Morgan Lewis

REPORT

HEALTHCARE AND LIFE SCIENCES:

KEY INSIGHTS AND CONSIDERATIONS FOR STAKEHOLDERS IN 2025

CONTENTS

Morgan Lewis

This report compiles several important developments that shaped the healthcare and life sciences industries in 2024 and spotlights key areas to watch in 2025. Each section addresses either an industry sector within healthcare or the life sciences broadly or a specific topic that was exposed to significant change over the past year. This report is designed to serve as a guide for stakeholders and aims to equip industry professionals with actionable insights as they prepare for and navigate the challenges and opportunities that will present themselves in 2025.

AI AND OTHER NEW TECHNOLOGIES

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A Compliance and Enforcement Perspective for 2025

The continuing development and accessibility of artificial intelligence (AI) and the implementation of AI in the healthcare and life sciences industries is one of the more interesting developments of 2024 and will likely have a significant impact on the evolution of industry compliance and government enforcement efforts in 2025 and beyond, regardless of which political party controls the White House or US Congress.

AI use comes with unanswered questions, specifically regarding its incorporation into both business operations and corporate compliance programs. In 2024, saw some action from government authorities on these questions, but if they haven't already, stakeholders would be wise to begin addressing AI oversight in 2025, even without clear guidance from regulatory and enforcement agencies.

Given the continued claims from enforcement agencies like the US Department of Justice (DOJ) and the US Department of Health and Human Services Office of Inspector General (HHS OIG) about investment of resources in their own data-driven investigative techniques, stakeholders may risk falling behind the government if they don't also take initial steps to improve their compliance programs by including AI.

2025 is the time for stakeholders to focus their efforts on designing and implementing adequate controls for their use of AI to keep pace with these governmental actors.

DOJ's Prosecutorial Guidance Poses Daunting Questions for Stakeholders

In September 2024, the DOJ Criminal Division issued an update to its Evaluation of Corporate Compliance Programs (ECCP) document, which is the Criminal Division's guidance for its prosecutors on the factors they should use to evaluate the effectiveness of corporate compliance programs. Although the ECCP is designed to inform the federal government's potential criminal charging decisions and/or resolutions, the questions DOJ asks prosecutors to consider address underlying compliance principles from which stakeholders design, implement, and evaluate their programs.

Guidance issued by enforcement agencies typically lags new technologies, but DOJ appears to be trying to get out in front of—or at least keep pace with—the emergence of AI. DOJ in the September 2024 update to the ECCP dives squarely into new technologies in general, and AI in particular, regarding how AI is *both* deployed in a company's business operations and is incorporated into a company's compliance program to make the program more effective. The ECCP defines AI broadly and states that "no system should be considered too simple to qualify as a covered AI system due to lack of technical complexity," including but not limited to machine learning and generative AI systems that operate with or without human oversight.

Expectations Regarding AI Use in Business Operations

The ECCP instructs prosecutors to consider AI and other new and emerging technologies that a company uses to conduct company business, whether the company has conducted a risk assessment regarding the use of that technology, and whether the company has taken appropriate steps to mitigate any corresponding risk to ensure compliance with its own code of conduct and all applicable laws.

The ECCP suggests that prosecutors ask, among other technology-related questions, whether controls exist to ensure that AI is used only for its intended purposes and how the company curbs potential negative or unintended consequences resulting from the use of AI when prosecutors assess whether a company has implemented adequate controls around the use of AI in business operations.

It is likely that few compliance programs have even attempted to identify whether and how AI is being used in a company's business operations, let alone assess whether it has answers to the questions posed by the ECCP. Compliance programs nevertheless would be wise to use the sections of the ECCP related to emerging technologies to guide compliance operations in 2025.

The unavoidable implication is that DOJ will not look kindly on companies suspected of committing fraud that have barreled ahead with the use of AI without considering compliance risks and implementing commensurate controls. And the questions only get stakeholders so far because it remains to be seen how enforcement and regulatory agencies will assess how a company manages risk related to ethical use of AI and other new technologies, which at least allows companies initially to be creative in how they mitigate such risks.

Expectations Regarding AI Use in Compliance Programs: Opportunity for Enhancements in 2025

Separately, the ECCP clearly communicates an expectation that compliance programs be designed to use and leverage AI. The ECCP suggests that prosecutors assess whether a company is using new technologies such as AI in its compliance program, whether the compliance program is monitoring such technologies used by the business to evaluate whether they are functioning in a manner consistent with the company's code of conduct, and the speed with which the company can detect and correct decisions made by AI that are inconsistent with the company's values. Again, it's likely that few compliance programs have thought about these issues, let alone begun to incorporate AI into the operations of the compliance program itself.

The ECCP underscores that healthcare and life sciences stakeholders have an opportunity to assess, design, and improve their oversight of AI and other technologies in their business while recognizing the uncertainty and challenges they present. An immediate opportunity for stakeholders is to evaluate the ethical use of AI in their business operations, which should be top of mind for compliance programs in 2025. It is also well known that effective monitoring and auditing is one of HHS OIG's seven elements of an effective compliance program.

Stakeholders will need to address how oversight of AI technologies, something that HHS OIG has not specifically addressed regarding compliance program guidance, fits into their broader auditing and monitoring functions. Compliance programs will need to determine how AI technologies can be used to enhance compliance auditing and monitoring, how the program effectively governs and monitors its own use of AI, and what risks are presented by a double-layered approach of AI-assisted monitoring of AI-assisted business operations. Regulatory and enforcement agencies did not begin to grapple with these types of critical issues in 2024, which leaves stakeholders on their own to find their way forward in 2025.

The New Normal of Data-Driven Enforcement

Stakeholders risk falling behind their governmental counterparts if they delay investing in these compliance opportunities. Under the Biden administration, DOJ representatives commented regularly on the department's increased scrutiny and analysis of the wealth of data provided and produced to the government, especially from government healthcare programs like Medicare and Medicaid, to identify potential fraud and abuse.

There are some indicators that this increased focus on data to at least initiate enforcement actions under laws like the False Claims Act (FCA) has been effective. In 2023, the last year for which data are available, DOJ initiated 500 investigations under the FCA, compared to 712 initiated by whistleblowers under the FCA's qui tam provision.

While still a steep delta, the number of non-qui tam cases did increase substantially compared to past years. This is significant given the FCA is, and will likely continue to be, DOJ's top enforcement tool in

combatting fraud and abuse in healthcare and life sciences. It is unclear whether this emphasis on "home-grown" FCA investigations based on data analytics will likely be a continued focus under the Trump-Vance administration, but it is likely the tools and infrastructure will be available to and continue to be used by DOJ regardless of any potential leadership turnover.

Data Touted as Major Contributor to Combatting COVID-19 Pandemic-Related Fraud

The public emphasis on data and preemptively identifying "hot spots" of fraud also corresponds with congressional support for investigation and enforcement efforts addressing fraud on COVID-19 pandemic programs like the Paycheck Protection Program (PPP).

The Pandemic Response Accountability Committee's (PRAC) Pandemic Analytics Center of Excellence (PACE), an analytics hub of data scientists and investigative analysts tasked to identify potential fraud in data associated with pandemic relief programs, drew praise and bipartisan support from the Biden administration and members of Congress. PACE marshaled vast amounts of resources and data through 47 memorandums of understanding with corresponding Offices of Inspectors General and law enforcement agencies to support more than 700 COVID-19 pandemic-related investigations.

The PRAC is scheduled to sunshine in 2025, along with PACE. The Biden administration and congressional leaders expressed support for continuing and even expanding the PRAC and the next generation of PACE to apply to all federal spending. Senator Gary Peters of Michigan and outgoing Senator Mitt Romney of Utah introduced a bill to establish a PRAC successor and continue its use and application of data analytics and machine learning to combat fraud in government spending. The bill, introduced in April 2024, has not moved for further consideration, and its status is unclear heading into the new Congress in 2025.

The advancements and vast resources available to the PRAC and PACE, however, are unlikely to remain untouched by regulators in the absence of legislative authorization, even as the country moves further away from the COVID-19 pandemic. Data sharing and analytics are here to stay, and stakeholders should be prepared for that reality in 2025.

Looking Ahead to 2025

Healthcare and life sciences stakeholders will likely continue to navigate the incorporation of AI and related technologies into their businesses in 2025, including as part of their compliance programs. Guidance is needed, however, from regulatory agencies to provide clearer guardrails for the implementation of AI in functions like auditing and monitoring.

Until then, stakeholders should use the questions presented in preliminary guidance, like the ECCP, to carefully evaluate and consider developing internal controls governing the use of AI and other new technologies in their business and compliance program operations. Providing updated training and education on these technologies will also be crucial to ensuring that employees are not unwittingly engaging in unethical conduct with the help of AI.

Not doing so could lead to serious consequences. It is clear that data sharing and analytics across agencies are now permanent tools for enforcement agencies like DOJ and HHS OIG. While the enforcement priorities under the Trump-Vance administration may differ from its predecessor, the new administration is inheriting a strong data analytics infrastructure. Even with regulatory uncertainty, stakeholders should still consider mitigating the risk of an enforcement action by using similar AI and analytics-based strategies in their own compliance programs to identify similar indicators of fraud in 2025.

RARE DISEASES

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Manufacturers, Laboratories, Providers, and Patients Await Further Regulatory Clarity and Enforcement Activity in 2025

Rare diseases present a confluence of extraordinary circumstances for patients. One 2022 study revealed, in evaluating 24 rare disease treatments, the per patient, per year overall economic burden ranged from $121,000 to $334,000, which, at that time, was approximately 10 times the cost associated with non-rare disease treatments.

This challenge presents a critical question: What is the best way to help patients get the medications and treatment they need without running afoul of anti-fraud, waste, and abuse laws, such as the FCA and the Anti-Kickback Statute (AKS), and regulatory guidance from the HHS OIG? 2024 provided some answers, and stakeholders should be prepared for additional regulatory and enforcement activity in 2025 as they evaluate whether to pursue programs that provide support and other services to patients.

HHS OIG Focuses on Manufacturer Support Arrangements in 2024

2024 saw HHS OIG address multiple proposed arrangements designed to provide financial and other forms of assistance to patients receiving specialized treatments. HHS OIG issued three advisory opinions, AOs 24-03, 05, and 06, that analyzed whether it would impose sanctions based upon the proposed financial support arrangements for patients submitted by a pharmaceutical manufacturer.

The requestor's drugs were a US Food and Drug Administration (FDA)-approved gene therapy designed to treat a severe disorder that required patients to undergo regular blood transfusions. The gene therapy, a one-time potentially curative treatment for the disorder, involved multiple treatment stages for patients, including a stay in a designated treatment center for four to six weeks after the therapeutic infusion.

Each proposed arrangement involved the requestor providing certain forms of financial support for eligible patients undergoing treatment with its product. The support was divided into two forms:

- Lodging, transportation, and other costs associated with the treatment center stay
- Fertility services

The manufacturer represented to HHS OIG that the gene therapy presented a risk of infertility, and patients may otherwise not take the treatment because of their inability to afford fertility treatments. HHS OIG said it would not impose sanctions on the first form of financial support. In each AO, HHS OIG found that the proposed arrangement was sufficiently low risk because of factors associated with the gene therapy treatment. These factors not only included factors typical of HHS OIG's past guidance, such as eligibility determinations for low-income patients and the fact that the gene therapy was a one-time treatment less susceptible to abuse, but also an explicit recognition that the support removed a barrier for patients seeking medically necessary care.

Conversely, the fertility treatments did not receive favorable treatment from HHS OIG. In AOs 24-05 and 06, HHS OIG concluded that it did not have enough data to determine whether the fertility support would present a comparatively low risk of fraud and abuse. The AOs made clear, however, that HHS OIG could change its position based on continued analysis of data including costs, benefits and outcomes associated with fertility treatments. This included an express suggestion that the Centers for Medicare and Medicaid Services (CMS) could test a model for incorporating fertility services through the agency's "Innovation Center."

FCA Enforcement Bookends 2024

The increased regulatory focus on manufacturer-sponsored support programs dovetailed with notable enforcement activity in 2024. In late 2023, the DOJ and US Attorney's Office for the District of Massachusetts (USAO) announced a $6 million settlement with Ultragenyx Pharmaceutical Inc. to resolve allegations that the company had caused the submission of false claims to CMS by providing kickbacks to beneficiaries and physicians in order to induce referrals for its drug Crysvita.

Six months later, acting US Attorney for the USAO Joshua Levy announced that he expected an increase in FCA cases involving the multiple interrelated stakeholders in the rare disease space. True to his word, the USAO announced on November 15, 2024 that it had reached a $47 million settlement with QOL Medical LLC for conduct akin to that of the Ultragenyx case, which involved kickbacks intended to induce prescriptions of its drug Sucraid. The conduct underlying both settlements is highly relevant for stakeholders in the rare disease space to consider heading into 2025.

Both settlements specifically involved an arrangement for free genetic testing for patients. Ultragenyx and QOL paid a genetic testing laboratory to (1) conduct genetic tests for the diseases treated by their respective drugs at no charge to healthcare providers and (2) provided the results of the test to Ultragenyx and QOL with relevant information, including the healthcare provider that ordered the test. Ultragenyx and QOL then disseminated the information to its sales force to make calls to healthcare providers (HCPs). DOJ considered this provision of free tests and the use of the data in sales to induce prescriptions of their respective products.

