting from violations under either statute may also be considered ‘false or fraudulent’ under the FCA.

The ACA is a healthcare reform law that sought to expand and improve healthcare access, especially for low-income, uninsured, and otherwise disadvantaged persons. As discussed below, the ACA, in part, created a centralised marketplace (Marketplace) for individuals to purchase affordable healthcare and removed barriers to coverage for persons with pre-existing conditions. For employer-sponsored insurance plans, ERISA provides various protections for enrollees, such as setting minimum standards and regulating appeal processes for participant claims. Unlike Medicare and Medicaid, as discussed below, the Employee Benefits Security Administration under the US Department of Labor is primarily responsible for enforcing ERISA.

States also enact their own varying laws related to healthcare financing, particularly in connection to private insurance regulation, state Medicaid programmes, and, in some states, Corporate Practice of Medicine (CPOM) legislation. CPOM statutes prohibit non-physician-owned entities from providing medical and licensed healthcare (eg, psychologists, speech therapists, and dentists) or employing providers of such healthcare services. For example, California has enacted particularly stringent CPOM restrictions and continues to generate significant case law around the topic.

3. What are the key regulators and supervisory bodies regarding healthcare financing and reimbursement?

As noted above, a wide variety of government actors are involved in regulating and supervising healthcare financing. However, the three branches of the federal government (ie, legislative, executive, and the judiciary) have remained especially influential in establishing and regulating healthcare financing and insurance carriers. The US Congress, for example, is

responsible for enacting and amending key legislation. In 1950, Congress first acted to allow the federal government to participate in financing state payments made on behalf of persons receiving public assistance for healthcare costs. Ultimately, their efforts culminated in Title XVIII and Title XIX of the Social Security Act, which established the Medicare and Medicaid programmes, respectively, and continues to provide the statutory authority for both regimes today.

Pursuant to acts of Congress, the President and federal agencies produce regulations, guidance, and executive orders to implement legislation and generate policy. In particular, the Centers for Medicare & Medicaid Services (CMS), within the US Department of Health and Human Services (HHS), is the federal agency that, in part, runs the Medicare, Medicaid, and the Marketplace. Between the Medicare and Medicaid programs, CMS is the single largest payer for healthcare in the United States, and issues federal rules, memorandums, and other compliance documents that impact providers, suppliers, enrollees, and health plans.

The US federal courts, in turn, serve to safeguard the respective powers and responsibilities of the legislature, President, and executive agencies by ensuring each actor is operating within the scope of their legal authority. For example, the courts may prevent CMS from implementing healthcare regulations beyond its authority under the Social Security Act.

Certain public insurance healthcare finance and reimbursement disputes are typically subject to an administrative review process, including review of Medicare policies by Administrative Law Judges (ALJs). Similarly, Medicaid challenges are often brought before state-run Medicaid agencies' tribunals.

4. Has there been a change with healthcare financing and reimbursement as a consequence of the Covid-19 pandemic?

The Covid-19 pandemic did not fundamentally alter the current healthcare financing scheme. However, in response to the pandemic, commercial and public insurers expanded regulatory reimbursement flexibilities. Many such flexibilities expired after the US declared an end to the Public Health Emergency. The pandemic resulted in a significant increase in health care expenditures, federal spending (eg, related to Covid-19 costs and lost healthcare revenue), and a host of additional temporary and permanent changes to the operation of the Medicaid and Medicare programs.

For example, the federal government created the Provider Relief Fund to make payments to eligible providers who had lost revenues attributed to the pandemic. The Families First Coronavirus Response Act (FFCRA) also authorised a 'continuous enrollment condition' for Medicaid beneficiaries, such that states were required to maintain coverage for otherwise ineligible individuals as a condition on additional federal funding. This stay has since ended and states have resumed their normal termination processes. Similarly, in response to the increased need for telemedicine and telehealth services, HHS made a number of legislatively authorised changes to increase access for Medicare recipients – some of which, such as allowing Medicare patients to receive in-home mental and behavioural telehealth services, in part, by removing geographic restrictions on telehealth providers (ie, such that a provider licensed in a particular state need not be physically present in that state to render services), have become permanent.

