Top 10 Healthcare and Life Sciences Issues to Watch in 2025

January 10, 2025

Introduction

Throughout 2024, industry stakeholders contended with growing economic and financial uncertainties, heightened state and federal enforcement efforts, and an increasingly complex regulatory environment. With the incoming Trump administration, the changing political and regulatory environment may benefit some stakeholders and create new challenges for others. Stakeholders that proactively address such challenges (to the extent feasible) will be best positioned to manage risk in an uncertain market. In this article, we summarize some of the most notable developments expected to impact healthcare and life sciences companies in the coming year.

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FDA Under the New Trump Administration

Based in part upon the nomination of Robert F. Kennedy Jr. to lead the Department of Health and Human Services ("HHS"), we anticipate major changes at the Food and Drug Administration ("FDA") under the new Trump administration. Although FDA falls under the jurisdiction of HHS, HHS secretaries have historically allowed FDA to operate with little interference. Regardless of whether Mr. Kennedy is ultimately confirmed, we expect HHS to exercise increased oversight of FDA policy and activities under the new Trump administration. This stands in contrast with the first Trump administration, when FDA Commissioner Scott Gottlieb operated with minimal HHS interference prior to the COVID-19 pandemic.

In addition to executive branch involvement in establishing FDA policy, Congress is also expected to play an increasingly important role both through traditional channels and its authority under the Congressional Review Act to review and potentially rescind FDA rules and guidance issued by the Biden administration after August 1, 2024.

President-elect Trump nominated Dr. Martin A. Makary, a Johns Hopkins University surgeon, as FDA commissioner. Dr. Makary is respected within the medical community and is a proponent of technology-driven, innovative approaches to healthcare, which will be essential as FDA continues to develop policies addressing the use of artificial intelligence in medical devices, drug discovery, and manufacturing.[1]

FDA funding and staffing are expected to be hot-button issues in the new administration. President-elect Trump has expressed an intent to shrink the government workforce generally, and Mr. Kennedy favors staffing cuts at FDA and has proposed cutting FDA's budget in half or doing away with user fees (although Congress would need to approve budgetary changes). User fees comprise just under half of FDA's annual budget and help FDA ensure predictable timelines for its review process by funding staffing in certain areas. If user fees are reduced or eliminated, it would have a significant negative effect on product review timelines absent a large appropriation from Congress to make up the difference. Similarly, any large staffing reductions could slow drug and device approvals and other regulatory processes essential to product development. Staffing shortages could also be caused by the attrition of career scientists

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[1] *See* Debevoise In Depth: Artificial Intelligence and the Life Sciences Industry: FDA and FTC Regulatory Update (May 16, 2023). Earlier this month, FDA released two draft guidance documents related to artificial intelligence ("AI"). The first provides recommendations on the use of AI intended to support a regulatory decision about a drug or biological product's safety, effectiveness or quality. Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products (Jan. 2025). The second provides recommendations to support the development and marketing of safe and effective AI-enabled medical devices and includes guidelines on bias and transparency. Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products (Jan. 2025).

and other FDA employees with the change in administration or the phase-out of remote work.

We anticipate a decrease in FDA rulemaking under the new administration. The Supreme Court's recent *Loper Bright Enterprises v. Raimondo* decision is also expected to affect FDA policymaking during the new administration, as the agency may opt to issue nonbinding guidance instead of rules, which may be more difficult to challenge via litigation.[2] In addition, the new Department of Government Efficiency ("DOGE") announced by President-elect Trump is expected to identify and seek to eliminate regulations deemed to be unnecessary or counterproductive. During Trump's first administration, he promulgated a "2 for 1" policy whereby agencies were expected to eliminate two rules for every new one added. President-elect Trump has now hinted that he plans on expanding this policy, potentially requiring a larger number of rules to be eliminated every time a new rule is added.

We anticipate greater scrutiny of vaccine safety, both regarding vaccines under development and those already on the market. Mr. Kennedy has expressed concerns over vaccine safety over many years, and Dr. Makary questioned FDA's recommendations of COVID-19 boosters for young people due to the higher risk of complications such as myocarditis compared with the lower mortality risk in this age cohort.

Another area of focus may be alternative, non-medical treatments to treat chronic disease and obesity. Both Dr. Makary and Mr. Kennedy believe Americans would benefit from an increased focus on lifestyle changes such as diet and exercise instead of prescription drugs. Mr. Kennedy's "Make America Healthy Again" agenda—encouraging the proliferation of nutritious, unprocessed foods—may also affect FDA regulation of foods and color additives. The interest in nonmedical treatments may lead to a more lenient regulatory environment for certain product categories such as dietary supplements and to an increased focus on consumer health (including digital health innovations and over-the-counter drugs that permit greater self-care without physician intervention).

