Managed Care Outlook

2024

ReedSmith

Driving progress
through partnership

Contents

Click a number to jump to the page or section of the document.

Business and management

Legal and regulatory challenges

Artificial intelligence, technology and data privacy

Litigation and trends

Introduction

Back to contents.

In the ever-evolving landscape of health care, where policy changes, technological advancements and societal shifts play pivotal roles, staying ahead of the curve is not just a strategy; it's a necessity. As legal professionals and business leaders in managed care organizations (MCOs), your role is more crucial than ever in shaping the industry's future while ensuring compliance and navigating complex regulatory frameworks.

Welcome to the 2024 edition of the Managed Care Outlook, your compass in the dynamic sea of health care management. In this comprehensive series of articles, we aim to provide an insightful preview of the hot topics and emerging trends that will define the managed care industry in 2024. Our goal is to equip legal departments and their business partners with the knowledge and foresight needed to proactively address challenges and capitalize on opportunities, fostering a resilient and forward-thinking approach.

With so much development in the law, regulation and politics surrounding health care and MCOs, it is nearly impossible to reduce the landscape down to all-encompassing categories or themes. Complexity notwithstanding, there are three key themes that our practice will be focused on in 2024, all of which permeate this edition of the Managed Care Outlook:

The winds of policy change are ever shifting, and 2024 promises no reprieve. From politically charged developments in the regulation of abortion and gender-affirming care for minors, to potential updates to telehealth regulations, to the continuous debate over drug pricing, the Managed Care Outlook delves into the regulatory landscape. We dissect how legislative developments may impact managed care organizations, offering strategic guidance on compliance and potential shifts in operational paradigms.

As the digital revolution sweeps across industries, health care stands at the forefront of transformation. The adoption of telehealth services, artificial intelligence (AI) and data analytics presents both opportunities and challenges. How can legal departments navigate the intricate web of privacy laws while embracing innovative technologies? And how will MCOs embrace AI's potential while avoiding the developing legal and regulatory risks? Join us as we explore the legal implications of the digital age in managed care and strategies to harness its potential.

In the intricate dance between payors and providers, collaboration is key. Yet, as the landscape shifts, so do the dynamics of these relationships. We explore the legal nuances of payor-provider collaborations, addressing topics such as network adequacy, contract negotiations and risk-sharing arrangements. Learn how legal departments can foster mutually beneficial partnerships in an evolving health care ecosystem.

Embark on this journey with us as we unpack the Managed Care Outlook for 2024. The legal landscape is dynamic, but armed with knowledge and foresight, your legal department can shape the future of managed care, ensuring not only compliance but also innovation and excellence in the legal issues facing your managed care organization.

We built our managed care practice for you, the lawyers and business leaders looking for strategic legal partners who understand both the local backdrop and national perspective of our highly-specialized industry. As is customary with our practice, I invite you to reach out and have a conversation with me or any one of our 60-plus attorneys dedicated to this field to discuss the issues we address here and what they mean for your organization.

Marty Bishop
Partner
+1 312 207 2831
mbishop@reedsmith.com

Business and management

Back to contents.

Back to contents.

Joint ventures: An ounce of prevention protects everyone involved

Takeaways

- Several market factors are spurring interest in joint venture arrangements
- Joint ventures present different risks and considerations than full acquisitions
- It is important to structure JVs so that they facilitate the goals of all participants

As interest rate increases made deal-making more challenging in 2023, market participants responded by increasing their use of other deal structures, including joint ventures, to gain access to new markets and distribution channels, and to develop new products and technologies.

Indeed, more traditional M&A activity in the health care space is down significantly from its pandemic highs. As one example, private equity firms recorded or announced an estimated 151 health care-related deals in the third quarter of 2023, the lowest mark since Q2 2020, and significantly less than half the deal count of Q4 2021, the market peak. In light of this, many actors are looking to joint ventures as an alternative to more traditional acquisition activity in order to pursue business combinations in the health care space.

At its core, a joint venture (JV) is a contractual business arrangement in which two or more parties pool their resources and expertise to achieve a particular goal. Although joint ventures can serve as a useful alternative to an outright acquisition of another company, they require long-range planning at the outset. Failure to consider an organization's objectives and ensure that JV documents facilitate those objectives

can lead to unintended consequences, financial losses (or failure to capture financial gains), a strained relationship with JV partners, and costly disputes. An organization's excitement to pursue a new venture with a partner should be tempered by careful evaluation of issues that are unique to JV structures.