The effect of prior guidance from HHS OIG on both settlements was clear. According to the Ultragenyx settlement, the company stopped providing testing results to its sales force for marketing purposes after HHS OIG issued AO 22-06, one of the only pieces of guidance from the agency to address arrangements for free genetic testing sponsored by pharmaceutical manufacturers. AO 22-06 involved a proposal submitted by a similarly situated pharmaceutical manufacturer where it would provide free genetic screening and counseling services, for a single disorder, to eligible patients. The manufacturer expressly represented that it did not provide its sales representatives with materials that included any HCPs' utilization of the arrangement or HCPs' prescribing history.

HHS OIG found the arrangement presented a low risk of fraud and abuse, noting it did not present a sufficient "nexus" between the genetic testing and counseling and the ultimate prescribing of the requestor's drug. Ultragenyx's dissemination of data from the genetic testing lab to its sales force appeared to be an important difference between the program described in AO 22-06 and the conduct DOJ found to violate the AKS.

Patient Assistance Programs Still Loom Large

Patient Assistance Programs (PAPs) are specific programs designed to help patients who lack health insurance or prescription drug coverage obtain critical, and often lifesaving, medications. PAPs have come under intense scrutiny from HHS OIG due to concerns that the programs may violate, among others, the AKS and civil money penalty (CMP) laws. PAPs pay for the products manufacturers produce and market, and thus, the risk of potential misuse of such programs invites government oversight and scrutiny. However, in 2024, HHS OIG appeared to suggest that there may be some flexibility for PAPs, specifically for those designed to help patients suffering from disease states with exceptionally limited and/or expensive treatments.

In AO 24-02, HHS OIG evaluated a sponsor's rare disease PAP. According to the sponsor, it had established several disease funds designed around clinically recognized disease states. Within this program, each disease fund had a single donor, and each donor was a pharmaceutical manufacturer that manufactures or markets a drug to treat the disease state addressed by the disease fund. To access

financial assistance, patients had to apply for enrollment and meet certain predetermined financial need criteria as established by the program sponsor. Additionally, the program attempted to mitigate AKS and FCA risks by representing that the manufacturer donors would not—among other protections—exert, directly or through an affiliate, any influence or control over the identification, delineation, establishment, or modification or any specific disease fund. Patients were never made aware of the funding source of the program.

HHS resolved not to impose administrative sanctions on the sponsor for several reasons, recognizing that disease funds would ultimately be provided to rare disease patients who have demonstrated a financial need. However, HHS OIG's opinion was based on current legal frameworks, and it is currently unable to know how full implementation of the Inflation Reduction Act's $2,000 out-of-pocket cap, which went into effect on January 1, 2025, will impact its analysis of PAPs.

Looking Ahead to 2025

2024 presented an increased regulatory focus on arrangements designed to alleviate the heavy financial burden of patients facing rare diseases. Given the undoubted benefit to patients, but also the inherent potential for fraud and abuse, it is not surprising that manufacturers have sought clarity regarding increasingly more creative proposals, like providing support for fertility treatments. Stakeholders can expect additional data points from HHS OIG as it evaluates more data and, possibly, more creative proposed arrangements to help patients.

Stakeholders should not be lulled into any false sense of security in 2025, however, even as HHS OIG has issued several favorable opinions in 2024 related to financial support and leaving open the possibility for favorable opinions for other forms of support. The Ultragenyx and QOL settlements make clear that advisory opinions are not permission slips for stakeholders to push the limits of facilitating testing, financial assistance, or treatment of patients. However, it is unclear whether the Trump-Vance administration's DOJ, and any forthcoming picks for US Attorney in preeminent healthcare fraud districts like the District of Massachusetts and the Eastern District of Pennsylvania, may change the enforcement priorities and take a different view of these types of arrangements.

Moreover, the lack of guidance from HHS OIG related to the other stakeholders involved in some of these arrangements, like genetic testing labs, leaves the outer limit of such arrangements between stakeholders as an unknown, the contours of which may become better defined in 2025. Ultimately, stakeholders should be prepared to take in new information and modify existing programs as HHS OIG potentially issues more guidance in 2025.

They also should carefully evaluate whether programs that they sponsor, or are involved with, closely align with current guidance. Even with some regulatory clarity, the recent enforcement activity cautions that forging ahead with programs or arrangements designed to provide assistance or services to patients, particularly those that are novel, is fraught with risk.

TELEMEDICINE AND DIGITAL HEALTH

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Virtual Care, Real Scrutiny: Legal and Ethical Challenges in Digital Health and AI in Healthcare

As healthcare continues to rapidly progress with advancements in telehealth, digital heath solutions, and AI applications, the legal framework governing these areas is constantly evolving to address emerging challenges and continued opportunities for growth. Given this reality, it has been challenging for policymakers and enforcement agencies to effectively control the growth of these technologies, as they are tasked with balancing the advantages of innovation with the potential fraud, abuse, and patient safety challenges. In addition, these technologies stress the existing healthcare reimbursement mechanisms, making it difficult for healthcare companies to receive adequate payment for deploying new technologies.

Telehealth Coverage and Medicare Reauthorization

The expansion of telehealth—stemming from the COVID-19 pandemic public health emergency (PHE)—highlighted its potential to enhance access to care, prompting efforts to ensure its sustainability beyond the PHE.

Perhaps most notably, the proposed Telehealth Modernization Act of 2024—which was passed out of committee on September 18, 2024—aims to permanently extend certain flexibilities that were initially only temporarily authorized during the PHE. These flexibilities include, but are not limited to: (1) allowing rural health clinics (RHCs) and federally qualified health centers (FQHCs) to serve as the distant site; (2) allowing the home of a beneficiary to serve as the originating site for all services; and (3) allowing more types of practitioners to furnish telehealth services, as determined by CMS.

Similarly, the Creating Opportunities Now for Necessary and Effective Care Technologies for Health Act (CONNECT Act) advocates for the comprehensive expansion of access to telehealth services under Medicare. Of course, each of these bills will need to be reintroduced in the incoming Congress and, while they have broad bipartisan support, it remains difficult to predict Congress's immediate priorities.

Reinforcing the advancements and protections proposed by the Telehealth Modernization Act and CONNECT Act, CMS has issued a final rule that, among other things, aims to further facilitate the use of digital health and communications-based technologies to make care more efficient. These measures include: (1) allowing a distant site practitioner to use their currently enrolled practice location, rather than their home address, when providing telehealth services from their home; and (2) extending, through 2025, the definition of "direct supervision" to permit the presence and immediate availability of the supervising practitioner through real-time audio and visual interactive communications (and permanently extending expanded direct supervision for certain inherently lower risk services).

While this final rule and the pending legislation represent significant progress, permanent solutions will require congressional action to preserve these changes beyond a temporary extension, which is currently set to expire on March 31, 2025.

DEA's Extension for Telehealth Prescribing of Controlled Substances

The Drug Enforcement Administration (DEA)—in concert with the US Department of Health and Human Services (HHS)—issued a temporary rule in November 2024 that extends the flexibilities for prescribing controlled substances via telehealth without an in-person evaluation through December 31, 2025. This extension addressed significant concerns that were raised by practitioners and patients, particularly those

in the behavioral health space, where access to certain medications for conditions such as opioid use disorder and ADHD remain critical to maintaining adequate and continuous treatment.

The DEA had previously proposed an onerous rule that would significantly limit telehealth prescribing practices. It ultimately pulled that rule in the face of pressure from Congress and stakeholders. Now, the DEA has committed to establishing a permanent rule or guidelines that balances patient access to telehealth services with measures to prevent misuse and diversion, so it is likely that a revised proposed rule will be issued sometime in early-to-mid 2025.

Enforcement Actions in Telemedicine and Digital Health

Regulatory scrutiny on telehealth and digital health intensified in 2024, with a series of high-profile enforcement actions that underscore the federal government's insistence on setting an example in the telehealth and digital health space. For instance, multiple executives (including the founder/CEO and Clinical President) of a California-based digital health company were arrested for facilitating an alleged $100 million Adderall distribution and healthcare fraud scheme.

Generally illustrating the importance of ensuring that telehealth providers conduct thorough evaluations and take measures to prevent misbilling, poor outcomes, improper prescribing and patient confusion, this case highlights the increased attention from agencies such as the DOJ and the HHS-Office of Inspector General (HHS-OIG). Other notable enforcement trends include investigations into fraudulent billing practices and unauthorized data sharing.

Despite strong pushback from certain stakeholders, the telehealth industry remains mired in fraud concerns due to the ease in which claims and other data can be generated and transmitted without patient involvement. Given the increased scrutiny on certain telehealth and digital health practices, providers in this space should anticipate heightened audits and compliance requirements in 2025. And to further prevent regulatory violations and mitigate the risk of an enforcement action, organizations offering telehealth services should consider investing in robust internal controls, especially those participating in Medicare.

Lack of Enforcement on DTC Lifestyle Medications

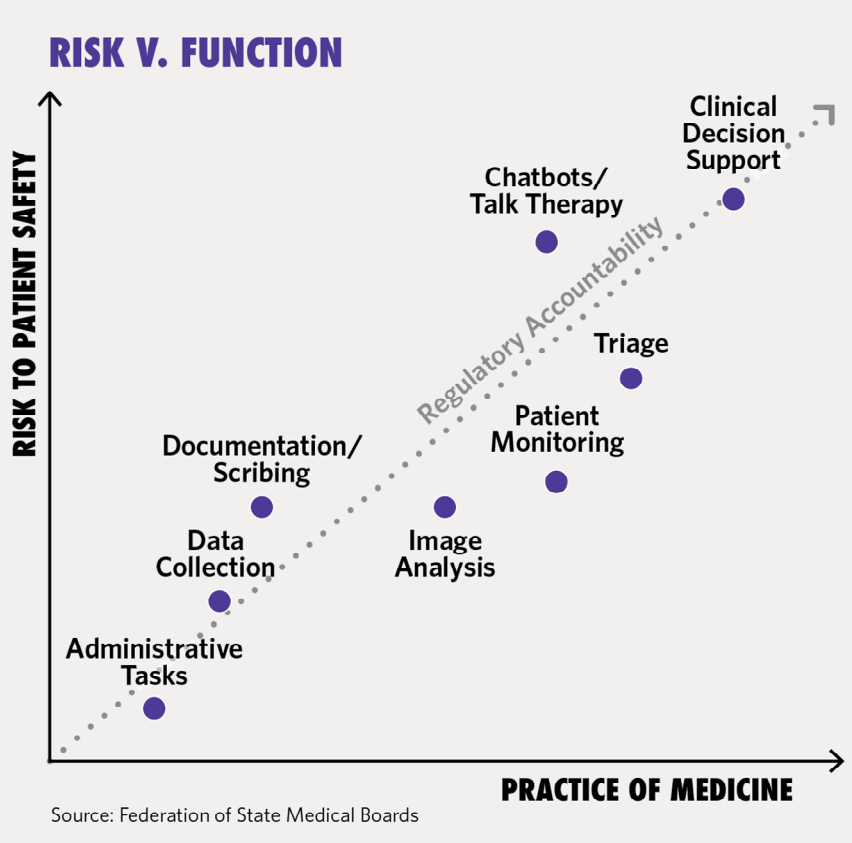
While regulatory scrutiny has intensified in some areas, direct-to-consumer (DTC) telehealth platforms offering lifestyle medications have largely avoided significant oversight in part due to their lack of insurance billing. These platforms typically offer streamlined virtual consultations and appointments with patients to prescribe weight loss drugs, hair restoration treatments, sexual and reproductive health products, and skincare treatments. These companies, and their network of providers, are only substantially regulated by state licensing agencies, which have historically only provided limited guidance and enforcement related to these providers.

While federal agencies, including the FDA and the Federal Trade Commission (FTC), have not yet established clear guidelines for DTC telehealth models, growing concerns about patient safety and transparency could prompt regulatory action in 2025, particularly if adverse outcomes draw public attention.

Ethical Considerations and State Regulation in Healthcare AI

AI is taking the world by storm, and healthcare is no exception. Still, meaningful regulation on AI for healthcare providers has not yet been provided. The Federation of State Medical Boards (FSMB) issued a report in 2024 that discusses the integration of AI in clinical practice, emphasizing ethical principles and human accountability. Outlining key areas, such as informed consent, data privacy, liability, and collaboration with experts, the report sets forth recommendations aimed at balancing innovation with

patient safety while also avoiding overregulation by government agencies. That said, few state licensing agencies, and no federal healthcare agencies, have issued updated regulations on how healthcare providers are to use AI in their clinical practices—or get paid for them. We anticipate that several additional medical boards will issue regulations in 2025.



AI is transforming healthcare, but its rapid adoption outpaces the development of comprehensive legislation, regulations, and guidance. As such, in September 2024, California passed the California AI Transparency Act, which introduces mandatory disclosures for AI systems used in healthcare settings, requiring providers to inform patients when AI significantly influences their care. Aiming to address growing concerns over transparency and accountability in AI-driven healthcare (particularly in diagnostic tools and treatment recommendations), the California AI Transparency Act—which will go into effect in 2026—is the most detailed state law on the use of AI in healthcare and sets a precedent for other states that may elect to adopt similar protections into law.

See the AI & Other Technologies section for more insight into compliance and enforcement considerations.

HOSPICE, HOME HEALTH, AND LONG-TERM CARE

HOSPICE, HOME HEALTH, AND LONG-TERM CARE

CMS Prioritized Oversight of Hospice, Home Health, and Long-Term Care Sectors in 2024, But Uncertainty Awaits in 2025

In 2024, CMS continued to shore up its program integrity and regulatory scrutiny efforts of hospice, home health, and long-term care (LTC) providers. CMS finalized significant rule changes and announced oversight initiatives set to define the regulatory landscape for these sectors in 2025. Future implementation of these efforts, however, could be challenging given the legal and political uncertainty that 2025 is likely to bring.