More stringent enforcement may also be expected in certain areas. For example, Mr. Kennedy has expressed a desire to ban direct-to-consumer prescription drug advertisements, and although a ban would be subject to challenge under the First

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[2] The Supreme Court's 2024 decision in Loper Bright, overturning the concept of "Chevron deference" (a standard mandating that courts defer to reasonable agency interpretations when an underlying statute is ambiguous), has also made it easier to challenge certain FDA regulatory decisions through litigation. FDA will continue to grapple with this decision in the next administration, and it may affect the rulemaking process. See After Chevron: FDA Regulations In The Crosshairs (July 8, 2024), https://www.law360.com/healthcare-authority/articles/1855819/after-chevron-fda-regulations-in-the-crosshairs.

Amendment, FDA's Office of Prescription Drug Promotion may nonetheless increase enforcement of prescription drug advertising. In addition, we anticipate greater scrutiny of foreign suppliers of FDA-regulated products and ingredients, particularly those located in China.

Changes to the ACA Under the Trump Administration

Having survived for more than a decade, the Affordable Care Act ("ACA") is unlikely to be repealed or subject to wholesale revisions. Nonetheless, we anticipate there will be significant developments in the coming years—some of which will not require Congressional approval—that will modify certain aspects of the ACA, particularly with respect to federal health insurance subsidies and regulations.

As part of the Inflation Reduction Act, the Biden administration extended certain subsidies to facilitate the purchase of ACA plans, enabling (i) people with incomes between 100-150% of the federal poverty level to pay nothing for "silver" plans (which are among the lowest premium plans on the ACA exchanges), and (ii) people with incomes above 400% of the federal poverty level to receive premium tax credits if the premiums exceed 8.5% of household income. The effect of these subsidies was to enable people who could not afford—or did not wish to pay for—ACA-qualified health insurance plans to purchase such plans at significantly discounted rates. These temporary subsidies, which will expire by their own terms at the end of 2025, are unlikely to be renewed by the Republican-controlled Congress. The Congressional Budget Office anticipates that approximately four million people will stop being enrolled in ACA plans if the subsidies are discontinued.

We also anticipate a proliferation of non-ACA plans in the coming years. ACA-qualified plans incorporate extensive consumer protections because insurers cannot engage in medical underwriting (exclusions for pre-existing conditions), annual and lifetime limits on coverage are unlawful, and plans must cover a broad swath of conditions. That coverage comes at a cost: ACA-qualified plans are expensive.

During President-elect Trump's first term, HHS issued a rule that allowed for short-term insurance plans to be purchased for a period of 364 days and renewed up to three times. These short-term insurance plans were not required to comply with federal market requirements, and as a result these plans were cheaper options that offered significantly less coverage. Under the Biden administration, HHS engaged in rulemaking to limit these plans to a term of just three months. With President-elect Trump taking office in January, we anticipate regulatory changes that restore the rules that facilitated short-term insurance plans during the first Trump administration.

Congress may also modify the ACA to enable qualifying persons to apply ACA subsidies to non-ACA plans.

The effects of expanding access to non-ACA plans are difficult to predict—especially because they may coincide with other changes such as the expiration of ACA subsidies. Some people who would otherwise elect to be uninsured may decide to enroll in non-ACA plans instead. But we may also witness adverse selection: individuals who are healthy may decide to purchase low-cost non-ACA plans, resulting in a pool of beneficiaries of ACA plans that are relatively sicker and more costly to ensure. That, in turn, may make ACA plans more expensive.

Under the Trump administration, Congress may also take steps to roll back the ACA Medicaid expansion, which makes Medicaid available to "childless adults" whose income falls below 138% of the federal poverty level. As a result of a Supreme Court decision, each state can decide for itself whether to join the expansion. Some Congressional Republicans believe that the Medicaid expansion is far too expansive: the federal government pays 90% of the costs of Medicaid for the expansion population, whereas the federal government pays a much lower percentage of Medicaid costs incurred in connection with "traditional" Medicaid beneficiaries. If Congress lowers the reimbursement rate below certain thresholds, then some states with "trigger" laws will automatically stop participating in the Medicaid expansion and others might decide to do so in light of the additional costs the states would have to incur. Either way, the result could be a significant increase in the size of the uninsured population.

Heightened Antitrust Scrutiny Complicates Healthcare M&A Landscape

The past year saw a continued focus in US antitrust enforcement in healthcare, with many wondering what is in store for 2025 and beyond. While certain Federal Trade Commission ("FTC") and Department of Justice Antitrust Division ("DOJ") (collectively, the "agencies") positions may be tempered under the new administration, healthcare M&A enforcement is likely to remain a bipartisan issue.