A joint venture structure presents benefits and risks to a participant that should be assessed. Benefits include access to increased resources and talent, potential for innovation, and the opening of new markets. Additionally, as compared to a full acquisition, a joint venture can be less capital intensive and allow for risk sharing among JV partners. Risks presented by joint ventures include a need to rely on the performance of the other party as well as the tension that can be generated by the disparate cultures and goals of JV partners. Additionally, although outside the scope of this article, the parties should consider and evaluate antitrust risk in connection with any JV arrangement and health care regulatory risk associated with JV arrangements involving practices receiving any federal health care program payments, such as Medicare Advantage organizations.

Joint ventures are usually highly negotiated and bespoke to the opportunity that the parties are collectively pursuing. However, a party exploring entering a joint venture should consider a number of important factors early in the process. These factors include the scope and purpose of the venture; the appropriate corporate, capital and tax structure; considerations about the capital contributions of each party and related returns; the management structure; governance rights; and exit rights.

Although it may seem counterintuitive, it is imperative to address exit rights at the onset of the JV relationship. The types and scope of rights appropriate for any party will directly relate to that party's goals and negotiating position. Is the investment objective primarily motivated by a financial return or is it important to a party to have an opportunity to fully acquire the joint venture's business at some point in time?

Governance rights are similarly important in a joint venture. First, a party should determine the role it should have in the management of the joint venture. Typically, the scope of governance rights is commensurate with a party's ownership. Majority owners, of course, have greater control than minority owners. Minority owners should carefully consider the level of input they have through board seats and minority protections.

Joint ventures constructed as equal partnerships present additional governance challenges that should be carefully considered, including the possibility of deadlock. Some common methods to avoid a deadlock include the appointment of one or more independent members to the board of the joint venture and dispute escalation and resolution procedures that require any deadlock to be escalated to the senior management of the JV partners, with the possibility of a buy-out if the parties cannot agree.

At a time when managed care organizations (MCOs) are seeking growth, trying to enter new markets and confronted with factors, such as high interest rates, capital constraints and inexperience in certain markets, that make a traditional full acquisition less appealing, many are turning to joint ventures with other organizations. Similarly, non-traditional market entrants are seeking partnerships in markets in which managed care participants have deep experience. This confluence of factors has resulted, and we expect will continue to result, in MCOs exploring JV structures more frequently. Thoughtful up-front planning by organizations entering joint ventures best positions the venture for success.

For more information on this article, please contact Ken Siegel

Back to contents.

New state laws add time, disclosure obligations and uncertainty to health plan and provider transactions

Takeaways

- Health plans face heightened scrutiny under new state notification laws when involved in M&A, affiliations or other significant transactions.
- These laws introduce extended timelines for disclosures and, in certain circumstances, approval processes, which may encumber and slow down health plan transactions.
- The laws empower state agencies to conduct antitrust reviews and publish details about the proposed transaction to the public.
- Health plans operating across multiple states need to navigate a patchwork of laws and regulations, adapting their strategies to comply with the specific laws of each jurisdiction.

New state laws require notification and, potentially, approval before a health plan can acquire or combine with a health care provider or, in some cases, another health plan. Historically, states regulated health care transactions through state licensing laws and state attorney general offices. Now, following recent increases in private equity investment and consolidation of health care providers, state legislatures have sought greater oversight of health care transactions and empowered state agencies with new regulatory authority. These laws are having, and will increasingly have, a significant impact on the ability of health plans to expand service offerings through acquisition, create vertically integrated systems or make strategic investments.

Below are examples of states that have implemented new laws regulating health care transactions, along with their respective effective dates.

State	State law	Effective date*
California	Cal. Health & Safety Code § 127507	June 30, 2022
Connecticut	Conn. Gen. Stat. § 19a-486i	October 1, 2015**
Illinois	20 ILCS 3960/8.5	January 1, 2024^
Massachusetts	Mass. Gen. Laws Ch. 6D §13	January 1, 2013***
Minnesota	Minn. Stat. § 145D.01	May 24, 2023^^
Nevada	Nev. Rev. Stat. § 598A.390	October 1, 2021
New York	N.Y. Pub. Health Law § 4552	August 1, 2023
Oregon	Or. Rev. Stat. Ann. § 415.501	March 1, 2022
Washington	Wash. Rev. Code § 19.390.030	July 28, 2019

*The effective date of each statute may differ from the date on which parties to a transaction are required to file notifications. For example, the California law was adopted June 30, 2022, however, notifications obligations commenced January 1, 2024.

**The original Connecticut notice provision was effective October 1, 2015. It has been amended in 2016, 2017 and 2018. The most recent amendment was effective May 14, 2018 and just added the title of executive director of the Office of Health Strategy to the law.

^The Illinois provision has an automatic sunset date of December 31, 2029.

***The Massachusetts law was amended twice in 2013, with the most recent amendment taking effect on November 5, 2013.

^^ Notice provisions for small revenue transactions ($10 million–$80 million/year) are effective January 1, 2024.