5. Who has access to the healthcare system as a patient on the one side and as a medical service provider/supplier of medical goods on the other side? What are the conditions of admission?

In general, the provision of emergency medical care is compulsory for all individuals in the United States, regardless of their insurance status. Under the Emergency Medical Treatment and Labor Act (EMTALA), hospital emergency departments that receive Medicare funds (ie, nearly all hospitals in the US) are required to provide all persons with: (1) a medical screening for ‘emergency medical conditions’; (2) treatment to stabilise such conditions; and (3) transfer to alternative facilities, as needed to provide an appropriate level of care. However, generally, physicians are otherwise permitted to choose whether or not to treat a patient.

As noted in prior sections, access to healthcare coverage varies based on the source of funding, which each have their own set of eligibility requirements. Without access to healthcare insurance, the out-of-pocket cost of medical services and prescription drugs is often prohibitive.

Medicare eligibility is determined by age and disability status. Medicare, in part, includes both hospital inpatient (ie, ‘Part A’) and medical (ie, ‘Part B’) insurance coverage. Each part includes slightly different enrollment processes and requirements, but, in general, it is available to individuals: (1) 65 years or older; (2) with End-Stage Renal Disease that regularly receive dialysis or have undergone a kidney transplant; (3) with Amyotrophic Lateral Sclerosis, the first month they are entitled to Social Security or Railroad Retirement Board (RRB) benefits; or (4) with other disabilities, who are entitled to Social Security or RRB benefits for varying periods of time.

As a federal-state joint programme, Medicaid eligibility depends on the specific state of residence. The Social Security Act requires states to include certain populations, like pregnant women, deemed newborns, and low-income families as a condition of participating in Medicaid (ie, and receiving federal funds). However, the ACA further authorised states to expand Medicaid for adults at or below 138 per cent of the federal poverty line, which currently sits at \$15,060 USD for a single-person household. While states are not required to do so, most have. Coverage typically only applies to services rendered in the originating state, outside of emergency medical treatment while traveling, for example. To note, as of June 2025, the Republican party continues to work on advancing a significant bill that, in part, proposes multi-billion-dollar cuts to Medicaid and the imposition of work requirements for adults without dependents or disabilities, up to the age of 64. For example, current iterations would require at least 80 hours of work per month for most individuals. Although this bill, along with other proposed Medicaid cuts, is not yet effective, it signals a likely and impending shift in the accessibility of Medicaid.

Through the ACA, federal and state healthcare exchanges (ie, the Marketplace or state-specific marketplaces) were created for direct consumer participation. There, individuals, families, and small businesses can, in part, search for, compare, and purchase private commercial insurance. Individuals may also purchase coverage through the general insurance market. In an effort to expand and protect equal access to healthcare, ACA-compliant plans offered on the Marketplace, or otherwise, are prohibited from denying coverage or charging more because of a pre-existing condition or discriminating on the basis of protected classes, including race, colour, national origin, sex, age, or disability status. However, non-ACA-compliant plans, such as ‘short-term, limited duration insurance’ are largely exempt from

such protections, and individuals may be denied or limited coverage based on pre-existing conditions.

On the provider side, providers and suppliers must enroll in government-sponsored programs (ie, Medicare and Medicaid) in order to receive reimbursement for services provided to patients insured by those programs. Additionally, providers may contract with health plans, including private insurance and certain Medicare and Medicaid plans (eg, Medicare Advantage and Medicaid Managed Care) to become ‘in-network’ providers. In-network providers may agree to charge pre-negotiated (often lower) rates for plan members, which, in turn, allows patients to pay less in co-insurance costs than they would for out-of-network providers.