Enforcement Efforts

The agencies implemented their December 2023 revised merger guidelines throughout 2024, bringing a more holistic and (critics would say) paternalistic approach to merger analysis that is intended to capture a broader array of anticompetitive conduct. A specific focus on healthcare M&A was obvious early in the year. In March 2024, the FTC hosted a public workshop, *Private Capital, Public Impact: An FTC Workshop on Private Equity in Health Care*, aimed at examining anticompetitive harms related to private equity investment in health care markets. The agencies also launched, together with the

Department of Health and Human Services, a cross-government public inquiry into private equity and other corporations' increasing control over healthcare, including a formal Request for Information to solicit "public comment on deals conducted by health systems, private payers, private equity funds, and other alternative asset managers that involve health care providers, facilities, or ancillary products or services."

The agencies' focus on healthcare led to several notable merger challenges in 2024. The DOJ in November 2024 sued to block UnitedHealth Group's acquisition of Amedisys due to the overlap between the companies' home health and hospice services. In addition to the alleged anticompetitive effects of the merger, the DOJ claims that Amedisys failed to produce required documents or disclose the deletion of documents in connection with its HSR filing. Earlier in the year, the FTC sued to block Novant Health, Inc.'s acquisition of two Community Health Systems, Inc. hospitals. The district court ruled in favor of the merging parties, finding that the two hospitals would likely close absent the transaction. The FTC appealed to the Fourth Circuit, however, which enjoined the merger pending appeal. The companies subsequently abandoned the transaction.

Finally, in October 2024, the FTC finalized long-awaited updates to the Hart-Scott-Rodino ("HSR") form that implement sweeping changes to the instructions and requirements for premerger notification under the HSR Act. The final rule—which applies to all industries, healthcare included—greatly increases the time, burden and expense of HSR filings by broadening the scope of information, data, and documents that parties are required to submit for reportable transactions.[3] The new rule is intended to enhance the information available to the agencies during HSR to more accurately assess potential antitrust concerns and effectively screen transactions before they are finalized. The FTC passed the rule with a unanimous 5-0 vote, including two Republican-appointed commissioners, and the rule is scheduled to go into effect on February 10, 2025. While the Trump administration could delay the rule's effective date or seek to roll back some of its more austere requirements through subsequent rulemaking[4], the administration is unlikely to abandon the changes in their entirety. Alongside the HSR form revisions, the FTC also opened a new online portal for the public to comment on pending transactions.

Looking Ahead

Antitrust enforcement in President-elect Trump's first term was stronger than previous Republican administrations and included multiple healthcare merger challenges. For example, in 2016 the DOJ sued to block the Aetna/Humana merger due to alleged

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[3] Notably, the final rule did not amend the current HSR reporting thresholds.

[4] The final rule is also subject to review under the Congressional Review Act, pursuant to which the next Congress could issue a joint resolution to invalidate the rule.

anticompetitive effects among Medicare Advantage providers, and the parties abandoned the transaction after the DOJ rejected their proposed divestiture. The FTC in 2017 challenged Advocate Health Care Network's acquisition of NorthShore University HealthSystem, which similarly abandoned their transaction following a preliminary injunction.

Considering Trump's first-term record and the populist appeal of antitrust enforcement generally, the new administration is unlikely to take a laissez-faire approach towards healthcare transactions. However, the agencies under Trump are expected to reduce the antipathy towards big business, private equity and corporate concentration that was emblematic of Biden-era enforcement. To that end, the administration could return to some or all of the agencies' prior merger guidelines in effect from 2010–2023—either by rescinding the current guidelines or by simply refusing to enforce their more stringent positions. The agencies' merger analysis will also likely return to traditional economics—*e.g.*, a transaction's impact on prices and innovation—rather than nontraditional factors such as the transaction's potential effects on labor or a pattern of strategic acquisitions. Finally, the agencies under Trump will likely be more open to, and accepting of, deal fixes through divestitures and consent orders, which stands in stark contrast to the agencies' hardline stance against such remedies under the Biden administration.

In terms of agency personnel, Trump has pegged former FTC staffer and Trump administration economic adviser Gail Slater to run the DOJ's Antitrust Division. Slater's extensive antitrust experience and well-rounded background in both government and the private sector suggest that she will favor a more balanced and traditional approach towards enforcement. As for the FTC, Trump named current commissioner Andrew N. Ferguson as FTC Chair. Ferguson was sworn in as a commissioner in April 2024 and will replace current Democratic Chair Lina Khan once Trump is inaugurated. Trump also nominated Mark Meador as the third Republican on the five-member commission. Meador is a former FTC and DOJ staffer who served as Deputy Chief Counsel for Antitrust and Competition Policy to Senator Mike Lee, senior Republican on the Senate Judiciary Antitrust Subcommittee.[5] Ferguson's elevation and Meador's nomination suggest that the FTC may adopt a more measured and traditional approach towards healthcare enforcement. Regardless of leadership, however, agency staff will largely remain the same between the two administrations, and accordingly it may take time before any significant policy changes are implemented.