In general, the state laws vest state agencies with authority to review mergers, acquisitions, affiliations, and other transactions involving health care providers and facilities. The type of transaction covered varies by state. Under the new California law, health care transactions will be subject to agency review if they involve a change to ownership, operations or governance structure. In particular, transactions will be subject to review if they (a) involve the sale, transfer, lease, exchange, option, encumbrance, conveyance or disposal of a material amount of a health care entity's assets to one or more entities or (b) transfer control, responsibility or governance of a material amount of the assets or operations of the health care entity to one or more other entities. The law or regulations of each state defines the type of transactions subject to the disclosure requirements.

State law also dictates the type of entities covered under the law. Most of these state laws impact transactions involving physician practices. In California, the review process applies to physician practices (generally those with 25 or more physicians), hospitals and health systems, clinics, ambulatory surgical centers, clinical laboratories, imaging centers, pharmacy benefit managers and health plans. New York and Oregon also expressly include health plans as entities covered under state law.

Entities seeking to engage in a covered transaction are generally required to disclose key details of the transaction anywhere from 30 days to 180 days (in the case of Oregon) prior to closing the transaction, adding complexity and uncertainty to the timing of a covered transaction. Upon receipt of notice, state agencies have the opportunity to conduct a cost and market impact review. In most states, the applicable state agency will produce a preliminary report and solicit comment from the public and the parties.

9
states

have passed laws in recent years requiring the disclosure of or approval for the sale, transfer or lease of a material amount of assets or equity of health care entities.

Key statistics

If the state agency raises concerns about the impact of the transaction on cost or competition, the agency may refer the transaction to the state attorney general for further review of potentially unfair methods of competition, anticompetitive behavior or anticompetitive effects, and the attorney general may pursue litigation to block the transaction under antitrust laws or allow it to proceed subject to certain conditions, including implementation of a monitor, ongoing reporting requirements and restrictions on managed care contracting and rate setting.

Issues for health plans to consider when planning a transaction:

1. Type of entities covered under state statute
2. Type of transactions covered under state statute
3. Transactions or entities exempt from statutory requirements
4. Pre-closing notice requirements (e.g., 30, 60, 90 or 180 days)
5. Information required to be disclosed to state agency
6. Further regulatory review potentially available to state agency (e.g., referral to attorney general's office)
7. Information that may be disclosed to the public

State notification laws mark a significant shift in the approach to the regulation of competition and transactions in the health care space. By introducing a comprehensive review process for health care transactions, the states have imposed a significant additional burden on health plans when looking for opportunities for growth and new models of care delivery.

For more information on this article, please contact Paul Pitts

Helping MCOs navigate challenges to corporate DEI initiatives

Takeaways

- Supreme Court's anti-race-based admissions decision paves the way for legal challenges, raising concerns about sustainability and legality of corporate DEI initiatives.
- Managed care organizations face legal warnings and lawsuits challenging DEI programs, emphasizing need for clear goals, evidence and non-discriminatory criteria.
- Lawsuits targeting law firm diversity programs may influence MCOs' external counsel choices.

When the U.S. Supreme Court declared the use of race in the college admissions process to be unconstitutional in June 2023, the impacts were felt far beyond academia. The decision and the rhetoric that has ensued have spawned anti-diversity litigation extending beyond higher education that has raised a universal concern about the sustainability of diversity, equity and inclusion (DEI) initiatives by corporations, including those in the managed care space. Below, we discuss some of the challenges raised and potential strategies to foster DEI in the corporate world in the face of this new case law.

By way of background, shortly after the decision *Students for Fair Admissions, Inc. v. President & Fellows of Harvard College* and *Students for Fair Admissions v. The University of North Carolina* (the SFFA decision), several significant actions took place:

- The chair of the U.S. Equal Employment Opportunity Commission issued a statement opining that the Supreme Court's decision did not address employer efforts to foster diverse and inclusive workforces or engage the talents of all qualified workers regardless of their background and thus did not negate employer DEI initiatives.
- A collection of Republican state attorneys general issued a letter to corporations warning them that their DEI initiatives may run afoul of the law.
- In response, a collection of Democratic state attorneys general issued a counter-letter detailing why most DEI initiatives did not run afoul of the law.
- Senator Tom Cotton wrote to over 50 law firms warning them that they should be careful in advising their clients about the propriety of DEI initiatives in the wake of the Harvard and UNC decisions.
- Edward Blum, founder of the Students for Fair Admission, and his nonprofit, the American Alliance for Equal Rights (AAER), sued several law firms alleging that diversity fellowships were unlawful and discriminatory.

Like many other corporations and industries, managed care thrives on the diversity of its workforces, and many have made commitments to foster diversity. With the recent ruling issued by the Supreme Court, a flurry of challenges have ensued, promising to reshape the way corporations, including managed care and related organizations, will implement their DEI initiatives.