Hospice and Home Health Providers Adjust and Prepare for Increased Regulatory Oversight and Activity

Hospice

CMS remained highly focused on hospice program integrity in 2024. Following intense media and congressional scrutiny of unscrupulous hospices, particularly in California, the agency announced increased oversight of new hospice providers in Arizona, California, Nevada, and Texas because of ongoing fraud concerns. This announcement built on the period of enhanced oversight initially launched in July 2023. The expanded CMS program covers any new hospice programs or those pursuing a change of ownership in those four respective states. However, there have also been reports of heightened CMS scrutiny of new hospices outside of those four states as well.

CMS is poised to continue similar increased oversight efforts in 2025. The agency intends to complete its first full year of the Hospice Special Focus Program (SFP), as finalized in the Calendar Year 2024 Home Health Prospective Payment System Final Rule. The SFP, which selected its first cohort of hospices in November 2024, is designed to identify "poor performing" hospices based on select quality indicators and implement enhanced oversight, including the imposition of enforcement actions, as necessary. The consequences of the SFP are severe, including potential termination from the Medicare program. This cycle of review restarts in the fourth quarter of each calendar year, during which CMS selects an additional 50 hospices for review under the SFP.

In addition to the increased oversight, CMS plans to introduce the Hospice Outcomes and Patient Evaluation (HOPE) tool in October 2025 to enhance hospice programs' measurement of quality-of-care metrics. The HOPE tool is CMS's successor to the Hospice Item Set (HIS) and is designed to collect patient-specific data in real time during the entirety of the patient's hospice stay to contribute to the patient's plan of care at additional timepoints. With the HOPE tool's formal adoption slated for October 1, 2025, hospice providers should familiarize themselves with CMS's expectations for data collection and compliance, as well as seek to understand how providers can use this expanded data set to evaluate quality metrics.

On hospice payment issues, CMS announced it was ending the hospice value-based insurance design (VBID) model as of December 31, 2024, which tested the Medicare Advantage (Part C) carve-in for hospice. Interest and participation among MA plans seem to have waned, and CMS announced it would continue to evaluate the data from the hospice VBID program. This likely marks the end of any major push, in the near term, of a hospice MA carve-in, but that could change as the Trump-Vance administration and Republican-led Congress look to embrace Medicare spending controls.

Finally, hospices across the country continue to experience heavy CMS contractor audit scrutiny from the Supplemental Medical Review Contractor, Targeted Probe and Educate reviews from MACs, and Unified Program Integrity Contractor audits (including most recently for Medicaid compliance). The costs of

responding to these audits is high, but the new administration is likely to continue these audits apace given their recent public statements regarding targeting fraud, waste, and abuse in Medicare and Medicaid as a spending control.

Home Health

Home health stakeholders also experienced increased regulatory scrutiny in 2024. Despite significant industry opposition, CMS established the Medicaid 80/20 Rule through finalization of the Ensuring Access to Medicaid Services Rule. The 80/20 Rule requires states to ensure that a minimum of 80% of Medicaid payments for homemaker, home health aide, and personal care services are spent on compensation for direct care workers. The rule also seeks to increase transparency by requiring states to report certain quality and payment rate measures for home- and community-based services. Though implementation and reporting on compliance with these 80/20 payment requirements is delayed until 2030, states must commence reporting on Medicaid payments for covered care by 2028.

CMS also introduced a new Condition of Participation for home health related to maintenance of patient acceptance-to-service policies. This new standard requires home health agencies to develop, implement, and maintain a patient acceptance-to-service policy that addresses (1) the anticipated needs of the referred prospective patient, (2) the agency's caseload and case mix, (3) the agency's staffing levels, and (4) the skills and competencies of agency staff. To comply with the condition, CMS requires that the policy be applied consistently to each prospective patient referred for home health care and that this policy is reviewed at least annually.

LTC Minimum Staffing Rule Defines 2024 for LTC Stakeholders

2024 saw a regulatory sea change for nursing facilities. CMS's final rule for minimum staffing standards, published in May, was the culmination of the Biden Administration's regulatory efforts to implement meaningful changes to the care provided at nursing facilities in the United States after the COVID-19 pandemic. The magnitude of the potential effects of the final rule is difficult to overstate. The staffing floor mandates a minimum of 3.48 hours of care per resident per day, requires a registered nurse to be on site 24 hours, seven days a week, and includes enhanced facility assessments that reflect ambitious staffing requirements. Meeting these requirements would take significant investments from LTC stakeholders prior to implementation over the next three years, all while facing an ongoing staffing shortage.

The final rule presented immediate challenges for stakeholders. CMS's rule announcement did not provide information on the incentive initiative that would invest more than $75 million as part of a nursing home staffing campaign. This left stakeholders with an unfunded mandate, and the agency has not yet issued updates regarding the proposed investment or other measures to help alleviate the clinical staffing shortage facing the industry. These challenges prompted swift legal challenges to the final rule. The American Healthcare Association and 20 state attorneys general filed separate lawsuits in the US district courts for the Northern District of Texas and the Northern District of Iowa, respectively, each challenging the final rule under the Administrative Procedure Act (APA). Both cases are expected to be resolved in 2025, putting the rollout of the final rule in jeopardy before the major aspects are set to be implemented.

The effects of the legal challenges to the final rule may be far-reaching, including as to other significant regulatory developments this year. In November 2024, HHS OIG issued its Industry Segment-Specific Compliance Program Guidance for Nursing Facilities. The guidance reflects HHS OIG's first specific compliance guidance for nursing facilities since 2008. The first risk area the Guidance addresses staffing levels, shortages, and competencies, providing recommendations on how facilities can recruit and maintain staffing levels in accordance with the final rule. While the guidance addresses many other applicable compliance risk areas, the outcome of the legal challenges will invariably impact how stakeholders look to such voluntary compliance guidance in 2025.

Looking Ahead to 2025

CMS and other agencies prioritized regulatory reform and oversight of the hospice, home health, and LTC sectors in 2024. Industry stakeholders must understand and tackle these changes. Some will be phased in over the next number of years, while others take effect in 2025. There will be growing pains as, for example, hospice providers begin to transition to the HOPE tool and LTC stakeholders evaluate their compliance program based on HHS OIG's Industry Segment-Specific Compliance Program Guidance for Nursing Facilities.

On a positive note, at the eleventh hour, Congress included several time-limited healthcare extenders in the Continuing Appropriations and Other Matters Act, a budget bill that included continued Medicare coverage of telehealth visits for hospice face-to-face recertifications. Though the original bill included a two-year extension, the final bill only extended this flexibility until March 25, 2025, and the Republican-led Congress must take up new legislation in the new year to provide continued flexibility on telehealth.

These challenges may be exacerbated by the legal and political uncertainty that comes with the transition to 2025. The legal challenges to CMS's minimum staffing rule for nursing facilities may result in a court ruling that the final rule violates the APA, which, in turn, could lead to delays in its implementation as any such ruling makes its way through the appellate process. It remains unclear what the Trump-Vance administration's priorities will be for CMS, and whether any aspect of the rules set to take effect in 2025 will be rolled back. It is likely the new administration will remain committed to fraud, waste, and abuse efforts using CMS audits and in support of the use of the FCA and AKS. Stakeholders should be mindful and take active steps to ensure compliance with the new regulatory norms set forth in 2024, while also being prepared to adapt as more developments take shape in 2025.

PRIVATE EQUITY

PRIVATE EQUITY

Private Equity Remained Driving Force in Healthcare in 2024, with Change Certain to Define 2025

Private equity (PE) investment in the healthcare industry—more than $500 billion in the last decade—continued at a high level in 2024. That influx of capital, however, was accompanied by increasing CMS transparency and disclosure requirements, as well as enhanced scrutiny from the DOJ and the FTC (together, the Antitrust Agencies) during the Biden administration, as well as from state agencies.

Though the new year might bring a more relaxed environment for transactions with the Trump-Vance administration, stakeholders should be mindful that the change in administration will not eliminate all regulatory requirements and enforcement risks.

PE Prepares for New Antitrust Normal in 2025

While it is too early to tell how aggressively the Antitrust Agencies under President Trump will scrutinize PE transactions involving healthcare assets, we expect that the enforcement environment in President Trump's second term will generally be more conducive to PE and healthcare transactions than under President Biden's term.

Structural Remedies

The Antitrust Agencies during President Biden's term consistently rejected the use of structural remedies such as divestitures to resolve concerns about the competitive impact of proposed transactions; instead, they favored litigation to block deals. The Antitrust Agencies under President Trump are expected to revive the use of conditioning transaction closings on structural remedies. This will result in more deal certainty for merging parties, even when a proposed transaction has some antitrust risk.

Labor Market Competition

The Antitrust Agencies during President Biden's term frequently considered whether a proposed transaction would harm labor markets, workers, or unions. In addition, the Antitrust Agencies heavily scrutinized the use of non-compete covenants for medical professionals. The Antitrust Agencies under President Trump are expected to lessen their focus on labor-related issues during merger reviews.

Competitive Positioning

The Antitrust Agencies during President Biden's term frequently considered whether a proposed transaction would weaken the competitive position of a private-equity-affiliated portfolio company. For example, during merger reviews, the Antitrust Agencies investigated whether common PE practices, such as sale-leaseback arrangements, debt-heavy structures, or large management fees, would render a hospital or physician practice unable to compete as effectively post-closing. The Antitrust Agencies under President Trump are expected to approach these common PE practices with less skepticism.

Updated Merger Guidelines

The Antitrust Agencies during President Biden's term enacted new Merger Guidelines that expanded merger scrutiny to new or less conventional theories of harm, such as PE roll-up transactions, and

brought a lawsuit challenging a PE firm's "roll-up" acquisitions of physician practices.[1] The Antitrust Agencies under President Trump may replace these Merger Guidelines with more business-friendly guidance or, at the very least, selectively enforce aspects of these Merger Guidelines.

Premerger Filing Requirements

Finally, PE firms must prepare for more demanding federal premerger filing requirements. On February 10, 2025, new premerger filing rules under the Hart-Scott-Rodino (HSR) Act will take effect following a unanimous 5-0 bipartisan vote by the FTC's commissioners. These updated HSR Act rules significantly expand the scope of disclosure and document production obligations for PE firms in connection with an HSR Act filing, touching on several core areas, including, but not limited to, the disclosure of supervisory deal team leads, draft documents shared with any member of the board of directors or investment committee, and minority holders and limited partners.

Transparency and Reporting Requirements Remain Key Considerations

In 2024, multiple state legislatures proposed legislation that would implement disclosure requirements for healthcare transactions involving PE firms. These proposed laws would supplement previously enacted "mini-HSR" laws reflecting efforts by states to identify and review healthcare transactions. Some of these state laws are targeted directly at PE transactions, while other state laws' broad definition of terms such as "affiliate" may draw in PE owners or their portfolio companies that are not involved in the transaction at issue.[2] In public comments, many state attorneys general have also criticized PE involvement in healthcare, and we anticipate that they may become more active in merger reviews of PE transactions in healthcare if they perceive that the Antitrust Agencies under President Trump are being too lenient.

PE stakeholders should also prepare for continued transparency and reporting efforts at the federal level. In President Trump's first term, CMS issued a final rule that enhanced the requirements for providers and suppliers to disclose adverse actions involving affiliates. Specifically, the rule broadened the definition of "affiliation" regarding disclosable event reporting, like suspension or exclusion from participation in federal healthcare programs, to capture entities that have a direct or indirect ownership of 5% or greater. While the rollout and enforcement of this rule were slowed, likely due to the PHE, it is consistent with CMS and HHS goals under both Republican and Democratic leadership. This prior agency action shows that the Trump-Vance administration could continue regulatory efforts to enhance ownership transparency in the healthcare space.

Financial Realities Keep Enforcement Focus on PE Stakeholders

PE and the FCA have been on a collision course for much of the last two decades. PE's investment in healthcare carries real (and growing) enforcement risks.

Emerging Legal Theories Under the FCA

The growing dominance of PE in the highly regulated healthcare industry changes FCA enforcement in many ways—some obvious and others more nuanced. PE firms should expect to be named as defendants

[1] DOJ and FTC, Merger Guidelines § 2.8 (Dec. 18, 2023) ("A firm that engages in an anticompetitive pattern or strategy of multiple acquisitions in the same or related business lines may violate Section 7."); *see also* Compl., *FTC v. U.S. Anesthesia Partners, Inc.*, No. 23-3560 (S.D. Tex. filed Sept. 21, 2023).

[2] *See* LawFlash, Growing Number of US States Target Private Equity Transactions in Healthcare (Aug. 28, 2024).

in more FCA suits and to receive more Civil Investigative Demands (even if not a defendant). This carries grave financial and reputational risks for the PE firm. But holding a PE firm liable is no layup.

PE-backed companies, called "portfolio companies" or "portcos," are often financially strained given that buyouts saddle them with substantial debt. That makes conventional FCA enforcement less effective as the classic defendant, the healthcare company, may be unable to pay what DOJ would deem to be a "fair" settlement. The PE firm, with its deeper pockets, will increasingly become a more attractive target.

How might classic FCA theories apply to PE firms when they are not the direct biller of a possible false claim? Case law and past settlements provide some color. But as this is a new area of law, the contours of liability are still emerging. Potential theories of liability include direct liability and conspiratorial liability. The FCA, inter alia, bars one from making or causing to be made a false claim to the government for payment.[3] Under a theory of direct liability, while the PE firm will rarely be the entity making a false claim, the PE firm may have "caused" the submission thereof if it has taken part in the fraudulent conduct (e.g., approved of the malfeasance or directed certain practices).