[5] Senate confirmation is necessary to appoint Meador, a new commissioner, but there is no congressional oversight over the appointment of Ferguson to chair the commission.

Continued State Focus on Healthcare Transaction Oversight Laws

Policymakers continue to expand state regulatory authority over healthcare transactions, contributing to the increasingly complex and ever-changing regulatory landscape. A growing number of states have enacted healthcare transaction oversight laws in order to address competition, access and cost in the healthcare industry. Although such laws vary widely by state, they generally require certain healthcare entities to provide written notice, which can include detailed descriptions of the transaction and transacting parties, to the relevant state authorities for comprehensive review, and potentially approval, prior to closing.

States have also increased focus on private equity ("PE") sponsor investment in the healthcare industry. For example, earlier this year, California put forward a proposed bill, AB 3129, aimed at increasing oversight of PE and hedge fund investments in the state's healthcare sector. AB 3129, which was approved by the full legislature, would have (i) required PE companies and hedge funds to notify, and obtain written consent from, the California Attorney General ("AG") at least 90 days before making certain healthcare investments and (ii) imposed restrictions on management relationships between PE or hedge fund-backed management services organizations and physician/dental practices. On September 28, 2024, California Governor Gavin Newsom vetoed AB 3129, citing concerns regarding the redundancy of the bill, given the California Office of Health Care Affordability's extant authority to review and evaluate healthcare transactions.[6] The proposed bill's author, Assemblymember Jim Wood, is not seeking reelection; it is unclear whether its co-sponsor, Senator Melissa Hurtado, will reintroduce a version of the bill in the 2025 legislative session.

Several states with existing healthcare transaction oversight laws have, or are expected to, put forward PE-focused bills. Most recently, on December 30, 2024—one day before the expiration of the 2024 legislative session—the Massachusetts House and Senate found common ground to pass House Bill 5159 ("HB 5159").[7]Among other things, the law significantly broadens the extant oversight authority of the Health Policy Commission ("HPC"), particularly with respect to activities of any "significant equity investor"—defined as (i) any private equity company with a financial interest in a provider, provider organization, or management services organization ("MSO")—or (ii) an investor, group of investors or other entity with a direct or indirect possession of equity in the capital, stock or profits totaling more than 10 percent of a provider,

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6 A copy of Governor Newsom's veto message available here.

7 The Massachusetts legislature also passed Senate Bill 3012 ("SB 3012"). S 3012, among other things, materially increases oversight of PBMs, authorizing (i) the Division of Insurance to license and regulate PBMs, and (ii) the CHIA to collect a range of drug cost information from PBMs, as well as pharmaceutical manufacturers, and (iii) the HPC to include PBMs and manufacturers in its Annual Health Care Cost Trend Hearing.

provider organization, or MSO.[8] The HPC's healthcare transaction review authority has been expanded to (i) require 60-day advanced notice of any transaction involving a significant equity investor that would result in a change of ownership or control of a provider or provider organization, and (ii) require, as part of such notice, disclosure of information regarding the significant equity investor's capital structure, general financial condition, ownership and management structure, and audited financial statements. In addition, the HPC may include significant equity investors, MSOs, and other stakeholders in its Annual Health Care Cost Trend Hearing, requiring such stakeholders to provide public testimony on the factors that influence healthcare costs. HB 5159 also bolsters the oversight authority of the Center for Health Information and Analysis ("CHIA") by (i) adding data reporting requirements for hospitals and provider organizations, including significant equity investors, and (ii) increasing penalties for non-compliance with reporting requirements, from $1,000/week to $25,000/week, uncapped. Further, HB 5159 expands the Massachusetts Attorney General's authority to monitor healthcare trends, and to enforce the state False Claims Act ("FCA"), by allowing the office to seek information from significant equity investors and MSOs. In particular, the law expressly extends liability under the FCA to anyone (i) with an "ownership or investment interest" in a person who violates the FCA, (ii) who knows of the FCA violation and (iii) who fails to report the violation within 60 days of identifying the FCA violation. In addition to Massachusetts, we note that proposed PE-focused healthcare bills in Connecticut[9] and Washington,[10] which failed in the 2024 legislative session, are expected to be reintroduced this year.

As states revisit and continue to expand their authority over healthcare transactions, transacting parties should expect to face an increasingly restrictive regulatory landscape. Stakeholders engaged in sufficiently large transactions are likely to trigger review in multiple states, as well as at the federal level; because states can, generally, toll their review periods while waiting for (i) transacting parties to submit additional information and (ii) other regulatory agencies or courts to perform their respective reviews of the transaction, parties should expect significant potential delays to closing. Therefore,

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8 "Private equity company" is defined as any company that collects capital investments from individuals or entities and purchases, as a parent company or through another entity that the company completely or partially owns or controls, a direct or indirect ownership share of a provider, provider organization or MSO. Venture capital firms exclusively funding startups or other early-stage businesses are expressly excluded from the definitions of "private equity company" and "significant equity investor."