First, in establishing DEI goals and objectives, a company should ensure that they be **articulated with sufficient clarity** to pass legal, including constitutional, challenges and be accompanied by evidence supporting the rationale for those objectives. In a recent case, *National Center for Public Policy Research. v. Schultz*, 2023 U.S. Dist. LEXIS 161680 (E.D. Wash. Sep. 11, 2023), Starbucks defeated a shareholder derivative suit against the company and its board of directors seeking a declaratory judgment that the DEI initiatives violate federal and state laws, and injunctive relief against the initiatives' continuation by demonstrating that it had considered a variety of factors in determining that the DEI initiatives it adopted were good for its business and within the fiduciary responsibility of the board.

Second, it is important that criteria for any "benefits" offered under DEI programs be **available to all**. Put another way, eligibility criteria that appear to exclude applicants based on a protected characteristic risk running afoul of the law. Importantly, in the same *Starbucks* decision, it is not suggested that initiatives to promote DEI in one's businesses or educational institutions are themselves unlawful. Instead, they address the methodology used to accomplish the objectives to ensure the programs do not discriminate in any way based on a protected characteristic. Requiring essays regarding one's commitment to DEI and/or how that applicant's socioeconomic status and life experiences have affected or influenced their qualification for the program for which they are applying would appear to survive any claims of discrimination based on race or other protected characteristic.

Ultimately, the legal challenges by AAER against law firm diversity programs might have trickle-down effects on external counsel and alter the composition of external legal teams that MCOs can use. Many companies, including MCOs, require diverse outside counsel teams.

AAER's aim at diversity fellowships has resulted in one firm canceling the fellowship and others modifying it. In response, law firms can change their fellowship criteria to include a commitment to diversity and inclusion efforts in the legal profession. By changing their criteria, they can continue to fulfill their commitment to DEI while also comporting with the law.

As the law continues to develop in this area, businesses must remain diligent in establishing DEI objectives, and develop evidence supporting the rationale for those objectives and the methodology adopted to achieve them. Doing so should not only better equip businesses to navigate the new legal challenges that may befall DEI initiatives but also enable them to measure their effectiveness and enhance their accountability to their stakeholders.

When boards and corporations take thoughtful, well-considered positions within the scope of the business judgment rule, courts are less likely to interfere with those business decisions. Decisions made on behalf of the corporation should be informed, in good faith, and with the honest belief that they are in the best interests of the corporation.

For more information on this article, please contact Tyree Jones and Edrius Stagg

Back to contents.

Two California ESG disclosure laws promise to increase burdens on managed care organizations

Takeaways

- California is requiring MCOs with significant revenues doing business in the state to disclose emissions and produce climate-related reports.
- Even if based outside of California, MCOs must comply if they generate revenue above applicable thresholds in California.
- Annual or biennial reporting under both laws is set to begin in January 2026.

As the U.S. Securities and Exchange Commission's (SEC) climate disclosure rules loom, California has forged ahead with its own legislation related to environmental, social and governance (ESG) disclosures and reporting. Governor Gavin Newsom signed Senate Bills (SBs) 253 and 261 into law on October 7, 2023, and both laws will be administered by the California Air Resources Board (CARB). Because the laws automatically apply to companies doing business in California that exceed set revenue thresholds, they are expected to impact around 10,000 companies, and not just those in industries typically considered to have environmental impacts. Managed care organizations (MCOs) that exceed the revenue thresholds set by SB 253 and SB 261 should therefore understand the laws' requirements and begin planning ahead to ensure compliance.

SB 253 – Greenhouse gas emissions disclosures

SB 253 applies to all companies, including MCOs, with total annual revenues in excess of $1 billion and that do business in California. Revenues are based on total numbers, not just revenues generated within California.

Based on the revenue threshold, SB 253 is predicted to impact over 5,300 companies operating in California. SB 253 mandates annual reporting of:

California's new ESG laws are expected to affect over

10,000 companies

doing business in the state.

Key statistics

- **Scope 1 emissions** – Emissions from sources directly owned or controlled by the company, such as company vehicles.
- **Scope 2 emissions** – Indirect emissions, such as emissions from the generation of electricity consumed by the company.
- **Scope 3 emissions** – All other indirect emissions not covered by Scope 2, including fuel and energy related activities, leased assets, employee commuting and business travel.

Reporting under SB 253 begins in 2026 and will cover Scope 1 and Scope 2 emissions generated in 2025. Scope 3 emissions will need to be reported starting in 2027. MCOs should be aware that tracking Scope 3 emissions may be particularly challenging given the potentially broad interpretation of indirect emissions. For example, emissions generated from data centers and cloud storage may need to be reported under Scope 3 emissions, as they could be considered fuel and energy related activities.