The FCA also prohibits conspiring to make or cause the submission of a false claim. For conspiratorial liability, conspirators can be jointly and severally liable for all harm derived from the conspiracy. Whether the intracorporate conspiracy doctrine applies to the FCA is unsettled—and whether that defense would apply to a PE firm is even less clear.[4]

There have been a handful of FCA settlements with PE firms to date. Save for one of them, all FCA/PE settlements have been in the last five years. Portcos, meanwhile, have paid more than $500 million in at least 34 FCA settlements. So far, emerging case law on PE liability has included claims of knowledge of and failure to stop alleged fraud, alleged directed action, and operation under policies causing others to submit false claims.

Enforcement Contributors: Growing Financial Realities

Financial realities make enforcement against PE firms more likely. Faced with a highly indebted portco, DOJ may find a deep-pocketed PE firm that ultimately benefits from the alleged fraud to be an appealing target.

Many (but not all) PE firms take a hands-on role in the portco's management. Particularly if alleged fraud is systemic (e.g., a major part of the business), it will be more likely that the PE firm is aware of (or even directly involved in) the misconduct. This means that *more systemic fraud* at a portco tends to make a case against a PE firm more likely. These concerns—specifically that PE investors and other third parties may have influence over patient care decisions or other operations—were recently highlighted by DOJ officials during the Biden administration. While it's too early to predict whether this will remain an FCA enforcement priority under the Trump-Vance administration, stakeholders need to guard against this type of risk because of the outsized influence of qui tam relators in FCA enforcement.

Additionally, scienter—knowledge of fraudulent conduct under the FCA—is often a key defense for PE firms. If the fraud is limited, highly nuanced, or technical, the PE firm may legitimately be unaware of the misconduct. PE firms with limited or hands-off managerial control or knowledge of the portco's practices may avoid liability. Even then, the PE firm may still be investigated.

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[3] 31 U.S.C. § 3729(a)(1)(A).

[4] See *Martino-Fleming v. S. Bay Mental Health Ctr. Inc.*, 334 F. Supp. 3d 394, 403 (D. Mass. 2018) (doctrine may not apply where PE firm and portco are "independent centers of decision making").

Looking Ahead to 2025

The change of administration is likely to mark a significant shift in scrutiny of PE-backed transactions in the healthcare sector. The likely change in priorities under the Trump-Vance administration's Antitrust Agencies should not be viewed as a total reversal on all regulatory requirements for private equity-backed companies. Not only is there continued focus on transparency requirements at the state level, the Trump-Pence administration also implemented broader transparency rules applicable to suppliers and providers participating in federal healthcare programs. Stakeholders should be sure to carefully evaluate the state and federal landscape with regard to such requirements throughout 2025.

Moreover, the change in administrations does not change the inherent financial structure of PE-backed healthcare companies and the related enforcement incentives. FCA enforcement in the PE industry is more recent but growing. DOJ and state Attorneys General have made clear that PE firms are now on their radar. Recent settlements prove this. FCA cases against PE firms are not easy, but as the jurisprudence increasingly shows, there are potentially viable case theories.

As DOJ and relators gain traction, future cases against PE firms grow more likely. In other words, the playbook is being written and will continue to be developed, even if the Trump-Vance administration implements different FCA enforcement priorities than the Biden administration. While there remain strong defenses for PE firms to FCA enforcement, PE's expanding role in healthcare companies will invariably create new focal points for enforcement and novel levers for resolution.


LOPER BRIGHT
AND RELENTLESS

LOPER BRIGHT AND *RELENTLESS*

End of the Chevron Era

It has been more than six months since the US Supreme Court decided *Loper Bright Enterprises v. Raimondo* and *Relentless v. Department of Commerce*, overruling the Chevron doctrine and marking a seismic shift in the state of administrative law in the United States. While the change may have a significant impact on many regulated industries, this section focuses on the repercussions that healthcare companies might anticipate as we close out 2024.

The Supreme Court's Decision in *Loper Bright* and *Relentless*

Forty years ago, the Supreme Court held in *Chevron U.S.A. Inc. v. Natural Resources Defense Council* that if a statute is silent or ambiguous, courts must defer to an agency's interpretation of the statute if it is reasonable. The rationale behind this decision was that Congress intended to delegate to the relevant agency the authority to fill in the statutory gaps. Courts could not substitute their own construction of the statute, even if they concluded there was a better interpretation, so long as the agency met the low bar of reasonability. While the decision historically had an enormous impact on administrative law, the Supreme Court has not directly relied on the Chevron doctrine in over a decade.

In *Loper Bright*, the US Supreme Court overturned *Chevron*, holding that courts "may not defer" to the agency's interpretation of an ambiguous or silent law.[5] The Supreme Court, referencing separation of powers principles, reaffirmed what had been said in *Marbury v. Madison*—it is emphatically the judiciary's role to "say what the law is."[6] The Court also held that *Chevron* was inconsistent with the requirement under the Administrative Procedure Act (APA) that courts "decide all relevant questions of law" and "interpret constitutional and statutory provisions."[7]

Under the new *Loper Bright* framework, courts "must exercise their independent judgement" to decide whether an agency's interpretation of a statute is the *best interpretation*. As a result, and without *Chevron*, if a court decides there is a better interpretation of a statute, the agency's construction will be overruled.

Impacts on the Healthcare and Life Sciences Industries

The healthcare industry is heavily regulated by federal agencies, such as the US Department of Health and Human Services (HHS), HHS OIG, and CMS. Post *Loper Bright*, these agencies may face heightened judicial scrutiny of their rulemaking and interpretive guidance, which is heavily relied upon by healthcare providers. This section discusses anticipated changes and areas that may expect minimal fallout from the reversal of *Chevron.*

Federal Regulations

Questions continue to circulate on how agencies will adapt to the heightened judicial scrutiny standard under *Loper Bright*, particularly in regard to the implementation of federal regulations. In 2025, we may see some of the following high-level impacts described here as the dust continues to settle.

[5] 144 S. Ct. 2244, 2273 (2024).

[6] 5 US 137, 177 (1803).

[7] 5 U.S.C. § 706.

Considering agencies face an increased chance of a rule being vacated, a chilling effect may cause agencies to engage in less rulemaking to avoid potential legal challenges. Less regulation may result in greater uncertainty for stakeholders seeking clarity on emerging healthcare technologies such as AI, remote monitoring, portable diagnostics, telehealth and digital healthcare (e.g., virtual reality and augmented reality), and other innovative care delivery models. Additionally, from a practical standpoint, there may be a decrease in agency efficiency and transparency as a result of resources being diverted to prevent and defend against more frequent challenges.

Importantly, the *Loper Bright* decision did not prohibit all deference, and agencies may attempt to leverage these exceptions to the rule against deference. Specifically, agencies may be inclined to focus on factual findings, which continue to receive deference, rather than legal interpretations, which do not receive deference, when undertaking rulemaking and provider-specific decisions. Additionally, courts may offer some deference where Congress delegates authority to an agency or uses keywords in a statute indicating greater agency discretion (e.g., "appropriate" or "necessary").

This may also result in agencies working with Congress to include express delegations in new legislation going forward. Finally, some weight may be afforded to historic and longstanding interpretations (albeit less weight than was given under *Chevron*). As a result, agency rules that have remained consistent over time may receive the benefit of due respect. However, challengers may argue that agency positions that have changed from administration to administration should not be considered longstanding.

While the US Supreme Court cautioned that it was not overruling prior decisions where a court relied on the Chevron doctrine, it subsequently clarified in *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.* that the statute of limitations for APA claims extends six years from the date of the plaintiff's injury, rather than six years after the agency action becomes final.[8] As a result, new judicial challenges of old regulations are likely to occur in 2025.

Reimbursement

The impact of *Loper Bright* may be most significant in the context of formula-driven reimbursements, particularly under the Medicare program. Many complex payment mechanisms for providers such as hospitals, health plans, and specialized providers (e.g., FQHCs and SNPs) are based on sparse or convoluted federal statutes and considerable agency gap-filling. Agency interpretations are frequent and result in the loss or gain of billions of federal dollars for these healthcare entities.

In the past, cases related to Medicare reimbursement have posed a challenge for the courts. In 2021, the Supreme Court addressed CMS's interpretation of a Medicare payment formula. During oral arguments, Justice Breyer stated he was "baffled" and said, "I'm still stuck on what we—well, what we do" when confronted with undefined terms in the Medicare Act.[9] In 2014, the Court of Appeals for the District of Columbia Circuit described the different reimbursement schemes for hospitals as "the labyrinthine world of Medicare."[10] This sentiment was reiterated in the 2021 decision, *Ascension Borgess Hosp. v. Becerra*.[11] Despite (or perhaps, because of) its complexity, many Medicare reimbursement schemes are regularly challenged. We can expect more reimbursement-related suits now that challengers have a greater

[8] 603 US 799 (2024).

[9] *Becerra v. Empire Health Foundation*, 2021 WL 6051134 (US), 60 (US Oral. Arg., 2021).

[10] *Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 694 (DC Cir. 2014).

[11] 557 F. Supp. 3d 122, 124 (D.D.C. 2021).

likelihood of success under a more favorable standard of review for regulated parties. Courts will have to become experts to engage in *de novo* review and navigate the Medicare maze.

The DC Circuit illustrated its willingness to dive into the intricacies of the Medicare statute in *Bridgeport Hospital v. Becerra*,[12] in which the court found that CMS lacked the authority to adopt the agency's "low wage index relief" policy for hospitals under the Inpatient Prospective Payment System (IPPS) statute. The Ninth Circuit ended the year with a similar ruling in *Kaweah Delta Health Care District, et al. v. Becerra.*[13] Both courts specifically relied on the details of the controlling statute to override the stated policy initiatives of CMS, despite the rationale explanation offered by the agency for the policy. As noted in the Hospitals and Health Systems section, CMS seeks to adopt the same low wage index relief policy for the outpatient prospective payment system, which will likely face a similar statutory challenge.

Other recent court decisions offer additional insight into what the future may hold for reimbursement challenges. On November 8, 2024, the US District Court for the District of Columbia decided *Ardelyx Inc. v. Becerra*, which focused on the "composite rate system" for reimbursement of dialysis services for Medicare beneficiaries suffering from end-stage renal disease.[14]

The regulation at issue related to CMS's inclusion of certain oral-only drugs in a bundled payment system for renal dialysis services. Drugs included in the bundled payment typically receive lower reimbursement. A pharmaceutical manufacturer sued CMS, arguing that its drug is not a "renal dialysis service" under the statutory definition and CMS had no authority to include the drug in the bundled payment. The court found that, under the *Loper Bright* framework, the regulatory language was consistent with and the best reading of the statute, but ultimately granted the government's motion to dismiss based on its finding that judicial review was precluded by 42 U.S.C. § 1395rr(b)(14)(G).[15]

Additionally, another challenge is pending before the Supreme Court related to CMS's interpretation of the disproportionate share formula for Medicare hospital reimbursement.[16] The Court will again wrestle with the same disproportionate share hospital (DSH) statutory scheme that it clarified only last year in *Becerra v. Empire Health Foundation.* According to the statute, DSH payment adjustments must be calculated using a formula that is principally based on the sum of two separate fractions designed to quantify the volume of low-income Medicare patients and low-income non-Medicare patients served by the hospital.

The language at issue under the Medicare Act states that CMS must count those "entitled to [Supplemental Security Income] benefits" as low-income patients. The plaintiff hospital argues that CMS's actual-receipt test—counting patients as entitled to SSI benefits only if they actually received a cash payment—is not the best interpretation of the federal statute because it does not use the definition of "entitled to" that court used in *Empire Health* when applying the phrase to Medicare Part C patients. Among other arguments, the government asserts that its construction is consistent with the operation of the SSI program.

[12] 108 F.4th 882 (D.C. Cir. 2024).

[13] Nos. 23-55157, 23-55209 (Dec. 11, 2024).

[14] *See* No. 24-CV-02095 (BAH), 2024 WL 4723068, at *1 (D.D.C. Nov. 8, 2024).

[15] *Id.*

[16] *See Advoc. Christ Med. Ctr. v. Becerra*, 144 S. Ct. 2629 (2024).

Fraud, Waste, and Abuse Laws

The effect of *Loper Bright* on healthcare fraud, waste, and abuse laws, including the FCA, the AKS, and the Physician Self-Referral Law (or Stark law), is less certain. 2025 may showcase novel challenges and inconsistent federal court opinions.

Consider the Stark law, a slim federal law that imposes strict liability for referrals of Medicare/Medicaid beneficiaries for designated health services to entities with which a provider has a financial relationship.[17] Voluminous federal regulations build the foundation of Stark Law definitions and safe harbors. On September 12, 2024, the US District Court for the Southern District of West Virginia ordered the parties involved in an FCA lawsuit alleging Stark Law violations to file additional briefing on the impact of the *Loper Bright* decision. The judge stated:

> I do not know how *Loper Bright* will affect Relator's Stark Law claim. . . . What concerns me is this: I cannot determine if Relator has stated a claim without first determining the contours of the statute. Deeper still, the statute is fleshed out in the regulations.

Generally, both parties argued that the court could rely solely on the statute for its decision on the motion to dismiss. On November 7, 2024, the court granted the government's motion holding that the Relator failed to plead with particularity.[18] While this court's decision left the regulatory landscape of the Stark Law undisturbed, it is unclear whether other courts will follow suit when it comes to substantive Stark Law matters. In contrast, the AKS is a federal law that prohibits the exchange of remunerations (i.e., anything of value) to induce or reward Medicare/Medicaid patient referrals.[19] HHS OIG regulations set out voluntary safe harbors for payment and business practices that, although they potentially implicate the AKS, are not treated as offenses under the statute. The statute expressly delegates to HHS the authority to specify through regulation "any payment practices" not subject to the prohibition on referrals. As noted above, *Loper Bright* allows agency interpretations to receive some deference when a matter is expressly delegated to its discretion.