9 In Connecticut, a failed 2024 bill, HB 5319, would have required the state's Office of Health Strategies to develop a plan regarding PE ownership of Connecticut-licensed healthcare facilities, including (i) evaluating whether a certificate of need should be required for a PE firms' acquisition of a healthcare facility and (ii) recommending requirements for the disclosure of information by a healthcare facility that has PE ownership.

10 In Washington, a failed 2024 bill, SB 5241, would have extended the scope of the current review process, including lengthening the notice period, expanding the scope of entities subject to notice requirements and enhancing the AG's enforcement authority.

transacting parties should, at the outset of a transaction, analyze relevant state-specific laws governing healthcare transactions and allow sufficient time to complete all required filings.

Cyber Breaches Impacting Healthcare Companies and Transactions

On December 27, 2024, the Department of Health and Human Services Office of Civil Rights ("OCR") issued a Notice of Proposed Rulemaking ("NPRM") to modify the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") to strengthen cybersecurity protections for electronic personal health information ("ePHI") records. The NPRM, which is the first update to HIPAA since 2013, proposes to strengthen the Security Rule's standards and implementation specifications with new proposals and clarifications. If adopted as proposed, the updated Security Rule will require regulated entities to implement more stringent technical measures alongside more robust compliance monitoring, testing, and notification requirements.

The proposed rule comes at the end of a landmark year for cybersecurity attacks affecting the healthcare sector. In February, Change Healthcare, a subsidiary of United Healthcare, experienced a significant ransomware attack that had widespread operational impacts across the healthcare sector, disrupting electronic payments, medical claims processing, and scheduling, among other services. This incident resulted in the exposure of ePHI associated with more than 100 million Americans. It was just one of the almost dozen cybersecurity attacks in the healthcare space reported by OCR this year to have affected more than one million people.

Among the proposed changes are proposed updates in the following five domains.

- Technology Asset Inventory. Covered entities will be required to develop and revise a technology asset inventory and network map that documents the movement of ePHI throughout an entity's electronic systems. The technology asset inventory and network map must be updated every 12 months as well as in response to any changes in the entity's environment or operations that may affect ePHI.

- Risk Assessment. The rule will require companies to conduct a risk assessment and provide a written report that contains, among other things: (1) a review of the technology asset inventory and network map; (2) identification of all reasonably anticipated threats to the confidentiality, integrity, and availability of ePHI; (3) identification of potential vulnerabilities and predisposing conditions to the regulatory entity's relevant electronic information systems; and (4) an assessment of

the risk level for each identified threat and vulnerability, based on the likelihood that each identified threat will exploit the identified vulnerabilities.

- Access Control Modifications. Covered entities would be required to notify other covered entities and business associates within 24 hours when there is a change in or termination of an authorized employee's access to ePHI or to a system holding ePHI.

- Contingency Planning. The NPRM would further strengthen contingency and incident response planning. Covered entities would be required to assess the criticality of systems to determine restoration priority and establish procedures to restore the covered entity's or business associate's critical relevant electronic information systems and data within 72 hours of loss.

- Enhanced Technical Controls. Regulated entities would be required to establish certain technical controls, including use of multi-factor authentication, deployment of anti-malware protection, removal of outdated or unused software from relevant systems, and closure of network ports consistent with the covered entity's risk assessment.

The NPRM is now subject to a 60-day notice and comment period, after which a final rule will be issued. Given the increasing cybersecurity risk to the healthcare sector, the growing number of healthcare data breaches over the past 12 years, and the bi-partisan nature of cybersecurity, it is likely that an update to HIPAA is forthcoming. Covered entities and business associates will want to monitor the rulemaking process and carefully evaluate the maturity of their information security programs. Regulated entities should also expect that the updated rule's inclusion of clear notification deadlines and prescriptive measures will make post-incident inquiries regarding a covered entity's compliance even more frequent, with greater low-hanging fruit for enforcement.

Upcoming Policy Shifts Regarding Regulatory Oversight of Artificial Intelligence

Generative artificial intelligence ("AI") is currently being used in healthcare to support patient engagement, drug discovery and development, and medical imaging. Companies capitalizing on AI technology to further business development can expect a more relaxed regulatory framework under the Trump administration: President-elect Trump will likely move to roll back certain Biden-era policies.