Reports must follow the globally recognized Greenhouse Gas Protocol standard for emissions accounting and reporting. Reportable emissions will also need to be verified by a third-party.

SB 261 – Climate reporting

SB 261 applies to companies with total annual revenues over $500 million doing business in California. The law mandates disclosure of climate-related financial risks and measures for risk reduction. The law covers physical risks (e.g., extreme weather events) and transitional risks (e.g., energy and fuel costs). Disclosure reports required by the law must align with the internationally recognized Task Force on Climate-Related Financial Disclosures (TFCD) framework or an equivalent framework. If the SEC's proposed rules on climate-related disclosures are finalized as is, the reporting requirements under SB 261 would satisfy both California's SB 261 and the proposed SEC rules.

Starting in January 2026, MCOs subject to the law will be required to prepare a climate-related financial risk report that discloses climate-related financial risks and the measures taken to mitigate those risks. Reporting will occur biennially and must be made available on the company's website.

Doing business in California

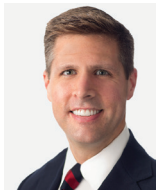
It is important to note that SB 253 and SB 261 apply to companies with revenues above the applicable thresholds and that are "doing business" in California. Neither law has adopted a definition of "doing business," but the term will likely be interpreted similar to the definition found under the California Revenue Code (CRC). The CRC defines "doing business" as "actively engaging in any transaction for the purpose of financial or pecuniary gain or profit." (18 CCR 23101). Additionally, the California Franchise Tax Board (CFTB) considers a company to be "doing business" if the company:

- Engages in any transaction for the purpose of financial gain within California;
- Is organized or domiciled in California; or
- Has California sales, property or payroll in excess of certain amounts (as listed on the CFTB website).

The need to report will be based on revenues from the prior fiscal year. If annual revenues do not meet the requisite thresholds ($1 billion under SB 253 and $500 million under SB 261), the company will be exempt from reporting for the corresponding year. For MCOs doing business in California that meet the revenue thresholds and are doing business in California, reporting under SB 253 and SB 261 will be required.

The new laws require that implementing regulations be adopted, which will likely clarify applicability before companies need to report, before January 1, 2025. However, the implementing regulations might still be challenged under the California Administrative Procedure Act or California Environmental Quality Act.






For more information on this article, please contact Jen Smokelin, Ben Patton, A.J. Wissinger and Sara Marie Eddy

Back to contents.

Shift to teleworking make wage and hour risks harder to identify

Takeaways

- Remote/hybrid work is transforming federal and state wage and hour laws; employers must keep up with changes.
- State laws can vary greatly and compliance complexity increases as more employees work remotely in different states.
- Employers should be on the lookout for state legislation that requires immediate action or imposes significant costs.

Across the country, employees continue to return to offices. However, this post-pandemic transition has not been ubiquitous, as many employers adopt hybrid models or allow some or all of their employees to work from home permanently. In many cases, employees may work in a different state than that of the employer, and employers, including those in the managed care industry, are often faced with navigating the bevy of federal, state and local laws that may now apply to their multi-state workforce. Of particular importance are wage and hour laws, which may indicate how often an employee must be paid, how much overtime compensation a non-exempt employee must make and the number of meal and/or rest breaks an employee must receive during the workday. In today's environment of fluid work arrangements, employers in the managed care industry must remain knowledgeable of the wage and hour laws that apply to their workforce and the risks of noncompliance.

Wage and hour laws across the country vary greatly from federal standards. For instance, states and even localities adopt greater minimum wages than the federal minimum wage and in many of these jurisdictions, the minimum wage increases at annual intervals. Another important distinction between state and federal law arises with overtime pay. For example, some states adopt a different overtime compensation structure, such that employees may qualify for overtime pay after working a certain number of hours in a day. While it is always important to understand the wage and hour laws that apply to an employer's workforce, it is particularly important when an employer has a remote or hybrid workforce. With remote and hybrid employees, it can be more difficult to know when an employee starts and stops working or when (or if) they are taking their meal and rest breaks, for instance. This challenge reinforces the importance of notifying and training hybrid or remote employees on an employer's timekeeping practices and policies and having measures in place to monitor compliance, for example.

Noncompliance with federal, state and local wage and hour laws can come at a significant legal, monetary and reputational cost. For instance, in 2017, Humana was sued by a collective action of more than 200 nurses who alleged that the health insurer misclassified them as exempt employees under federal law and failed to pay them overtime compensation. Following approximately three years of litigation, Humana reached an $11.2 million settlement with the collective to end the lawsuit. Humana denied any liability when it entered into the settlement. Moreover, in recent years, the U.S. Department of Labor has undergone a nationwide effort to improve compliance by care-focused industry employers, including residential care, nursing facilities and home health services, with federal wage and hour laws. In 2022, the Department of Labor announced its completion of more than 1,600 investigations, which identified violations in 80% of its reviews and led to recovery and assessments against employers in the tens of millions of dollars, including back pay, damages, and civil monetary penalties.