There are often additional barriers to healthcare coverage for non-citizens, or those residing outside legal channels in the United States. For example, only non-incarcerated US citizens or legal residents can access insurance through the Marketplace. Similarly, Medicaid enrolment is also restricted to US citizens and ‘qualified non-citizens’, such as permanent residents. Individuals otherwise traveling to the US may receive medical care, but the government does not offer visitor benefits. Visiting patients are responsible for coordinating payment out-of-pocket or through their insurance policy.

Lastly, there is specialised coverage and care for certain US military veterans through the Veterans Health Administration (VA). In particular, veterans that served in active military, naval, or air service duty without dishonourable discharge may qualify pursuant to additional eligibility requirements. The VA is, in part, funded by federal budget allocations, and patients can receive free healthcare for ‘service-connected’ illnesses, injuries, and disabilities. Veterans may have to contribute to their healthcare costs for non-service-connected care, however, exact cost-sharing rates are determined based on factors like income, service history, disability rating, and special awards like the Medal of Honor.

However, under the second Trump administration, the VA has experienced a wave of staffing and funding cuts as part of the Department of Government Efficiency’s (DOGE) push to ‘reduce waste’ throughout the federal government. As a result, VA entities nationwide have reported decreased access to care, in part, due to discontinued research tools and clinical trials, some of which provided veterans with access to key cancer treatments.

HEALTH INSURANCE FINANCING AND COVERAGE

6. How are health insurance carriers financed? How are premiums determined?

Medicare, state Medicaid programs, and private health insurance are each financed differently.

Medicare is financed by two federal trust funds, the Hospital Insurance (HI) Trust Fund and the Supplementary Medical Insurance (SMI) Trust Fund. In turn, each trust fund is capitalised by a variety of taxes, congressional funds, enrollee premiums, and accrued interest from the fund itself. For example, the HI Trust Fund draws from payroll taxes paid by most employees and employers, regardless of whether the individual payer is enrolled in Medicare. The SMI Trust Fund, in part, uses premiums paid by individuals with Medicare Part B (ie, outpatient medical) and Part D (ie, prescription drug) coverage. Premiums are set annually by the federal government and, in some portions, are based on individual income. Medicare Part A (ie, hospital insurance) coverage is free for most enrollees, aside from inpatient co-

payments and an annual deductible. Part B premiums start at \$185 USD/month for 2025 and increase based on an enrollee's modified adjusted gross income for the tax year two years prior. Medicare patients generally pay a 20 per cent co-payment for most healthcare services.

Medicaid programmes are jointly financed by the federal and state governments. Federal contributions to each state depends on: (1) the costs that the state incurs from provider reimbursements and administering the programme; and (2) the federal medical assistance percentage (FMAP), where states with lower per capita incomes compared to the national average receive more federal funding. To that end, states that spend more on their Medicaid programmes also receive more federal dollars. In addition, the federal government regulates the amount states can charge for premiums. For example, premiums are not permitted for individuals with incomes below 150 per cent of the federal poverty line.

Private insurers rely on enrollee premiums and cost-sharing (ie, co-insurance or co-payments) to fund their plans. Although individual states regulate and review premium costs, doing so has proved notoriously difficult. For example, only some states have the legal authority in place to limit premium increases or the resources to conduct such reviews. To that end, premium rates have risen significantly across the country over recent years. In an effort to combat such increases and aid state governments, the federal government has provided states with Health Insurance Premium Review Grants under the ACA.

In general, fee-for-service reimbursement models (ie, where providers are paid for each individual service, test, or treatment), including Medicare Part A and Part B, are the most common healthcare financing scheme in the United States. Fee-for-service is often critiqued for discouraging coordinated patient care and incentivising duplicative or unnecessary services and testing. To that end, as discussed below, there has been a significant push toward value-based care as an alternative reimbursement model.

7. How is coverage of medical services by health insurance carriers regulated? Are there differences in coverage for in person medical appointments and telemedicine appointments?