Additionally, unlike the Stark Law safe harbors, the AKS safe harbors are voluntary, meaning that, while complying with a safe harbor offers protection, failure to adhere to one does not render one strictly liable. As such, providers are unlikely to challenge the safe harbors. Any judicial review would likely focus on whether the agency is acting within the scope of its expressly delegated authority. *Loper Bright* may not have a significant impact here.

Takeaway

The implications of the *Loper Bright* decision are far from being fully realized. Providers may be encouraged to challenge agency interpretations in court, potentially disrupting payment systems and complicating efforts to implement innovative care delivery models. Additionally, courts may need to become experts on the nuances of hospital cost reports and reimbursement to exercise their best judgment and determine whether agency gap-filling is the best interpretation of the federal statute. To assist you with remaining up to date on these changes to the administrative landscape, the firm's Chevron Task Force continues to monitor all developments and will issue updates as necessary.

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[17] *See* 42 U.S.C. § 1395nn.

[18] *United States ex rel. Kyer v. Thomas Health Sys. Inc.*, No. 2:20-CV-00732, 2024 WL 4707811 (S.D.W. Va. Nov. 7, 2024).

[19] 42 U.S.C. § 1320a-7b(b).

HEALTHCARE PRIVACY

HEALTHCARE PRIVACY

HIPAA Changes Regarding Reproductive Health Information

In response to the US Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, the HHS, Office for Civil Rights (OCR) published a final rule[20] regarding implementing changes to the Health Insurance and Portability and Accountability Act of 1996 (HIPAA), effective June 25, 2024.

As published, the rule prohibits the use or disclosure of protected health information (PHI) by a covered health care provider, health plan, or health care clearinghouse (or their business associate): (1) to conduct a criminal, civil, or administrative investigation into or impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care, where such health care is lawful under the circumstances in which it is provided; or for (2) the identification of any person for the purpose of conducting such investigation or imposing such liability.

The prohibition applies where covered entities or business associates have reasonably determined that: (1) the reproductive health care is lawful under the law of the state in which such health care is provided under the circumstances in which it is provided; or (2) the reproductive health care is protected, required, or authorized by Federal law, including the US Constitution, regardless of the state in which such health care is provided; or (3) the reproductive health care was provided by a person other than the covered entity or business associate that receives the request for PHI, and the presumption described in the rule applies.

To implement the prohibition, the rule requires covered entities and business associates to obtain a signed attestation that the use or disclosure is not for a prohibited purpose when it receives a request for PHI potentially related to reproductive health care in the context of health oversight activities, judicial and administrative proceedings, law enforcement activities, and disclosures to coroners and medical examiners. The rule also requires covered entities to revise their Notices of Privacy Practices (NPPs) to support reproductive healthcare privacy. HIPAA-regulated entities must update their HIPAA policies and procedures and business associate agreements, as well as provide updated workforce training by December 23, 2024. Similarly, covered entities must revise their NPPs by February 16, 2026.

Notably, on December 22, 2024, just one day before the new rule's compliance deadline, a federal district judge in the Northern District of Texas issued a preliminary injunction enjoining HHS from enforcing the rule as to the named Plaintiffs, and ordered further briefing to determine whether permanent injunctive relief was warranted.[21]

HIPAA and Online Tracking Technologies

On March 18, 2024, OCR updated its guidance regarding the use of online tracking technologies, significantly expanding existing guidance.[22] Entities using tracking technologies (*e.g.*, cookies, web beacons, tracking pixels) must be alert to whether those technologies capture unique identifiers of web visitors, including a device ID or advertising ID. Individually identifiable health information (IIHI), or a combination of identifiers, that enable the creation of individualized customer profiles could result in the unauthorized use or disclosure of PHI. OCR's guidance distinguished between tracking technologies used

[20] 89 *Fed. Reg.* 32976 (April 26, 2024).

[21] *See Carmen Purl et al. v. HHS et al.*, No. 2:24-CV-228-Z (N.D. Texas).

[22] *See* Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates, HHS (June 26, 2024).

on authenticated versus unauthenticated pages. OCR explained that, while many unauthenticated pages do not have access to an individual's PHI, in some cases, PHI is accessible through an unauthenticated page, and the HIPAA rules would apply.

On June 20, 2024, the US District Court for the Northern District of Texas issued an order vacating a portion of this guidance document.[23] Specifically, the court vacated the guidance to the extent it provided that HIPAA obligations are triggered in "circumstances where an online technology connects (1) an individual's IP address with (2) a visit to a[n] [unauthenticated public webpage] addressing specific health conditions or healthcare providers."

The court explained that "IIHI is unambiguously defined as PHI that (1) 'relates to' an individual's 'past, present, or future physical or mental health or condition,' the individual's receipt of 'health care,' or the individual's 'payment' for 'healthcare'; *and* (2) 'identifies the individual' or provides 'a reasonable basis to believe that the information can be used to identify the individual." Because the guidance required entities to draw an inference regarding *why* people visit a healthcare website and because it was impossible to know the intent of people visiting the websites at issue, the guidance imposed a policy decision on data that did not and could not constitute IIHI. This portion of the guidance was rejected as a matter of law.

Although HHS originally appealed the district court decision, it subsequently withdrew the appeal and updated the online tracking guidance to reflect what portion of the guidance was vacated.[24]

Federal Privacy Legislation

Efforts to enact a federal privacy law to protect consumer data have been ongoing for years, and legislation introduced in 2024 shows Congress' continued interest.

The American Privacy Rights Act of 2024 (APRA), formally introduced on June 25, 2024, aimed to establish a comprehensive federal consumer privacy framework.[25] The APRA would grant consumers the right to access, correct, delete, and export their data and empower individuals to opt-out of data-based targeted advertising and transfer of their covered data to third parties. While broad in scope, the APRA would provide an exception for data processed in compliance with HIPAA.

Introduced in the US Senate on September 25, 2024, the Health Infrastructure Security and Accountability Act (HISAA) would require HHS to implement regulations establishing minimum security requirements for all HIPAA-regulated entities and additional security requirements for HIPAA-regulated entities determined by HHS as of systematic importance or importance to national security.[26] The HISAA would also require annual HIPAA security risk assessments, establish new penalties for noncompliance, and remove existing statutory caps on penalties.

Neither of these bills are likely to pass before the new Congress is seated, and it seems unlikely that consumer privacy will be a top priority of the new administration.

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[23] *See Am. Hosp. Ass'n v. Becerra*, — F. Supp. 3d ----, No. 4:23-cv-1110, 2024 WL 3075865 (N.D. Tex. June 20, 2024).

[24] Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates (June 26, 2024).

[25] H.R. 8818, 118th Congress (2024).

[26] S. 5218 118th Congress (2024).

State Consumer Health Data Laws

In 2023, Washington and Nevada joined Connecticut's ranks and implemented state-level health consumer data laws. In the aftermath of the Supreme Court's decision in *Dobbs v. Jackson Women's Health*, these three states enacted these laws to protect consumer health data that may not be regulated by HIPAA. While these laws have similarities, each contains distinctions that require regulated entities to assess their data processing activities and policies and procedures to ensure compliance. While HIPAA-regulated entities may qualify for broad exemptions (data level or entity level) under the state consumer health data laws, other healthcare industry players may be subject to these laws given their broad scope.

Look for state agency enforcement activity and/or private lawsuits (Washington State only) related to these laws to ratchet up in 2025 and beyond.

Information Blocking Rules

Information blocking is conduct that is likely to interfere with the access, exchange, or use of electronic health information (EHI) unless an exception or law permits the practice. Information blocking is a practice currently regulated pursuant to the 21st Century Cures Act,[27] which applies to health information technology (HIT) developers, exchanges (HIEs), networks (HINs), and health care providers. In 2023, HHS issued a final rule authorizing HHS to impose penalties on developers of certified health IT or other entities offering certified health IT, HIEs, and HINs.[28] In June 2024, HHS issued another rule authorizing penalties against health care providers participating in the Medicare Promoting Interoperability Program, clinicians in Medicare's Merit-based Inventive Payment System, and providers in accountable care arrangements under the Medicare Shared Savings Program.[29]

Under this rule, hospitals would lose 75% of the annual market basket increase, whereas critical access hospitals would have payments reduced from 101% to 100% of reasonable costs. Most recently, HHS published a final rule effective on December 17, 2024 that revised two information blocking exceptions and established another activity that does not constitute information blocking, referred to as the "Protecting Care Access Exception."[30]

What's Next?

2024 has been a busy year in the healthcare and privacy industries, and there is no slowdown in sight for 2025. New privacy priorities from HHS and potentially HHS OIG are expected as a new presidential administration takes shape. We also anticipate additional state legislative and enforcement activity in response to the anticipated shift in federal oversight priorities.

Stay apprised to our *Health Law Scan* for industry news and highlights, and reach out to one of our healthcare and privacy lawyers if you have legal questions.

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[27] Pub. Law No. 114-255, § 4004.

[28] 88 *Fed. Reg.* 42820 (July 3, 2023).

[29] 89 *Fed. Reg*. 54662 (July 1, 2024).

[30] 89 *Fed. Reg.* 102512 (Dec. 17, 2024).

MANAGED CARE

MANAGED CARE

Managed care has been the dominant delivery system for both Medicaid and Medicare for the last several years, and the program enrollment and expenditures continue to grow. State and federal spending on Medicaid in fiscal year 2023 was over $860 billion, and based on preliminary estimates, payments to Medicaid managed care organizations represented almost 60% of total Medicaid spending. The Congressional Budget Office projected that the federal government spent $462 billion on Medicare Advantage in 2024.

Managed care enforcement continues to be a priority for DOJ, HHS, HHS OIG, and many state authorities. This trend will likely continue with the new administration, given the significant federal dollars at stake and the articulated priority of reducing spending on healthcare.

Medicaid Enrollment Continues to Unwind, Impacting Managed Care

States are still struggling to return to pre-COVID-19 pandemic enrollment renewal requirements, and an estimated 25 million people lost Medicaid coverage during the year-long reinstitution of eligibility checks (many of whom CMS believed remained coverage eligible). In 2025 and 2026, states must implement plans to achieve compliance with federal renewal requirements. Moving forward, States may rely on managed care organizations (MCOs) that also have a stake in the continued enrollment of their members.

During the public health emergency (PHE), CMS imposed the continuous enrollment condition, which required states to maintain all Medicaid enrollments during the PHE in order to receive certain enhanced federal funds. In 2023, the continuous enrollment condition ended, and CMS launched the "unwinding," referring to a year-long period during which the states were required to redetermine eligibility of 94 million Medicaid enrollees consistent with the annual renewal requirements that were paused during the PHE.

The unwinding was fraught with missed deadlines, noncompliance, threats to withhold federal funding, and many other issues. CMS raised concerns about improper disenrollments and states where over half of Medicaid beneficiaries lost coverage. CMS estimated that 71% of all people disenrolled lost coverage due to administrative or procedural reasons. CMS identified an issue in 29 states that resulted in inappropriate disenrollments of over 400,000 children and families in multi-member households. To date, nearly all states have been required to implement at least one mitigation strategy during unwinding (e.g., reinstating beneficiaries or temporarily pausing renewal processing to protect coverage for eligible individuals).

On September 20, 2024, CMS issued a bulletin regarding the implementation of a standardized process to support states to achieve compliance with the federal renewal requirements. All states were required to complete a plan by December 31, 2024, outlining steps and milestones to address any noncompliance with annual eligibility renewals.[31] States must submit updates every six months and must achieve compliance no later than December 31, 2026.

Under the federal renewal requirements, states must allow beneficiaries to submit enrollment renewal forms through various modalities (e.g., online, by phone, in person, by mail). Among other requirements, states must allow for a reconsideration period and transfer ineligible members to other insurance affordability programs. CMS has warned that it is already exercising its enforcement discretion despite

[31] *See* 42 C.F.R. §§ 435.916, 457.343.

noncompliance by states with federal requirements, and further agency action may be taken if states fail to adhere to their compliance plans.

Recognizing that the states have been overwhelmed by the administrative burden of renewals, CMS issued guidance in March 2024 allowing states to utilize MCOs to assist with renewals and reiterated that option in its September 2024 bulletin. Moving forward, MCOs will likely play a significant role in renewals for the next two years. Specifically, states may lean on MCOs to gather updated enrollee contact information, review renewal files, and conduct outreach to enrollees, assist enrollees in completing and submitting renewal forms, contact disenrolled individuals who lost coverage for procedural reasons, and assist individuals in transitioning to Marketplace coverage.

MCOs may succeed where states have failed, given that MCOs have greater resources and an interest in mitigating procedural disenrollments and avoiding increased uninsured rates.

Challenges to Medicare Star Ratings

Last year concluded with an emerging trend of challenges to CMS's Medicare Star Ratings based on unforgiving evaluation standards. And with billions of dollars in bonus payments at stake, we expect these challenges may continue in 2025 with the possibility of such challenges having major impacts on Medicare Advantage plans (MA plans).

Medicare Advantage, also referred to as Part C, allows beneficiaries to receive coverage under a managed care model delivered through private insurers. When electing to enroll, beneficiaries can review each plan's Star Rating (scored between 1 and 5), representing certain plan performance metrics based, in part, on patient surveys and designed to assess plan responsiveness and care, member satisfaction, etc. Plans with 5 Stars are depicted on the enrollment website with a high-performing icon. Plans with higher Star Ratings tend to attract more enrollees, and the data shows that most enrollees are in MA plans with Star Ratings of 4 or above.