In maintaining compliance with current wage and hour laws that apply to their hybrid and remote workforces, employers should familiarize themselves with recently passed wage and hour laws in major states and localities. For example, new in Illinois last year is an expanded meal break law, which now provides an additional meal break to employees who have worked beyond a certain number of hours each day. The same law now requires employers to provide a day of rest to each employee within a certain number of consecutive work days.

As employers in the health care industry continue to navigate the unfamiliar terrain of a workplace comprised of in-person, hybrid and remote employees, employers must take extra steps to ensure compliance with all applicable federal, state and local wage and hour laws. Employers should be aware of where their hybrid and remote employees are working, ensure their employees have knowledge of applicable employer policies and practices pertaining to timekeeping and meal breaks, and engage in periodic reviews of the practices and physical locations of their employees.

For more information on this article, please contact Jill Vorobiev and Mallory McCarthy

Fraud, waste and abuse in 2024: Target areas for additional review

Takeaways

- Update payment policies for genetic testing to structure payments similar to the use of G-Codes for urine drug testing
- Audit DME claims to ensure no improper unbundling or miscoding
- Review med-spa claims and documentation to confirm appropriate billing of services

Managed care companies continue to face increased risk from some providers potentially engaging in improper provision of health care services and billing, which may implicate fraud, waste, and abuse. Three areas where additional focus is warranted in 2024 are: (1) genetic testing; (2) durable medical equipment billing; and (3) med-spa services.

Genetic testing

Rapid advancements in testing for various genetic disorders and diseases have led to exponential growth in genetic testing services. As a result of the rapid development of these services, lagging government regulation in this area and high charges associated with many of these services, genetic testing has become a ripe area for potential improper billing by some health care providers and laboratories. These ever-changing conditions and advancements in medicine also have made it challenging for payors to develop and update medical and payment policies for these services.

In October 2023, the U.S. Food and Drug Administration (FDA) published proposed new rules regarding laboratory-developed tests (LDTs), which if implemented will help curtail some potentially improper billing practices related to genetic testing by treating LDTs like other FDA- regulated devices. Should these rules be adopted, and given that they will not be fully implemented until April 1, 2028, there's an opportunity to enhance existing payment policies. Considering the medical reasons and cost-efficiencies associated with specific genetic testing, such as for certain types of cancer or advanced maternal age pregnancies, payors should continue to consider further developing existing payment policies for genetic testing to help reduce potentially improper billing for these services.

One interim recommendation is the development of payment policies for genetic testing requiring the use of "Z-Codes" for genetic tests. Medicare has required the use of Z-Codes since 2015. Use of those codes allows a payor to request additional information as a corresponding claims data element, thus enabling the payor to assess the circumstances of the lab testing services. Payors may also want to consider developing fee schedule payments for genetic testing services that are tied to specific Z-Codes, similar to what Medicare and many payors have implemented regarding payments for urine drug testing and the use of "G-Codes." Development of payment policies consistent with this payment structure will help disincentivize potential improper billing for these services while helping to ensure that legitimate services are being paid.

Durable medical equipment

DME billing is a second target area for close review. One potential billing risk is that certain providers and DME suppliers may be engaging in tactics to circumvent payors' bundled payment policies. Payors should be vigilant anytime a provider or DME supplier bills for equipment using a Place of Service Code 12 or 13 as that may be an indication of improper unbundling. Some DME suppliers have developed a strategy where they will ship the equipment to the member ahead of providing services to the member (such as a surgery at a surgery center) and then instruct the member to bring the equipment to the facility where they are obtaining services. Had the facility supplied the equipment directly to the member, no separate payment would be issued for the equipment as it would be subject to most payors' bundled payment policies. Braces used to stabilize a patient's knee or elbow are common examples. However, there is concern that this type of scheme could proliferate to where providers will use the same unbundling tactic by applying it to more expensive equipment or other high-cost items. Thus, payors should be aware of situations where providers bill for codes that make it appear that the device is being directly provided to a member at their home or assisted-living facility, but then there is a separate claim for surgical care billed by the same or a separate provider during or around the same time period.

A second example of where some providers are potentially improperly billing for DME is through the use of unspecified CPT codes. Some providers have started to make use of ambiguity in payor contracts or reimbursement policies by billing for these services under catch-all provisions that apply to any services being billed using unspecified CPT codes. Payors are advised to scrutinize these types of claims as some of these providers may be using incorrect codes to bill for the equipment. In a number of instances, the equipment should be billed using codes specified by the medical device manufacturer, and approved by the FDA, as opposed to using general catch-all unspecified service CPT codes that have elevated payment rates.