The Biden Administration has taken a cautious approach towards the advancement of AI technology, focusing on regulation and accountability across multiple sectors to

address both opportunities and risks associated with AI. Concerned by national security implications, as well as potential consumer harm, the Biden administration sought to regulate AI through several governmental routes, including reports, agency memos and the Executive Order on "Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence."[11] One feature of Biden's Executive Order used the Defense Production Act to require the industry's leading AI developers to release safety test results to the government and to disclose any plans to advance existing powerful AI models. The Biden administration also formed the AI Safety Institute at the National Institute for Standards and Technology to establish voluntary standards for tech industry groups, with the goal of advancing the ethical and responsible use of AI.[12] In its final year, the Biden administration has focused on developing protections for consumers as healthcare becomes increasingly digitized.

When Trump takes office in January 2025, companies can expect a departure from a strict regulatory approach and a shift towards self-governance. The Trump administration will likely focus on the deregulation of AI use and development, including the dismantling of Biden's Executive Order and AI regulatory framework. A priority for the Trump administration appears to be minimizing federal oversight and regulatory obstacles to foster competition and innovation in healthtech, permitting industry leaders more flexibility in choosing how they will adopt and implement AI technologies. A July 2024 report on artificial intelligence from conservative think tank Paragon Health Institute ("Paragon") could serve as a potential roadmap for the incoming administration's healthcare AI policy.[13] The Paragon report touts AI's potential cost savings in healthcare through productivity gains, quality improvements and autonomous care delivery.

Though federal AI regulation may not proceed, it is important to note that in the 2024 legislative session, at least 45 states, Puerto Rico, the Virgin Islands and Washington, D.C., introduced AI bills, with 31 states, Puerto Rico and the Virgin Islands adopting resolutions or enacting legislation.[14] Stakeholders should closely monitor developments in the broadly-regulated sector to appropriately draft, or restructure, their policies and procedures.

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[11] Exec. Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence (Oct. 30, 2023), https://www.whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/.

[12] Information on the U.S. Artificial Intelligence Safety Institute can be found here.

[13] A copy of the Paragon report can be found here. Brian Blase, the current president of Paragon, previously served as special assistant to President Trump for economic policy, where he focused on healthcare deregulation and insurance reforms.

[14] A copy of the National Conference of State Legislatures' report is available here.

Healthcare's Patient-Centric Future

Over the last six years, some of the most powerful consumer data-driven retail and technology giants have made enormous investments in the healthcare space—not least the e-commerce powerhouse, Amazon, which acquired One Medical for $3.9 billion in 2023.[15] This move towards patient-centric advances in healthcare signals a future where data and technology drive the consumer care experience, fill care gaps and improve Americans' overall health maintenance. Providers should therefore consider developing digital solutions to improve patient engagement and compete in virtual service lines that are expected to proliferate in the coming years.

Driven by a mission to be "the earth's most customer-centric company," Amazon is attempting to bridge the gap between testing, telemedicine and pharmacy services by placing such services under one umbrella for a more efficient and accessible healthcare experience. In 2018, Amazon bought online pharmacy startup PillPack,[16] the linchpin in its strategy to develop a full-service pharmacy offering. Indeed, for the past several years, "Amazon Pharmacy" has been a topic of discussion at Amazon's annual meeting: Amazon's "Alexa" virtual assistant technology could be harnessed to save physicians' time in ordering prescriptions, its "Subscribe and Save" feature could be utilized for automatic drug refills—Amazon has even created a pilot program for a drone-based pharmaceutical delivery service.[17] Because Amazon Pharmacy is a "digital-first" service, there is less focus on brick-and-mortar stores; nonetheless, Amazon has set a 2025 goal to open pharmacies in 20 cities across the country.[18]

As Amazon makes strides in the pharmaceutical industry, other pharmacy giants, such as CVS, have made their own investments in tech-enabled healthcare to compete with Amazon. Following its $69 billion merger with Aetna, CVS is working to leverage consumer data to improve engagement as well as clinical outcomes, combining AI technology with virtual health services to create a technology-empowered healthcare experience.[19] It has also partnered with Shipt to offer consumers same-day, on-demand prescription delivery.

As retail and technology giants continue to disrupt the healthcare industry, they will challenge legacy healthcare systems and practice in ways that will compel change. It remains to be seen whether an industry as complex and tactile as healthcare can be digitized into obsolescence, like video rentals and print film, but one thing is certain: to

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15 A press release on Amazon's acquisition of One Medical can be found here.

16 A press release on Amazon's acquisition of PillPack can be found here.

17 A press release regarding Amazon's drone delivery program can be found here.

18 A press release on Amazon's expansion into the pharmaceutical industry can be found here.

19 A press release on CVS's acquisition of Aetna can be found here.

remain competitive in a "consumer-first" era, providers must learn to leverage their historic strengths in care delivery while adopting new, innovative technologies. Indeed, incumbent providers are responding quickly to improve their healthtech offerings—including through wide-ranging technology partnerships with their digital insurgents.