Separately, Star Ratings directly impact reimbursement via qualified bonus payments (QBP) and rebate payments per enrollee. CMS is estimated to make $11.8 billion in 2024 bonus payments to MA plans. In short, MA plans are paid a specified percentage of the difference between a federal benchmark and the plan's bid (i.e., estimated cost for providing covered services). For MA plans with Star Ratings of 4 or above, the QBP increases the federal benchmark by 3.5% to 5%, resulting in greater reimbursement to the plan.

Additionally, the specified percentage of the difference between the benchmark and the bid is adjusted based on the MA plan's Star Rating (i.e., 70% for 4.5 Stars, 65% for 4 Stars, 65% for 3.5 Stars (no QBP adjustment), and 50% for 3.0 Stars or fewer (no QBP adjustment)). The impact of these adjustments can result in a difference of hundreds of millions in revenue, and a reduction in a Star Rating to less than 4 could potentially be catastrophic.

CMS calculates Star Ratings based on a complex methodology that it regularly adjusts. The 2024 Star Ratings introduced "Tukey outlier deletion," which involves removing outlier scores prior to determining measure-level cut points. CMS also announced it would *double* the weight of patient experience/complaints and access measures on Star Ratings.

These CMS adjustments and others, which are alleged to have resulted in overall Star Ratings score reductions and ineligibility for QBPs and rebate payments, are at the core of current litigation. Other common themes include opposition to unforgiving subregulatory guidance disallowing callbacks during telephone customer service (i.e., a dropped call constitutes a plan failure) and agency refusals to provide transparency and requested data. Some MA plans have had success at the motion for summary judgment

stage, where courts have ordered CMS to recalculate the MA plans' Star Ratings. We expect the litigation trend challenging Star Ratings to continue in 2025.

HHS OIG Special Fraud Alert on Medicare Advantage Marketing

Based on recent agency guidance, we anticipate greater governmental scrutiny of marketing arrangements under Medicare Advantage in 2025. MA plans and managed care providers would be well advised to consider reviewing their marketing arrangements to ensure none of the government's identified suspect characteristics are present. Additionally, safe harbor protections should be considered.

The AKS is a broad criminal law that prohibits knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service (drugs, supplies, health care services, etc.) payable by a federal health care program.[32] The AKS prohibits referrals by anyone and extends both to direct referrals and activities that constitute arranging for referrals, such as marketing. Prohibited acts include exchanging, or offering to exchange, anything of value, in an effort to influence or induce the referral of healthcare business.

On December 11, 2024, HHS OIG issued a Special Fraud Alert related to marketing arrangements between MA plans, healthcare professionals, and agents and brokers for MA plans that implicate the AKS due to unfair competition and improper steering of Medicare enrollees. Specifically, HHS OIG identified two types of remuneration it considered to be abusive:

- MA plan payments to healthcare professionals (or their staff) relating to plan marketing and enrollment
- Healthcare professional payments to agents/brokers/others relating to referring Medicare enrollees to a particular healthcare professional

HHS OIG noted that healthcare professionals are permitted to engage in certain limited marketing on behalf of an MA plan; however, they may not accept compensation.[33] Agents and brokers are licensed at the state level and permitted by federal regulations to receive payments, subject to certain conditions, from MA plans for marketing services.[34] HHS OIG's guidance focused on payments from healthcare professionals to agents/brokers, warning that enrollees may rely on recommendations from agents/brokers without knowledge of underlying financial arrangements.

HSS OIG outlined certain "suspect characteristics," including offering or paying remunerations

- to healthcare professionals, disguised as payment for legitimate services;
- to healthcare professionals, for sharing patient information that may be used for marketing;
- to healthcare professionals or agents/brokers, contingent upon or varied based on the demographics or health status of enrollees; and
- to healthcare professionals or agents/brokers, varied based on the number of individuals referred for enrollment.

[32] 42 U.S.C. § 1320a-7b.

[33] 42 C.F.R. § 422.2266(d).

[34] 42 C.F.R. § 422.2274.

The Special Fraud Alert may also result in an uptick in whistleblower lawsuits and state enforcement actions.

Medicaid Reform: Enrollment, Eligibility Checks, and Work Requirements May Resurface in 2025

The Medicaid program is subsidized by the federal government, and its expenditures have grown from $41 billion in 1985 to $860 billion in 2023, making it one of the fastest-growing federal programs on the books. And with ever-increasing expenses, it comes as no surprise that the Medicaid program may come under the microscope of the incoming administration when looking for cost savings.

While we cannot know for certain what Medicaid reforms, if any, the incoming administration may consider, certain reforms related to stricter program enrollment and enrollee work requirements have already been floated by members of the Republican Party as having the potential to yield savings of up to $260 billion. While these cost-saving estimates could change, they are of a magnitude that is likely to garner serious consideration by the Trump-Vance administration and the new Congress. And if we look to the prior Trump-Pence administration for guidance on potential Medicaid reforms, there we find several previous Medicaid reform efforts that may resurface.

The Trump-Pence administration, under its Section 1115 waiver policy, approved 13 waivers—respectively, in AR, AZ, GA, IN, KY, ME, MI, NE, NH, OH, SC, UT, and WI—that conditioned Medicaid eligibility on individuals meeting work and reporting requirements. Many of the waivers were challenged in court. For example, the US District Court for the District of Columbia deemed work requirements in Arkansas and Kentucky to be unlawful because the HHS Secretary can only approve 1115 waivers that are "likely to assist in promoting" Medicaid's purpose.[35] The court found that the secretary failed to offer evidence that an experiment designed to remove thousands of people promotes that purpose.[36] The case was subsequently vacated and remanded to be dismissed as moot when the Biden administration rescinded approval for the waivers.

The Biden administration also pursued reforms to improve access, including the Access Rule, Managed Care Rule, Long-Term Care Facility Staffing Rule, and streamlined Medicaid enrollment and renewal processes for the Medicare Savings Program as well as for Medicaid, CHIP, and the Basic Health Program.

If the "past is prologue," the possibility exists that the incoming administration will resurrect work requirements and other restrictions on eligibility (e.g., approved waivers permitted states to charge premiums and lock out enrollees who were disenrolled for unpaid premiums). Such waivers would likely face court challenges and a stricter standard of review under *Loper Bright*. The new administration could also delay implementation of certain provisions or issue new regulations that would undo the Biden administration's final regulations to improve access.

Alternatively, the incoming administration could issue subregulatory guidance to change eligibility or renewal policies on coverage and eligibility verification. Finally, enacting new Medicaid reform legislation also remains on the table. Anyone participating in Medicaid would be well advised to track program developments in 2025.

[35] 42 U.S.C. § 1315(a).

[36] *Gresham v. Azar*, 363 F. Supp. 3d 165, 172 (D.D.C. 2019), aff'd, 950 F.3d 93 (DC Cir. 2020).

HOSPITALS AND HEALTH SYSTEMS

HOSPITALS AND HEALTH SYSTEMS

CY 2025 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Rule Differs from Inpatient Prospective Payment System Rule

CMS changes to the Outpatient Prospective Payment System (OPPS) present a divergence from existing policy under the IPPS. On November 1, 2024, CMS issued a final rule[37] that updates the OPPS Medicare payment rates and the Medicare Ambulatory Surgical Center (ASC) Payment System for 2025. Effective January 1, 2025, the final rule implements a different wage index for the OPPS than that currently used for the IPPS.

For hospitals with a wage index value below the 25th percentile, the hospital's wage index will be increased by half the difference between the otherwise applicable wage index value for that hospital and the 25th percentile wage index value for all hospitals under the OPPS. The DC Circuit previously determined CMS lacked the statutory authority to adopt this low wage index relief policy under the IPPS statute in *Bridgeport Hospital v. Becerra*.[38] The Ninth Circuit ended the year with a similar ruling in *Kaweah Delta Health Care District, et al. v. Becerra*.[39] Nevertheless, CMS relied on similar "adjustment authority" in the OPPS statute to adopt the previously vacated IPPS low wage index policy into CMS' regulations for the OPPS for 2025.

Moreover, while CMS estimates that total payments, including beneficiary cost-sharing, to the approximately 3,500 facilities paid under the OPPS will increase by approximately $1.98 billion compared to 2024 payments, the 2.6% increase is lower than the 3.1% rate increase implemented in 2024. This smaller increase, combined with the effect of the low wage index policy for certain higher wage index hospitals, could present reimbursement challenges for the year ahead.

Medicare Finalizes Appeals Process for Reclassified Outpatient Observation Patients

On October 11, 2024, pursuant to a federal district court order, CMS issued a final rule,[40] establishing two new appeals processes for traditional Medicare beneficiaries who were initially admitted to a hospital as an inpatient and subsequently reclassified as an outpatient receiving observation.[41]

Beginning February 14, 2025, Medicare beneficiaries who disagree with a hospital's decision to reclassify their status from inpatient to outpatient receiving observation services, resulting in a denial of coverage for the hospital stay under Part A, will be able to file for an expedited appeal prior to release from the hospital. Appeals must be filed with a Beneficiary & Family Centered Care-Quality Improvement

[37] 89 *Fed. Reg.* 93912 (Nov. 27, 2024).

[38] 108 F.4th 882 (DC Cir. 2024).

[39] Nos. 23-55157, 23-55209 (Dec. 11, 2024).

[40] 89 *Fed. Reg.* 83240 (Oct. 15, 2024).

[41] *See Alexander v. Azar* (613 F. Supp. 3d 559 (D. Conn. 2020), aff'd sub nom., *Barrows v. Becerra*, 24 F.4th 116 (2d Cir. 2022); see also Hospital Appeals -Change of Inpatient Status (*Alexander v. Azar*), CMS (Dec. 17, 2024).

Organization, which will independently review the beneficiary's patient record to determine whether the inpatient admission satisfied the criteria for Part A coverage.

Beginning January 1, 2025, Medicare beneficiaries will be able to file an appeal for denials of Part A coverage of hospital services (and certain skilled nursing facility services) resulting from reclassification made by the hospital. Beneficiaries may appeal hospital stays that began on or after January 1, 2009 through February 14, 2024 (i.e., the prospective appeals process' implementation date). Beneficiaries must file such appeals by January 2, 2026.

Medicaid DSH Payment Reductions and DSH Litigation

Hospitals and health systems face Medicaid DSH payment reductions, but continue to push forward court cases that may increase DSH payments.

On February 23, 2024, CMS issued a final rule addressing changes required by the Consolidated Appropriations Act 2021 to the hospital-specific limit on DSH payments.[42] Eight billion dollars in Medicaid DSH payment reductions were implemented on January 1, 2025, and an additional $8 billion in reductions are scheduled for 2026 and 2027, respectively.

Meanwhile, litigation regarding DSH formula calculation rages on. Most recently, on November 4, 2024, the Supreme Court heard oral arguments for the *Advocate Christ Medical Center v. Becerra* case, originally filed in 2017. Hospital-petitioners argued those eligible for DSH include any individuals who are enrolled in Supplemental Security Income (SSI), even if they do not receive cash benefits for the month in question, whereas the government requires the individuals enrolled in SSI to be entitled to cash benefits for the month in question.

As with related cases in recent years, including *Azar vs. Allina Health Services* and *Becerra v. Empire Health Foundation*, petitioners argue that this difference in interpretation has shortchanged hospitals millions. The *Advocate Christ* petitioners seek to use the Supreme Court's decision in *Becerra v. Empire Health* (regarding an individual's entitlement to Medicare Part A) to their advantage. 2025 will offer additional clarity on this long-disputed issue.

Further, in *Baylor All Saints Medical Center dba Baylor Scott & White All Saints Medical Center-Fort Worth et al. v. Becerra*, the US District Court for the Northern District of Texas vacated an HHS regulation that excluded certain patient days funded by Uncompensated Care Cost pools from the Medicaid fraction used to calculate DSH adjustments.[43] The decision restores Uniform Commercial Code-funded patient days in the DSH payment calculation, potentially increasing DSH payments for qualifying hospitals.

Hospitals and health systems should track the outcome of such changes to inform their estimates and consider potential administrative appeals for additional DSH payments for 2025.

HHS OIG Report Recognizes Low Hospital Price Transparency Rule Compliance and Recommends CMS Strengthen Compliance Controls

On November 5, 2024, the HHS OIG issued a report summarizing its audit on hospitals' compliance with the hospital price transparency rule.[44] Based on its audit, HHS OIG estimates that 46% of hospitals

[42] 89 *Fed. Reg.* 13916 (Feb. 24, 2024).

[43] *Baylor All Saints Med. Ctr. v. Becerra*, No. 4:24-cv-00432-P, 2024 US Dist. LEXIS 145448 (N.D. Tex. Aug. 15, 2024).

[44] OIG, Not All Selected Hospitals Complied with the Hospital Price Transparency Rule (Nov. 5, 2024).

comply with the requirements to make information on their standard charges available to the public. HHS OIG further noted that CMS' enforcement activity is increasing—between January 1, 2021, when the rule became effective, and September 2022, CMS had issued two civil monetary penalties (CMPs) totaling $1.1 million.

However, by February 2024, CMS had issued 14 CMPs totaling $4 million. In response to HHS OIG's findings, CMS stated that it has "demonstrably increased" the number of compliance reviews of hospitals per year, and HHS OIG recognized that CMS has assigned additional staff to expedite its review of alleged noncompliance.