Another way to support correct billing in this instance is to develop a medical policy specifying that any time an unspecified service or equipment CPT/HCPCS code is billed, such as E1399, the claim will be pended or otherwise soft denied pending receipt of additional information from the provider. The additional information will help the payor assess what DME is being provided and whether the provider was using the correct code. Payors may also want to create pre- or post-claim audit teams specifically trained in the review of DME claims as there can be specialized issues regarding the technology underlying these services.

Medical spas

Some medical spas have faced issues around questionable services and/or potentially improper medical billing. For example, some medical spas have "hired" a doctor to serve as the spa's medical director for the purpose of using the doctor's in-network status with a payor and billing credentials to bill for services. In such instances, the doctor is often not on-site at the spa and not seeing members, but then the spa bills for services to the payor as if the doctor is rendering the care. A new twist on this arrangement is the spa using the doctor's credentials to prescribe high-cost drugs such as various weight loss medications. This then allows the spa to bill and obtain payment for the services despite there being no connection with the member. Effective use of claims data analysis is one way to help identify these potentially improper billing arrangements.

For more information on this article, please contact
Bryan Webster

Back to contents.

Insurance recovery in False Claims Act matters: Recent developments and tips to maximize coverage

Takeaways

- FCA matters still targeted at health care industry, extracting billions of dollars in settlements and judgments each year
- Insurance coverage for costly defense and settlement of FCA matters are very important to managed care companies
- Important case law developments in 2023 are helpful to insurance recovery efforts on FCA matters
- Health plans should assess and report FCA matters under all potentially implicated coverages and be mindful of insurance coverage in connection with possible settlements

The managed care industry for years has faced investigations and litigation alleging misuse of government funding in health care programs. On a positive note, however, in the past year, there have been favorable case law developments for managed care organization (MCO) policyholders in connection with possible insurance recovery for False Claims Act (FCA) matters. Most significantly, in *Astellas*, the Seventh Circuit held that there was coverage for a settlement in connection with an FCA investigation and rejected significant insurer defenses to avoid coverage. Beyond properly presenting the legal arguments, your MCO needs to take important steps in order to maximize the opportunity for insurance coverage for FCA matters. Do not let insurance coverage be an afterthought!

Insurance case law developments

In *Astellas U.S. Holding, Inc. v. Fed. Ins. Co*., 66 F.4th 1055 (7th Cir. 2023), the Seventh Circuit found that a drug manufacturer's settlement of an FCA investigation was covered and held that the policyholder's settlement did not constitute uninsurable restitution or disgorgement.

The U.S. Department of Justice issued a civil investigative demand (CID) in connection with an investigation of Astellas U.S. Holding relating to possible violations of the FCA and other federal laws. Astellas reported the Justice Department's investigation to its directors' and officers' (D&O) liability insurers. Astellas ultimately settled the case for $100 million, $50 million of which was expressly referred to in the settlement agreement as "restitution to the United States," but Astellas did not admit liability or any wrongdoing in the settlement agreement.

Astellas' D&O liability insurer denied coverage for the settlement. In the subsequent insurance coverage action, the federal district court ruled in Astellas' favor and rejected arguments that the settlement payment was uninsurable restitution or disgorgement because a portion of the payment was labeled "restitution" for tax reasons. The district court held that Illinois public policy did not bar coverage, despite the government's allegations about Astellas' intent to profit from its donations to the patient assistance plans. The district court found that the damages sought by the government were "primarily (if not solely) compensatory damages under the FCA meant to cover the government's losses in the form of Medicare payments."

On appeal, the Seventh Circuit affirmed and held that the insurer had not carried its burden of showing that the portion of the settlement payment for which Astellas sought coverage was uninsurable restitution under the D&O policy. The Seventh Circuit explained that there must be evidence of profit, benefits, or proceeds, and that the insurer had not met its burden of establishing that coverage was excluded. The Seventh Circuit found that the D&O policy provided coverage to the limits of applicable law and public policy and provided coverage for settlements, even for claims alleging deliberate fraud and willful violations of the law, so long as there was no final adjudication of such conduct..

The Seventh Circuit rejected the insurer's argument that coverage was excluded based on *Level 3 Commc'ns v. Fed. Ins. Co.*, 272 F.3d 908 (7th Cir. 2001), where it held that Illinois law "prohibits insurance coverage for losses incurred from settlement payments that are 'restitutionary in character.'" In determining whether insurance coverage was barred, the Seventh Circuit looked to the "primary focus" of the Astellas settlement and explained "if [the insurer] could show that the settlement payment was 'not even potentially covered,' then it would not need to cover Astellas' settlement."