See question 3, above.

Additionally, Medicare makes coverage decisions based on whether the treatment is 'reasonable and necessary'. Medicare coverage of services, medications, and items is based on: (1) federal and state laws; (2) national coverage determinations (NCDs) by CMS; and (3) local coverage determinations (LCDs) from CMS-contracted Medicare Administrative Contractors (MACs) assigned to geographic regions. NCDs are binding on all states, along with administrative actors such as internal review bodies, ALJs, and MACs. CMS-issued NCDs are derived from original CMS research, external consultancies, and public participation, and outline 'criteria and coverage limitations' for medical items and services. In turn, MACs issue LCDs that determine coverage for its geographic area, including whether a services, procedure, or item is 'medically necessary'.

Under Medicare Advantage (Medicare Part C), health plans must cover all Part A and Part B services but can offer additional benefits, including Part D drug coverage and wellness programmes or discounts. As managed care organisations, they are also permitted to use certain utilisation management tools and controls, such as requiring prior authorisation for some services.

Medicaid programmes define coverage on a state-by-state basis pursuant to broad federal guidelines. For example, the federal government requires certain mandatory benefits such as inpatient/outpatient hospital, home health, and laboratory services. States may elect to offer additional benefits like physical or occupational therapy.

Generally, both Medicare and Medicaid plans cover telemedicine services, though there can be additional restrictions, such as geographic and ‘originating site’ requirements. For example, although most Covid-19 flexibilities have since ended, Medicare will cover services included on the ‘telehealth list’. The telehealth list is updated annually by CMS, but generally includes services like therapy, urgent care, and treatment for reoccurring conditions. States have significant control over whether telemedicine is covered under their respective Medicaid programs, however, they are encouraged by CMS to permit clinically appropriate telehealth services. Common Medicaid limitations include restrictions on the conditions that may be monitored via telehealth, the services offered, and specialty constraints (eg, only permitting case management or mental health services via telehealth).

Private insurance coverage is regulated similarly to Medicaid such that ‘covered benefits’ vary across individual plans and carriers but are subject to state and federal requirements. Most individual and small group policies on the Marketplace, for instance, must include ‘essential health benefits’. Auxiliary dental or vision coverage is not required, but certain carriers may choose to include such benefits. Many states also require private insurance plans to cover telehealth visits, though these mandates vary. Notably, under the ACA, insurance carriers are subject to the ‘Medical Loss Ratio’, which requires them to spend at least 80 per cent of the funds from premium payments (or 85 per cent for companies that sell to large groups) on healthcare costs or quality improvement. If an insurer does not meet the Medical Loss Ratio, they must provide premium rebates to enrollees.

There have also been efforts to advance access to mental health and addiction treatment via reimbursement regulations. For example, in September 2024, the Departments of Treasury, Labor, and Health and Human Services collectively issued final rules around non-quantitative treatment limitations (NQTL) (ie, categorical or qualitative restrictions on services). In particular, these rules prevent health insurance issuers from using NQTLs that limit access to mental health or substance abuse disorder benefits more than other covered healthcare benefits.

HOSPITAL SECTOR

8. How are services provided by hospitals in the stationary (inpatient) and ambulatory (outpatient) settings financed and reimbursed?

As described above, inpatient and outpatient financing for hospital services, including rate determinations, vary based on the health insurance source. Hospital services for Medicare enrollees are reimbursed by CMS based on set rates updated annually by the agency. Most rates are set prospectively and hospitals are generally paid fixed rates for each service or group of services that vary by treatment and diagnosis, and may be augmented by additional factors, such as regional cost differences for labour, operations, etc.

Professional organisations and advisory groups play an important role in setting CMS reimbursement rates. In particular, the American Medical Association (AMA) houses the ‘Relative Value Scale Update Committee’ (RUC), which provides annual recommendations on the value of Medicare billing codes. Although CMS is not bound to their

recommendations, in practice, they are nearly all adopted. Similarly, the Medicare Payment Advisory Commission (MedPAC) counsels Congress on Medicare-related issues, including reimbursement.