Impact of the Demise of Chevron *Deference on Hospitals and Health Systems*

The US Supreme Court on June 28, 2024 decided *Loper Bright Enterprises v. Raimondo* and *Relentless v. Department of Commerce*, overruling the Chevron doctrine that for four decades required federal courts to defer to administrative agencies' interpretations of ambiguous or broad statutes. The decisions have prompted federal agencies to reevaluate how they approach rulemaking, Congress to introduce legislation to address agency deference, and federal judges to interpret ambiguous statutes using their own methods of statutory construction. These decisions will have a significant impact on hospitals and health systems given their highly regulated operations and reimbursement, and they should carefully assess the impact and monitor changes made in the wake of *Loper Bright*. Read more about the decisions in the *Loper Bright* and *Relentless* section of the report.

Federal Privacy Legislation and State Consumer Health Data Laws Affecting Hospitals

Efforts to pass federal US privacy legislation have been ongoing for years and continue to grow. Hospitals and health systems should monitor ongoing developments regarding federal privacy legislation, including the proposed American Privacy Rights Act of 2024 and proposed Health Infrastructure Security and Accountability Act, as described in the Healthcare Privacy section of the report.

Hospitals and health systems should also evaluate their compliance with the patchwork of state consumer health data privacy laws, such as Washington's My Health My Data Act, the Nevada Consumer Health Privacy Law, and the Connecticut Data Privacy Act. While these laws have similarities, each contains distinctions that require regulated entities to assess their data processing activities and policies and procedures to ensure compliance.

DRUG PRICING AND REIMBURSEMENT

DRUG PRICING AND REIMBURSEMENT

340B Drug Discount Program Litigation, PBM Transparency, Inflation Reduction Act Drug Price Negotiation Predictions, and Other Key Areas to Watch in 2025

In 2025, the Trump-Vance administration will control the White House, and Republicans will hold a narrow majority in both the House and Senate. This control trifecta is likely to impact both legislative and regulatory processes and provide pathways for potential changes to the drug pricing and reimbursement landscapes. While president-elect Trump has yet to articulate priorities regarding drug pricing and reimbursement, his reform efforts during his prior administration and the ongoing bipartisan focus on drug affordability suggest that drug pricing will continue to be an area of focus in 2025.

340B Drug Pricing Program: Contract Pharmacy Access Litigation and Manufacturer Rebate and Credit Drug Purchase Models Likely to Remain a Core Focus in 2025

The 340B program, a federal prescription drug affordability program permitting certain safety-net healthcare providers to purchase discounted outpatient drugs from manufacturers, has largely garnered bipartisan support over the years. However, the transition to a new presidential administration in 2025, coupled with ongoing program-related litigation, could bring a flurry of new guidance for program participants or legislative change. Contract pharmacy access and manufacturer proposed 340B rebate and credit drug purchase models took center stage in 2024 and will be important areas for the industry to monitor in 2025.

The Battle Over Contract Pharmacy Access and Manufacturer Restrictions Rages On

The issue of contract pharmacy access dates back to 1994, when HRSA issued guidance stating that a covered entity may use a "purchasing agent" to receive covered drugs from manufacturers for distribution to the covered entity. In 1996, HRSA issued additional guidance stating that covered entities could use *one* contract pharmacy each. Then, in 2010, HHS issued new guidance stating that covered entities could use an unlimited number of contract pharmacies. As a result, contract pharmacy access expanded from fewer than 1,200 in 2010 to more than 33,000 in 2023, enabling the 340B program to become the second-largest federal prescription drug program, behind only Medicare Part D, reaching $124.1 billion in sales in 2023.

In response to exponential program expansion, in 2020, manufacturers began imposing various restrictions on contract pharmacy access. Such restrictions included, but were not limited to, limiting covered entities without an in-house pharmacy to a single contract pharmacy, requiring claims data be submitted to the manufacturer to designate more than one contract pharmacy, and limiting contract pharmacy access to only those contract pharmacies that were within a certain distance from the covered entity (e.g., within 40 miles from the covered entity's location). 340B providers vigorously opposed manufacturer restrictions, and litigation ensued.

In May 2024, the DC Circuit issued a first of its kind opinion protecting the ability of program manufacturers to impose commercial contracting conditions on the distribution of covered outpatient drugs. Health Resources and Services Administration (HRSA), which had advised for over a decade that covered entities could contract with an unlimited number of outside pharmacies for distribution of covered drugs under the program, contested the conditions as violative of a manufacturer's statutory duty to offer drugs in a manner that cannot be qualified, restricted, or dependent on how the covered entity chooses to distribute the drugs. The court's holding confirmed the 340B program does not require

unabridged contract pharmacy access to covered drugs and served to further escalate contract pharmacy access disputes.

To date, eight states (AR, LA, MS, MO, KS, MN, WV, MD) have enacted 340B contract pharmacy access laws, and 13 others (OR, ID, UT, AZ, OK, NE, IA, IL, OH, SC, FL, NY, RI) have legislation pending. And while it appears that additional states will follow suit, we expect manufacturers will continue to challenge contract pharmacy access laws in 2025. However, most recently, Arkansas's 340B contract pharmacy access law, Arkansas Act 1103, which was the first state law to prohibit drug manufacturers from restricting access to 340B-priced drugs when dispensed through contract pharmacies, was upheld as constitutional by the US 8th Circuit Court of Appeals.

Given the dollars at stake, it should come as no surprise that contract pharmacy access disputes are likely to persist. We expect litigation to continue in 2025 with manufacturers exempting states with enacted contract pharmacy access laws from any manufacturer-imposed access restrictions.

Litigation Over Manufacturer Proposed 340B Drug Rebate and Credit Purchase Models Full Steam Ahead

Under the 340B program, participating manufacturers must offer outpatient drugs to 340B providers at prices that do not exceed the 340B ceiling price. Since the program's enactment in 1992, manufacturers have met this obligation by offering 340B prices through upfront discounts. Recently, however, in what manufacturers contend is an effort to ensure compliance with the program's prohibition on duplicate discounts and diversion, several manufacturers have proposed implementation of rebate or credit purchase models that would require 340B providers to purchase drugs at higher prices, likely at wholesale acquisition cost (WAC), and after dispensing or administering a drug to a 340B-eligible patient, submit a rebate or credit request to the manufacturer. If approved, the manufacturer would issue a refund for the difference between the WAC and 340B prices.

While the proposed rebate and credit models seek to preserve the 340B program's central purpose—to enable providers serving low-income, vulnerable, and medically underserved populations to stretch scarce resources and improve access to care—and ensure manufacturer compliance with program prohibitions on duplicate discounts and diversion, beginning in September 2024, HRSA began issuing warnings to manufacturers demanding they immediately cease implementation of the proposed rebate and credit models pending formal approval by the HHS Secretary. In some instances, HRSA went so far as to threaten manufacturers with sanctions and possible loss of participation in Medicare and Medicaid programs.

In response to HRSA's warning letters, several manufacturers filed lawsuits against HHS and HRSA, highlighting the growing conflict over interpretations of program requirements. While manufacturers have questioned HHS and HRSA statutory authorities inherent within the 340B program, federal regulators have asserted that the contested requirements are necessary to maintain program integrity and ensure equitable access to discounted drugs for safety net providers and their patients.

Looking Ahead to 2025

In the face of myriad judicial and regulatory conflicts over compliant implementation of 340B program requirements, Congress will likely be best suited to address program reforms long-term should bipartisan support continue in President Trump's second term. With some legislative efforts already pending—including the 340B Access Act and the 340B Patients Act—program participants should continue to monitor for updated guidance and program changes that may arise throughout 2025.

Pharmacy Benefit Manager (PBM) Transparency: Will 2025 be the year for change?

Pharmacy benefit managers (PBMs) remain under the microscope and subject to government scrutiny, and this trend is unlikely to change in 2025. The FTC issued its unfavorable report on PBM practices in July 2024, which was followed by a similar unfavorable report issued by the House Committee on Oversight and Accountability. Reducing drug prices for patients has been and is likely to remain a bipartisan focus in 2025, and PBM price transparency has been and is likely to remain a core part of that effort.

PBM Transparency Remains a Bipartisan Focus

The first Trump administration attempted PBM reform through its regulatory authority and enactment of the HHS OIG's Rebate Rule. The proposed Rebate Rule would have amended the discount safe harbor regulation to eliminate protection for Medicare Part D price concessions, including rebates, that are offered by pharmaceutical manufacturers to plan sponsors, or PBMs under contract with them. Although the Rebate Rule was ultimately withdrawn under the Biden administration, it could be an area the incoming Trump administration looks to revisit.

Reform efforts do not end there, however. Recently, a bipartisan bill was introduced in the Senate that would require healthcare companies that own health insurers or PBMs to sell pharmacy assets within three years. Specifically, the bill states in part, "[I]t shall be unlawful for any person to both (A) directly or indirectly own, operate, control, or direct the operation of the whole or any part of a pharmacy, and (B) directly or indirectly own, operate, or control the whole or any part of (i) an insurance company, or (ii) a pharmacy benefit manager."

Similarly, the US Senate Committee on the Judiciary recently sent a letter and document demand to one of the nation's largest PBMs, outlining its investigation into whether the PBM "is engaged in activities that harm competition, stifle innovation, and may violate antitrust laws." The letter goes on to assert that PBMs "can influence independent pharmacies because losing 'in-network' status . . . can mean that an independent pharmacy can no longer afford to serve the community that relies on its services."

Looking Ahead to 2025

PBM transparency and reform proposals continue to make headlines. And while we can't know if proposed legislation will gain traction or what the outcome of any investigation(s) will be, these data points signal PBM practices will remain under scrutiny and proposed reform will likely have bipartisan support in 2025. Any entity doing business with PBMs would be well advised to prepare to respond to what we anticipate may be significant changes in 2025.

The Inflation Reduction Act and Drug Price Negotiations: Predictions for 2025

The Inflation Reduction Act (IRA), signed into law by President Biden in 2022, implemented sprawling reforms related to drug pricing, including formalizing the Medicare Drug Price Negotiation Program, establishing inflation rebates for certain drug price increases, and reforming drug costs under Medicare Parts B and D. In the most recent State of the Union, the Biden administration signaled an intent to expand Medicare drug price negotiations under the IRA from the initial subset of 10 drugs to more than 500.

While the incoming Trump-Vance administration has not yet signaled whether it will be quite as aggressive on IRA implementation, the administration will face key program deadlines shortly after taking

office, with a $2,000 out-of-pocket cap on Medicare drug spending set to roll out in January 2025 and the list of 15 additional high-cost drugs to be selected for negotiations due on February 1, 2025.

The IRA was controversial at the time it was signed into law and remains so today. And while wholesale repeal of the IRA appears unlikely, trifecta control may provide the incoming administration with the ability to make significant modifications to its current form and scope. Alternatively, revised guidance over how drug price negotiations will proceed moving forward could issue in the very near term. Drug manufacturers whose products may be subject to price negotiations would be well advised to keep close track of any IRA developments.

Diagnostic Radiopharmaceuticals: Unpackaged Medicare Payment Rates May Increase Investment Opportunities for Costly Drugs and Beneficiary Access

A long-awaited improvement to reimbursement for certain high-cost drugs will take effect in calendar year 2025. Diagnostic radiopharmaceuticals are used in nuclear medicine scans such as Positron Emission Tomography (PET) and Single Photon Emission Computed Tomography (SPECT) scans. New payments for these drugs will likely result in greater access by Medicare beneficiaries to critical diagnostic and treatment services, investment and innovation in nuclear medicine, and better alignment with actual costs incurred by safety-net hospitals.

Evolution of Diagnostic Radiopharmaceutical Pricing and Reimbursement

Under the Hospital Outpatient Prospective Payment System (HOPPS or OPPS), no separate payment is made for certain items and services that are ancillary or supportive to a primary procedure or service. Rather, the ancillary items and services are "packaged" into a prospectively fixed rate, known as an Ambulatory Payment Classification (APC), that represents similar items and services in terms of clinical treatment and cost. CMS averages the costs of packaged items and services to determine reimbursement rates. To ensure appropriate reimbursement for high-cost ancillary items, most drugs and biologics are removed from CMS's packaging policy if they exceed a specific cost threshold.

Since 2008, federal regulation has required diagnostic radiopharmaceuticals used in diagnostic nuclear medicine scans to be packaged, regardless of cost. 42 C.F.R. § 419.2(b)(15). High manufacturing costs and limited half-life (e.g., six hours for technetium-99m) caused the costs of diagnostic radiopharmaceuticals to swell, while reimbursement continued to be limited and costs of higher-priced more-effective diagnostics were averaged with more general and widely used lower-cost less-effective drugs. Underpayments for diagnostic radiopharmaceuticals were so significant some providers refused to offer the diagnostic scans, which can be critical for those suffering from Alzheimer's and Parkinson's disease. This was particularly the case where mitigating pass-through payments expired.

In 2023, CMS solicited comments on five potential approaches for payment of diagnostic radiopharmaceuticals, but the agency did not finalize a new reimbursement scheme. In July 2024, CMS proposed to align diagnostic radiopharmaceuticals with the specific cost thresholds applicable to other drugs and biologics. CMS communicated an openness to industry feedback and asked for comments on four different approaches to the enhanced reimbursement. In a November 2024 final rule, CMS established a drug packaging threshold for diagnostic radiopharmaceuticals. As such, those drugs with a per day cost greater than $630 will be removed from the existing packaging policy and will be paid separately at their mean unit cost (a payment rate derived from hospital claims data). Any diagnostic radiopharmaceutical with a per day cost equal to or below that threshold will continue to be policy packaged, with the APC payment for the nuclear medicine tests.