Political Pressure on Healthcare Companies and Their Directors

The victories by Donald Trump and Congressional Republicans may result in greater political pressure on certain healthcare companies and hospitals—including senior leadership and board members—to restrict or diminish care provided to certain groups (which, under different scenarios, could potentially include care provided to undocumented patients, transgender individuals, or women seeking an abortion). Political pressure may be generated both within and outside the government.

From within the government, directors and senior leadership of healthcare companies and hospitals may be called to testify at congressional hearings where they would be subject to intense questioning by members of Congress.[20] They may also receive letters from Congress demanding the production of sensitive information. In some cases, they may also be subject to investigations by the Department of Justice or administrative actions by HHS, alleging that the provision of certain services constitutes unlawful conduct. The federal government may also seek to terminate contracts with certain companies.

Political activists are also likely to exert pressure from outside the government. For example, the think tank Consumers' Research—which provides "Woke Alerts" to consumers—recently highlighted several companies' executives who also serve on the boards of children's hospitals that provide care for transgender minors. Consumers' Research aimed to generate consumer pressure against the executives and their companies. Other groups have developed apps that allow consumers to scan a product and receive a score based on the company's values, created websites that guide consumers away from companies that have donated to particular nonprofits, and/or encouraged boycotts of certain healthcare companies.

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[20] *See* Debevoise Update: New Congress Brings Heightened Risk for Life Sciences Companies (November 19, 2018), https://www.debevoise.com/-/media/files/insights/publications/2018/11/20181119_new_congress_bringsheightened risk_of_investigations.pdf?rev=05460c265330467ba1e308f6e7656533&hash=314BEEF30ACE424AAEE729D61A1BAAD5; Debevoise Update: Congressional Investigation Highlights Potential Risks for Private Equity Healthcare Investments (Sept. 19, 2019), https://www.debevoise.com/-/media/files/insights/publications/2019/09/20190919-congressional-investigation-highlights.pdf?rev=c80604528d154e22ac21ac7bcaa32710&hash=954C7173C429C634E259815E82CCA92C.

Healthcare companies and executives who may be subject to political pressure should consider developing or updating comprehensive public relations and crisis management strategies to address these concerns. Companies and individuals subject to congressional subpoenas or investigations should work with counsel to develop strategies that enable them to continue delivering their core healthcare goods or services, as appropriate, while minimizing legal and reputational risks both for the company and its directors and officers.

False Claims Act

Enforcement of the False Claims Act ("FCA") is likely to remain a significant risk, as the statute has enabled the DOJ to recover billions of dollars per year from healthcare companies. Because the FCA can be enforced through claims brought by private plaintiffs on behalf of the federal government (known as relators), traditional FCA claims alleging that healthcare providers and others overbilled the government are likely to continue regardless of administration.

We may also witness a rise in a new species of FCA claims brought by certain activists against healthcare companies. These claims may seek to combat the provision of certain healthcare services (for example, involving abortion and transgender care) by bringing FCA suits alleging that the providers have made false certifications that they are seeking reimbursement for medically necessary care. Similarly, healthcare companies that are critical of the policies of the new administration may find themselves targeted by federal investigators who may seek evidence that could serve as the basis for an FCA lawsuit.

SCOTUS: Opinions to Watch for in 2025

Cases Addressing the Scope of Federal Administrative Agency Authority

In 2024, the Supreme Court issued a monumental opinion in *Loper Bright Enterprises v. Raimondo*, abolishing "*Chevron* deference," which had required courts to defer to an agency's interpretation of an ambiguous federal statute so long as the agency's interpretation was reasonable.[21] Two cases on the Supreme Court's current docket will address the scope of agency authority in the aftermath of *Loper Bright*.

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[21] *See Law360*: After Chevron: FDA Regulations In The Crosshairs (July 8, 2024) https://www.law360.com/articles/1855819/after-chevron-fda-regulations-in-the-crosshairs; *Westlaw*: The Death of Chevron: Implications of the Loper Decision for Public Companies (Sept. 14, 2024)

FDA v. Wages and White Lion Investments, L.L.C.

White Lion involves two companies whose applications to sell fruit and dessert flavored liquids for use in e-cigarettes were denied by FDA. The Family Smoking Prevention and Tobacco Control Act (the "Tobacco Act"), passed in 2009, granted FDA authority over tobacco products. The Tobacco Act requires manufacturers of certain new tobacco products to obtain FDA's authorization prior to sale and directs FDA to consider whether such products are "appropriate for the protection of the public health" by evaluating "the risks and benefits to the population as a whole."

In denying the applications of the two companies at issue, FDA reasoned that (1) dessert and fruit flavored e-cigarette liquids, like the ones the companies proposed, present a high risk to youth and (2) the companies' applications did not otherwise provide enough evidence that the benefits of their products to adult users would outweigh the potential risks to youth. The manufacturers challenged these denials on the basis that FDA was acting arbitrarily and capriciously by "shifting the goalposts" when FDA implemented new testing requirements after the companies had submitted their applications.