Medicaid programme reimbursement rates vary across states but are typically calculated according to either: (1) the resource-based relative value scale, a formula used by Medicare to calculate physician fees; (2) a percentage of Medicare-determined fees; or (3) a separate fee schedule developed by the state. Likewise, inpatient and ambulatory hospital services are paid via set rates, generally based on full cost reimbursement, the number of days a patient is treated, specific diagnoses, or using other fee schedules.

As a corollary to MedPAC, the Medicaid and CHIP Payment and Access Commission (MACPAC) advises Congress, federal agencies, and the states on Medicaid-related issues, including payment and coverage. Provider rates under Medicaid are frequently lower than those for Medicare enrollees, which has historically led to decreases in the number of providers that will treat Medicaid patients.

As previously noted, private insurance reimbursement, including to hospitals, is generally determined by pre-negotiated in-network rates or out-of-network costs. Out-of-network reimbursement is typically based on the ‘usual and customary rate’ for a particular area, or much like Medicaid, using a percentage of the relevant Medicare rate. However, despite differences in network rates, insurance carriers may not charge patients more via co-insurance or co-payment fees for receiving emergency care at an out-of-network hospital.

Under a recent ‘price transparency’ rule, most group health plans and group or individual health insurers are required to publish in-network rates for all covered items and services, allowed amount and billed charges for out-of-network providers, and an online price comparison tool that can generate an estimate of cost-sharing responsibilities for all items and services.

9. How are the prices of such services determined? How is economic efficiency controlled?

As described above, service pricing varies depending on whether a patient is covered by Medicare, Medicaid, or a private insurer and is based on a variety of factors, including fee schedules, costs incurred, and auxiliary recommendations (See question 8, above).

HEALTHCARE PROVIDERS IN PRIVATE PRACTICE

10. How are services provided by physicians, therapists, laboratories and other service providers financed and reimbursed?

As discussed above, nearly all providers in the United States, including hospitals, are private and reimbursed by participating with Medicare, Medicaid, and/or private insurers. Therefore, most healthcare services provided by physicians, therapists, laboratories, and other outpatient practitioners are financed and reimbursed in the same way as described above (See question 8, above).

There is a relatively small but growing subset of healthcare providers that operate outside of the health insurance system and offer care that is directly and fully paid by patients, typically via annual or monthly membership fees.

<p>11. How are the prices of such services determined? How is economic efficiency controlled?</p>
<p>For the same reason, the prices of such services are determined and controlled in the same way as described above (See question 8, above).</p>
<p>PHARMACEUTICALS AND MEDICAL DEVICES</p>
<p>12. How are pharmaceuticals and medical devices financed and reimbursed?</p>
<p>Medicare participants can obtain prescription drug coverage regardless of whether they are enrolled in ‘Original Medicare’ (ie, Part A hospital coverage and Part B medical insurance) or a Medicare Advantage plan (ie, Part C ‘bundled’ coverage) through the optional Medicare Part D prescription drug coverage. Under Original Medicare, pharmaceutical and device coverage is not generally included except for treatments prescribed during inpatient admission or administered at a physician’s office or ambulatory setting, such as infusion pumps and intravenous drugs, which is reimbursed as a Part A or Part B service, as described above. Generally, individuals with Medicare Advantage are offered participation in Medicare Part D through their Medicare Advantage health plan, though some medications may require pre-authorisation. CMS has also taken additional steps to increase access to ‘emerging technologies’ by expediting coverage of ‘breakthrough devices’, which could be provided to certain Medicare enrollees, even if they do not presently meet the ‘reasonable and necessary’ standard under the Social Security Act. Additionally, most key vaccines (eg, seasonal flu, Covid-19, etc.) are free for both Medicaid and Medicare participants.</p> <p>For Medicaid participants, federal Medicaid law does not require pharmaceutical coverage. However, currently, all states voluntarily provide prescription drug coverage to ‘categorically eligible’ enrollees (ie, pregnant individuals), along with many other optional participants. Importantly, manufacturers must participate in the Medicaid Drug Rebate Program (ie, where such manufacturers must provide rebates to state Medicaid programs) with CMS and HHS, which includes reporting certain pricing data, to receive reimbursement for Medicaid enrollees.</p> <p>Under the Veterans Health Care Act, manufacturers of ‘covered drugs’ (ie, excludes generic drugs) must also enter into agreements with the VA to receive reimbursement from, in part, the VA, State Medicaid programs, Medicare Part B, and other entities that receive funds under the Public Health Service Act.</p> <p>Similarly, most private insurance plans provide or offer drug coverage. As discussed above, individual and small-group ACA-compliant plans must include such coverage as an ‘essential benefit’. Large group plans (ie, for employers with a certain number of employees, usually 51 and above or 101 and above, depending on the state) and self-insured plans are not subject to the same requirement, though most plans offer pharmaceutical benefits regardless. Additionally, individual states may require private insurers to cover certain types of prescription drugs. For example, the majority of states require pharmaceutical coverage to include contraceptive drugs (eg, oral birth control pills) and devices.</p>
<p>13. How are the prices of pharmaceuticals and medical devices determined? How is economic efficiency controlled?</p>