Presently, there are 26 diagnostic radiopharmaceuticals eligible for separate payments, including Choline c-11 and Illuccix (PET scan tracers to detect prostate cancer) and Neurolite (SPECT scan tracer to

diagnose and treat strokes). Various stakeholders have endorsed CMS's final rule, including the Society of Nuclear Medicine and Molecular Imaging and the American Society of Nuclear Cardiology.

Looking Ahead to 2025

Moving into 2025, pharmaceutical manufacturers have expressed excitement that the new payments will promote future innovation of next-generation products and improve the ability of companies to sustain production in the radiopharmaceutical industry. Physicians and hospitals may be more likely to administer nuclear medicine scans with the removal of cost barriers. CMS emphasized its goal to improve beneficiary access to costly diagnostic radiopharmaceuticals where there is no clinical alternative, particularly in safety net hospitals serving a high proportion of Medicare beneficiaries and hospitals serving underserved communities. However, as is often the case with pricing thresholds, it is also possible that the drug packaging threshold could incentivize price inflation for diagnostic radiopharmaceuticals. This will remain an area to watch in 2025.

Bayh-Dole March-In Rights: An Unlikely Vehicle to Reduce Drug Prices in 2025

The Bayh-Dole Act applies when businesses and other organizations (researchers) conduct research and develop an invention that is either conceived of or first actually reduced to practice under a federally funded agreement. One of the key policy objectives of the Bayh-Dole Act is to encourage researchers to use or commercialize such an invention so that the public can benefit from the US government's financial support for the innovation.

To achieve this goal, the Bayh-Dole Act enables researchers to retain ownership of the patent rights, but the US government simultaneously will hold a government purpose license (GPL) and march-in rights to the patented invention that may be exercised if the titleholder does not achieve practical application or one of the three other statutorily defined criteria apply.

Drug pricing advocates have repeatedly argued that the US government should use its Bayh-Dole Act rights in certain drug products to influence the price of those products. Some argue that the government should use its GPL to allow third parties to manufacture Bayh-Dole Act covered drug products and offer them at a lower price. Others have argued that the government should "march-in" on Bayh-Dole Act covered drug products by asserting that such products have not achieved practical application and are not available on reasonable terms due to their price. To date, various US government agencies, including the National Institutes of Health, have resisted this pressure and the federal government has never exercised its march-in authority.

That said, over the last eight years use of march-in rights received attention within executive branch agencies and on Capitol Hill. As a result, use of march-in rights or an expansion of the GPL to allow third-party manufacturing of drug products for the purpose of influencing price remains an area of bipartisan interest that could have immediate impacts on patent portfolios and longer-term impacts on the innovative ecosystem that the Bayh-Dole Act has created. With IP being the bedrock of pharmaceutical development and commercialization, manufacturers would be well advised to stay abreast of any developments on the march-in rights front.

Most Favored Nation Drug Pricing Model: A Proposal Unlikely to Resurface in 2025

The first Trump administration issued a Most Favored Nation (MFN) Executive Order (EO) in September 2020 that purposed to ensure that US drug prices under Medicare would be at parity with drug prices in other countries. Specifically, the EO called for models that would cap the price Medicare pays for certain Part B and Part D drugs. In response to this EO, CMS issued an Interim Final Rule (the MFN Rule) in

November 2020 setting forth an MFN model that was designed to lower prescription drug costs for consumers by paying a cost equivalent to the lowest price that drug manufacturers receive in other similar countries for otherwise high-cost Medicare Part B drugs and biologicals.

Soon after CMS issued the MFN Rule, litigation was brought by pharmaceutical companies in several federal courts across the country challenging the proposal and seeking preliminary injunctions. These challenges resulted in legal stays that prevented the MFN Rule from going into effect. The MFN Rule was ultimately rescinded by CMS in late 2021 under the Biden administration. Given vigorous legal opposition to the proposed MFN Rule, it is unlikely this will surface as a priority for the incoming administration. However, the Republican Party's trifecta control could change the analysis, and as such, this should remain on the radar.

Drug Importation: Operational Challenges Likely to Persist in 2025

The cost of prescription drugs in the United States remains a top healthcare priority with bipartisan support. The first Trump administration finalized regulations (which the administration had initiated in 2019) toward the end of 2020 that created a pathway for states and American Indian tribes to import certain prescription drugs from Canada in an effort to reduce the cost of drugs for US consumers. Under the final regulations, the FDA must approve a Section 804 Importation Program (SIP) proposal before any drugs may be imported under the plan.

Despite efforts made by various states since the implementation of the final regulations, to date FDA has only authorized the Florida importation program (Colorado has a plan pending with the agency), and there have also been operational challenges to state implementation of approved plans. Despite these challenges, given that pharmaceutical drug pricing reform has bipartisan support, this may again become a renewed issue of focus for the incoming administration in 2025.

Key Takeaways

While there is still much uncertainty on exactly how the new administration's policies on pharmaceutical drug pricing and reimbursement reform will take shape, it is clear these issues have bipartisan support and change is likely to come in the not-too-distant future. Any entity in the pharmaceutical drug manufacturing and distribution ecosystem would be well advised to closely monitor these issues and take proactive steps to ensure your organization is prepared to quickly and efficiently respond to any changes that occur.

CMS'S NEW 60-DAY RULE

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Providers Prepare to Adapt to CMS's Changes to the 60-Day Rule in 2025

On December 9, 2024, CMS published much awaited revisions to its enforcement of the 60-Day Rule, effective January 1, 2025, aimed at clarifying its deadlines for providers to report and return overpayments. While the revisions are a welcome clarification to providers, who have grappled with the more indeterminate "reasonable diligence" standard for years, there are likely to be growing pains as providers begin to operate within the revised rule's new parameters.

Clarification of the Knowledge Requirements for Identifying an Overpayment

Under the 60-Day Rule, providers have a statutory obligation to report and return overpayments within 60 days after an overpayment has been identified. Since "identification" of an overpayment is not defined within the statute, providers have relied on CMS rulemaking to inform their obligations therein. Prior to 2025, CMS had advised providers that "identification" of an overpayment occurred when the provider had determined, or should have determined, that it received an overpayment (known as the "reasonable diligence" standard). In the wake of provider scrutiny over this standard's uncertainty, CMS updated its guidance to align the definition of "identification" with the established knowledge standards already in place under the FCA.

Conformity with Standard Practice for the Rule's Investigatory Period

With this Final Rule change, CMS also solidified a 180-day suspension period that tolls the 60-day clock if providers undertake a good faith investigation into related overpayments stemming from the initially identified overpayment. Once the suspension period and 60-day clock have expired, "identified" but not yet returned overpayments become a potential false claim. While CMS had previously acknowledged this six-month investigatory period through preamble commentary, this rule change is the first instance in which CMS has formally adopted this extension through regulation.

Looking Ahead to 2025

Providers and suppliers are expected to quickly adapt to changing 60-Day Rule standards as to when an overpayment has been identified and strategize if and when to take advantage of the 180-day suspension period. The extent to which government contractors may be willing to work with providers who have exhausted the 180-day investigatory period and the 60-day report and return period but have not yet quantified an overpayment will also be subject to the enforcement temperament of CMS under a changing presidential administration.

Accordingly, providers and suppliers should continue to exercise best practices in documenting investigations of suspected overpayments, as well as reviewing and updating policies and protocols to address exercise of the 180-day suspension period as necessary.

OPIOID TREATMENT PROGRAMS AND MENTAL HEALTH

OPIOID TREATMENT PROGRAMS AND MENTAL HEALTH

OTP and Behavioral Health Providers Remain Critical Vanguards, But Enforcement Trends Signal Continued Scrutiny in 2025

The opioid epidemic remained one of the most pressing public health crises in the United States in 2024. There were encouraging signs, however, that addiction treatment and other preventative measures have contributed to a meaningful decrease in overdose deaths from June 2023 to June 2024.

Starting as far back as 2020, the Trump-Pence administration and the Biden administration have supported Opioid Treatment Programs (OTPs) and related services through new federal mandates and regulatory flexibility. The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act mandated Medicaid coverage in all 50 states, and as of January 1, 2020, Medicare offers a new benefit for OTP, demonstrating the federal government's emphasis on ensuring that addiction treatment is made widely available and affordable. Additionally, the Consolidated Appropriations Act of 2023 eliminated the x-waiver, providing greater ability for practitioners to prescribe buprenorphine and eliminating the artificial cap on the number of patients.

These flexibilities put OTPs on the front lines of the opioid epidemic, but also subjected them to increased risk of fraud and abuse. Specifically, in 2024, OTP providers and related stakeholders faced significant enforcement activity under the FCA. Other regulatory oversight, including safeguarding controlled substances and compliance with DEA requirements and unfair/deceptive practice enforcement by the FTC, similarly remained prevalent and are likely to continue under the Trump-Vance administration. In addition to OTPs, inpatient mental health providers came under heightened enforcement scrutiny in 2024. These stakeholders, too, are likely to face continued investigation and enforcement activity in the Trump-Vance administration.

OTPs Drew Increased Oversight and Enforcement Scrutiny in 2024

In 2024, OTPs continued to navigate a complicated and variable reimbursement scheme caused by the intersection of various mandates and flexibilities and a matrix of federal, state, and commercial payors. This encompassed critical aspects of patient treatment, including medication-assisted therapy (MAT), urine drug screens (UDS), and counseling services.

This new regulatory landscape has presented challenges. Indeed, starting in 2021, OIG has conducted a multi-state assessment of Medicaid claims for OTP services and issued multiple audit reports detailing how state agencies have failed to comply with certain federal and state requirements. A final report on the multi-state assessment is expected in 2025.

The oversight from OIG was matched by increased FCA enforcement activity against OTP stakeholders in 2024. DOJ announced multiple settlements[45] against laboratories and other treatment providers specifically involving the UDS component of OTP treatment. As an example, in October 2024, DOJ announced a settlement with a toxicology laboratory for $27 million to resolve allegations that it violated the FCA by billing federal and state healthcare programs for UDS that were not medically necessary or reasonable. DOJ's press release indicated that the lab utilized "blanket orders" for UDS without obtaining an individualized determination from a physician, which was alleged to constitute double billing. This and other FCA settlements with toxicology labs were significant and underscored that, while UDS is an

[45] See also Pacific Toxicology Laboratories Agrees to Pay $1 Million to Resolve Allegations of Fraudulent Billing (July 10, 2024).

essential component of opioid use disorder treatment, it is a highly scrutinized aspect of patient treatment from a fraud, waste, and abuse perspective.

In addition to UDS, referral sources for OTPs remain a source of potential enforcement scrutiny, particularly given concerns about patient brokering and the vulnerable status of many OTP patients. While the FCA and AKS remained important enforcement tools in this area, the industry is still anticipating meaningful developments under the Eliminating Kickbacks in Recovery Act (EKRA). EKRA is a similar criminal law to the AKS, but applies to all "healthcare benefit programs" (i.e., private payors) and is limited to referrals to recovery homes, clinical treatment facilities, and laboratories. Though several courts have analyzed EKRA, there is not yet consistent and meaningful case law applying EKRA in most circumstances. In addition, enforcement agencies like DOJ have not issued any regulatory guidance regarding the applicability of the law. In the absence of such case law and guidance, stakeholders have been left with uncertainty about EKRA and how the law will potentially be applied.

Other oversight mechanisms, including DEA surveys regarding the security and safe use of MAT drugs by OTPs and FTC advertisement restrictions, similarly remain ever present for OTPs. In particular, the FTC continues to monitor OTPs, specifically with regard to "guaranteed" recovery or success rates, and non-evidence-based treatment approaches. The Opioid Addiction Recovery Fraud Prevention Act, which passed in 2018 under the Trump-Pence administration and saw increasing enforcement in 2023 and 2024, allows for the FTC to seek civil penalties for unfair or deceptive acts or practices for any substance use-disorder treatment service or product. The FTC is likely to continue such monitoring of OTPs in 2025 under the Trump-Vance administration—stakeholders should continue to take affirmative steps to ensure that all marketing materials and claims are compliant with these FTC advertising standards.

Inpatient Behavioral Health Services Providers Become Target of Enforcement in 2024

In addition to the enforcement activity surrounding outpatient OTPs, inpatient behavioral health providers came under scrutiny in 2024. Specifically, Acadia Healthcare agreed to settle allegations that it violated the FCA by submitting claims for services to federal healthcare program beneficiaries that were not eligible for inpatient treatment and by failing to properly discharge beneficiaries when they no longer needed treatment. The settlement came shortly after *The New York Times* published an investigative report detailing similar practices outlined in the FCA settlement. The settlement, at nearly $20 million, was significant, and signals potential future activity in 2025. This is an especially important signal for inpatient OTP stakeholders as the country continues to grapple with the mental health crisis born from the effects of the COVID-19 pandemic.

Looking Ahead to 2025

2024 was a year defined by increased regulatory scrutiny and enforcement activity for OTPs, MAT providers, and inpatient behavioral health services. Of course, with greater governmental funding comes greater scrutiny from governmental agencies. Behavioral health providers should anticipate similar enforcement activity to continue in 2025 and consider a meaningful review of their billing operations and arrangements with other companies, like toxicology labs, to ensure compliance and decrease enforcement risk.

2025 also presents an opportunity for new regulatory guidance, like OIG's final report regarding Medicaid claims for OTP services and additional case law and guidance under EKRA. Stakeholders should also not view the change in administration as a sign of potential regulatory oversight retrenchment. Under the Trump-Pence administration, agencies like the FTC and DEA recognized the potential for abuse in substance use-disorder treatments and took substantial steps to mitigate this issue. While OTP providers should remain focused on the important benefits offered by the services they furnish, these providers should remain careful about this enhanced regulatory scheme in 2025 and beyond.

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