The Fifth Circuit sided with the companies. Based on oral argument, many believe the Supreme Court is likely to reverse the Fifth Circuit and side with FDA.

TAKEAWAY: If FDA prevails, the decision will affirm FDA's broad discretion, even in the aftermath of *Loper Bright*, to make premarket approval decisions for certain types of tobacco products. Depending on how the opinion is written, it may have implications for other FDA-regulated product categories such as prescription drugs and medical devices.

McLaughlin Chiropractic Associates, Inc. v. McKesson Corporation

McLaughlin involves the Hobbs Act, which provides that an order of the Federal Communications Commission ("FCC") can be reviewed only by federal circuit courts—not district courts. The question before the Supreme Court is whether federal district courts must accept FCC's interpretation of the Telephone Consumer Protection Act ("TCPA") or whether a district court can address a challenge to FCC's conclusion.

This case arises from a class action lawsuit alleging that McKesson violated the TCPA by sending unsolicited advertisements to the class members via fax. The district court decertified a class action after FCC issued a ruling that provided that a fax received

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https://today.westlaw.com/Document/I55c387cc74f211efb5eab7c3554138a0/View/FullText.html?transitionType=Default&contextData=(sc.Default)&firstPage=true.

through an online fax service cannot create TCPA liability—and that fact-intensive inquiries would be required to determine whether a fax was sent to a traditional fax machine (in which case there could be TCPA liability) or to an electronic fax mailbox (in which case there could be no liability). In this case, the TCPA plaintiffs argued that they should have been given the opportunity to challenge FCC's rule in district court.

TAKEAWAY: If the Supreme Court agrees that FCC's TCPA rulings can be challenged by litigants in the district court, it could have the potential to lead to a proliferation of district court challenges to FCC rulings that interpret the TCPA and potentially other statutes as well. Although *Loper Bright* is often discussed as a victory for defendants seeking to overturn agency actions, here it is the opposite: it is the plaintiff who is challenging the agency rule and the defendant who benefits from it. Companies that employ risk mitigation strategies that are predicated on reliance upon governmental regulations may, depending on the circumstances, need to be prepared for the possibility that adversaries may seek to invalidate those regulations.

Transgender Care: *United States v. Skrmetti*

Plaintiffs, a group of transgender minors, their parents, and healthcare providers, challenged Tennessee's law that banned healthcare providers from administering gender-affirming treatments—including puberty blockers, hormone therapy, and gender-affirming procedures—to minors. The treatments are banned only for the purpose of gender-affirming care but may otherwise be prescribed. The same treatment that may be allowed for non-gender-dysphoria treatment is therefore prohibited under the ban if its purpose is to allow "a minor to identify with, or live as, a purported identity inconsistent with the minor's sex" or to treat "purported discomfort or distress from a discordance between the minor's sex and asserted identity." Plaintiffs argue that the ban violates Equal Protection under the Constitution and should be reviewed under heightened scrutiny.

TAKEAWAY: This decision will have an immediate impact on transgender minors across the nation and their healthcare providers. Based on the December 2024 oral argument, many commenters believe the Supreme Court will likely uphold Tennessee's ban—although the scope and rationale of the Supreme Court's opinion may have a significant impact on the scope of the Supreme Court's holding. A victory by Tennessee may also open the door to other medical bans based on gender-based classifications.

Medicare Reimbursement: *Advocate Christ Medical Center v. Becerra*

Advocate Christ Medical Center addresses the reimbursement that hospitals—particularly those in rural areas—will receive for treating low-income patients. By way of background, HHS reimburses hospitals under the "disproportionate share hospital"

("DSH") adjustment. This reimbursement provides additional compensation to hospitals serving a high percentage of low-income patients. This case addresses the calculation for the reimbursement that HHS provides to DSH Hospitals based on their treatment of Medicare patients. The question to be addressed by the Supreme Court is how the applicable formula takes into account eligibility for Supplemental Security Income ("SSI"). HHS takes the view that the formula should take into account only patients that are *actually receiving* SSI cash benefits – whereas the hospitals are arguing that the calculation should take into account anyone *eligible* for SSI benefits (whether or not they receive them).

TAKEAWAY: This decision is expected to have a notable impact on the ability of hospitals to seek higher Medicare reimbursement for low-income patients, and may especially impact hospitals in rural areas. According to a brief submitted by various trade organizations to the Supreme Court, HHS' calculation is costing hospitals about $1.5 billion annually.

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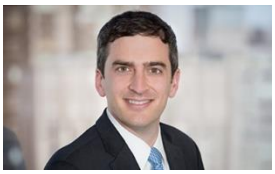

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