The United States does not have a uniform fee schedule or drug pricing regime across payers. Again, the cost of individual drugs and devices depends on whether the manufacturer is receiving reimbursement from Medicare, Medicaid, or a private insurer.

Drugs covered by Medicare Part B (ie, those typically administered in a professional setting) are typically paid according to the Average Sales Price (ASP), plus a six per cent reimbursement rate. Generally, the ASP is calculated using the total value of sales to all purchasers in the United States divided by the total number of units sold, excluding sales from the Medicaid Drug Rebate Program ‘best price’ (ie, the lowest price offered) and other nominal sales.

Medicare prescription drug coverage (known as Medicare Part D) is offered as an option to Medicare beneficiaries. Prescription drug plans under this benefit are offered by insurance companies and other private companies approved by Medicare. All plans must cover a wide range of prescription drugs that people with Medicare take, including most drugs in certain protected classes, like drugs to treat cancer, HIV/AIDS, or depression. A plan’s list of covered drugs is called a ‘formulary’, and each plan has its own formulary. Furthermore, Part D has been redesigned to, in part, create a \$2,000 out of pocket cap for patients, limit monthly insulin costs to \$35/month, and institute a Manufacturer Discount Program for Medicare enrollees. Pharmacy benefit managers (PBMs) also play an important role in drug reimbursement as the go-between for insurers and pharmacies and are responsible for reimbursing pharmacies, on behalf of insurers, for the drugs that they dispense to patients.

In addition, the Inflation Reduction Act of 2022 mandated global changes to Medicare price negotiation, rebate, and reimbursement processes. For example, the federal government will make ‘maximum fair price’ determinations (ie, creating an upper limit to competitive pricing) for selected Part D and Part B drugs and require rebates to be paid to Medicare if the net price of a drug increases faster than inflation. Otherwise, Part D plans have negotiated directly with manufacturers and pharmacies, which often leads to differing prices across insurers and individual plans.

At a high-level, Medicaid drug reimbursement rates are determined based on federal and states policies related to costs throughout the manufacturer, wholesaler, pharmacy, and pharmacy benefit manager to Medicaid pipeline. Most states have adopted maximum allowable costs for Medicaid payment, and the federal government has established a ‘federal upper limit’ (ie, a cap on federal funding) for generic drugs, which forces states to limit their own expenditures. Non-generic drugs (ie, those with no alternatives available) and other drugs not subject to the federal upper limit and/or state maximum allowable cost are controlled by limiting state payment amounts to the ‘actual acquisition cost’ (with a professional dispensing fee) or the usual and customary charge, whichever is lower.

Outside of Medicare and Medicaid, private insurance drug prices are set by negotiations with manufacturers pursuant to state legislation. States have enacted hundreds of drug pricing laws in recent years related to key reimbursement topics, including price reporting, cost-sharing caps, pharmacy benefit managers, and drug payment limits. For example, in California, manufacturers must provide advance notice of price increases for certain drugs to the state and registered private purchasers.

In addition to the pricing schemes described above, the second Trump administration recently introduced an executive order on 12 May 2025, that would implement ‘most-favored nation’ pricing in the United States for prescriptions drugs. The order, in part, includes a

mandate to the Secretary of HHS to ‘establish a mechanism through which American patients can buy their drugs directly from manufacturers who sell to Americans at a “Most-Favored-Nation” price.’ In the event drug manufacturers fail to offer most-favored-nation pricing, the order subsequently directs the Secretary of HHS to: (1) propose rules that impose most-favored-nation pricing; and (2) take other aggressive measures to significantly reduce the cost of prescription drugs to the American consumer and end anticompetitive practices. Although HHS and CMS have indicated that they are taking steps to implement these directives, the regulatory and practical outcomes remain to be seen.

Relatedly, another executive order, ‘Lowering Drug Prices by Once Again Putting Americans First’, purports to ensure accurate Medicaid drug rebates, promote innovation in Medicaid drug payment methodologies, and make insulin and injectable epinephrine more affordable for low-income individuals, through a series of regulatory actions. Like many of the recent orders, HHS has been charged with generating guidance and recommendations to advance these objectives, though, none have been finalised to date.

Similarly, beginning in February 2025, the Trump administration has threatened tariffs of 25 per cent or higher on pharmaceutical drugs, ingredients, and derivative products. Thereafter, the US Department of Commerce also initiated a Section 232 investigation to assess the national security implications of importing pharmaceuticals and pharmaceutical ingredients. However, as with the above, the implications of proposed tariffs on pharmaceutical imports and drug pricing are still unfolding.

LITIGATION INVOLVING HEALTHCARE FINANCING AND REIMBURSEMENT

14. Please provide a high-level overview of major litigation topics and landmark cases regarding healthcare financing and reimbursement.

Litigation relevant to healthcare financing and reimbursement generally falls into one of two categories: Administrative Procedure Act (APA) litigation or other reimbursement-related challenges.

The APA establishes procedures that federal agencies must follow, such as rulemaking and adjudication processes, and provides the legal basis for courts to set aside agency actions as unlawful. This is why the APA is a significant authority for CMS and HHS on healthcare financing and reimbursement regulation.

On July 28, 2024, the Supreme Court of the United States made a landmark decision on the APA standard of review in *Loper Bright Enterprises v Raimondo*. The Supreme Court ruled against the lower court and, in the process, overturned *Chevron v National Resources Defense Council*. *Chevron* once provided the framework for APA analysis and, in part, afforded federal agencies deference so long as their regulation was a ‘reasonable interpretation’ of the relevant statute. Although the underlying subject matter itself concerned an interpretation of the Magnuson-Stevens Fishery Conservation Act and did not touch healthcare directly, the end of the *Chevron* framework signals new regulatory challenges for federal agencies and is likely to have a significant impact on healthcare financing, reimbursement, and other related administrative challenges.

In addition to the APA, reimbursement litigation and appeals are generally governed by the Medicare Act in Title XIX of the Social Security Act, Medicare regulations, the Federal

Register, and various agency manuals and guidance. Before filing with a federal court, most cases are heard and appealed administratively. The Provider Reimbursement Review Board, for example, hears Medicare determination appeals from health care providers, and CMS may review such decisions. As noted above, Medicare claims appeals are also heard by an ALJ and may undergo several levels of administrative appeals.

Once there is an adverse decision from administrative reviews, or an expedited judicial review from the relevant administrative body, cases can be filed in federal court, appealed to Circuit Court, and, in limited cases, reach the Supreme Court.

RECENT DEVELOPMENTS AND TRENDS

15. What are the recent developments and trends for the next few years? Please outline any unresolved issues, proposed changes, or trends for healthcare financing and reimbursement and briefly indicate how these may foreseeably affect the medical sector in the near future.

The U.S. is experiencing a trend of fast-growing healthcare costs, especially in connection to its aging population. To that end, as more patients age into Medicare, there are concerns that the Medicare trust funds will be depleted and, ultimately, may not be sustainable on a long-term basis. Furthermore, as discussed above, although the ACA previously expanded Medicaid access, there have been significant proposals to retract that expansion, including through the addition of work requirements, for example.

CMS and private insurers are expanding reimbursement regimes to transition payment away from fee-for-service and into value-based-care, marking a key shift in healthcare financing and patient care. Value-based care models impact reimbursement rates by setting healthcare costs based on their quality rather than quantity. That is, providers are paid increased rates when they produce better patient outcomes, instead of the pure number of visits, services, tests, or procedures completed. In turn, patients may be charged less via ‘bundled’ services and receive more efficient, coordinated care.

In recent years, the health care industry has also seen increased market consolidation, through mergers and acquisitions of providers and health systems, as well as the vertical integration of healthcare, where, for example, providers and provider entities are owned by insurers. Similarly, private investment in healthcare by private equity funds is increasingly common. These trends are under scrutiny by regulators and have called into question the effect of such activities on the quality of healthcare.

Additionally, as noted above, *Loper Bright* and end of the *Chevron* Doctrine are poised to make it more difficult for the federal government to prevail in APA actions, including those implicating CMS, HHS, and reimbursement issues.

Lastly, in conjunction with the second Trump administration, there have been significant and ongoing changes in the formal regulation, regulatory materials, and aims of the federal government, including key agencies, such as CMS, HHS, and FDA. In particular, since January 2025, the administration has rolled out numerous executive orders, many of which directly or tangentially impact the healthcare industry as a whole. In addition to those mentioned above, in general, orders affecting the federal workforce, federal funding, and access to specific kinds of treatment have had, or are ripe to have, the biggest influence on healthcare financing and reimbursement thus far.

For example, the administration has initiated a series of actions, including ‘Implementing the President’s “Department of Government Efficiency” Workforce Optimization Initiative’ and ‘Commencing the Reduction of the Federal Bureaucracy’, that have substantially reduced operations at CMS, HHS, and FDA, among other agencies. To that end, a great deal of programmes and internal departments have been eliminated altogether and many of the processes described above, such as reimbursement appeals, may continue to slow as a result of reduced staff.

In addition, there has been a sharp decrease in federal funding of key healthcare entities. Recent data shows that over one billion dollars in grants to United States medical schools and hospitals have been cancelled, including those related to research and development. Furthermore, over \$600 million in cancelled grants had previously supported a range of clinical trials, including those related to HIV, cancer, and Covid-19. As a result, there is more limited access to care, and particularly novel therapies, delivered to patients through clinical trials.

The administration has also targeted certain types of healthcare, including gender-affirming care, abortion, and in-vitro fertilisation. Under two executive orders, ‘Enforcing the Hyde Amendment’ and ‘Protecting Children From Chemical and Surgical Mutilation’, the administration, in part, has acted to prevent federal funding of elective abortions and end gender-affirming medical treatments (including related research grants) for children and teenagers under the age of 19. Conversely, pursuant to ‘Expanding Access to In Vitro Fertilization [(IVF)]’, the administration has taken steps to ‘aggressively reducing out-of-pocket and health plan costs for IVF treatment’, despite ongoing state litigation over the topic. To that end, these orders are ripe to impact patient access (ie, via regulation and/or creating or eliminating financial barriers), both within and outside of the reimbursement and financing paradigms discussed here.