Among other things, the Seventh Circuit reviewed the history and purpose of the FCA and determined that the FCA did not provide for the remedy of restitution or disgorgement. The Seventh Circuit refused to treat "damages" under the FCA as "restitutionary" rather than compensatory. Significantly, the express reference in the settlement agreement to the settlement payment as "restitution to the United States" for tax reasons did not change the analysis. The *Astellas* decision recognized that certain forms of "compensatory damages" can be characterized as "restitution" or "restitutionary," but such insurer characterizations do not preclude coverage.

In another victory for policyholders, the Delaware Supreme Court recently held that a "professional services exclusion" in a management liability/D&O policy does not apply to bar coverage for a government FCA investigation of a mortgage lender. *See ACE Am. Ins. Co. v. Guaranteed Rate, Inc.*, 2023 WL 5965619 (Del. Sept. 14, 2023).

Practical tips and guidance

There are important considerations and steps for MCOs to take in order to maximize possible insurance recovery for FCA matters:

- Upon receipt of a government CID, complaint, or whistleblower lawsuit involving FCA allegations, review and assess D&O and errors and omissions (E&O) policies, as well as other potentially implicated insurance coverages.
- Follow reporting provisions and notify carriers **under all potentially implicated** insurance policies. This typically can be accomplished by sending the carrier the demand, complaint or lawsuit and simply saying "please see attached" **without** characterizing or taking positions.
- Be aware of any selection of counsel and carrier consent or approval of counsel/ defense fee expense requirements in the policies.
- Request coverage position letters from insurers promptly, which are based on the FCA allegations of the complaint, lawsuit, or demand (extensive information is not required for the carrier to provide an initial coverage position letter, despite extensive requests routinely made by insurers to policyholders).
- Consider entering into confidentiality agreements with your insurers.
- Be mindful of "cooperation" obligations. Keep your insurers apprised of developments, and provide **reasonably** requested information **as appropriate**, while protecting attorney–client privileged information (regardless of whether a confidentiality agreement has been entered with the insurers).
- Be aware of "consent to settle" provisions in the subject insurance policies and possible insurance coverage with respect to settlement demands in advance of settlement offers, mediations, and any settlement of FCA matters.

In conclusion, MCOs can take important steps to protect their rights and maximize possible insurance coverage of FCA matters. By following the right policyholder strategies, your company may be able to secure coverage for defense fees/expenses and settlements, depending on the circumstances and policy terms.



For more information on this article, please contact David Goodsir, Caitie Young and Vanessa Perumal

Legal and regulatory challenges

Back to contents.

Back to contents.

Antitrust developments in 2024 that will impact managed care

Takeaways

- Consolidation by providers and managed care companies, is being insistently scrutinized.
- Contracting practices of dominant providers have drawn challenges from enforcers and private plaintiffs.
- Certain states are passing laws enabling them to review smaller deals.

Efforts by private plaintiffs and both federal and state governments to enforce the antitrust laws show no signs of slowing down in 2024. The Biden administration has consistently made antitrust enforcement in the health care sector a priority, and that was reflected in federal antitrust enforcers' efforts to address allegedly anticompetitive conduct and mergers in 2023. Similarly, 2023 saw private antitrust plaintiffs pressing cases against allegedly dominant providers and payors. Finally, fourteen states (so far) have now enacted premerger filing and clearance statutes specifically governing even small health care transactions. These developments, including new actions filed at the end of 2023, will continue into 2024 and hold implications for managed care entities.

In 2024, government enforcers and private plaintiffs will continue to use the antitrust laws to curb provider power. These efforts will involve evidence developed from managed care entities and will impact the managed care sector directly. As a prime example, in a case filed in late September 2023, the Federal Trade Commission (FTC)

took direct aim at a private equity firm, Welsh Carson, that consolidated anesthesia practices in certain markets in Texas to develop U.S. Anesthesia Partner, Inc. (USAP) into a dominant anesthesia provider. The FTC alleges that USAP and Welsh Carson engaged in a rollup of major anesthesia practices in Texas starting in 2012 and involving more than a dozen practices, 1,000 doctors and 750 nurses. According to the FTC, the rollup strategy and resulting market power have led to higher prices and USAP has engaged in unlawful price setting and market allocation agreements with competitors. On November 20, 2023, USAP and Welsh Carson moved to dismiss, arguing, among other things, that the FTC's lawsuit exceeds its contractual and statutory authority and fails to allege a relevant market, monopoly power or exclusionary conduct plausibly. On the same day that the defendants moved to dismiss the FTC's case, a putative class action addressing the same conduct was filed by union employee benefit plans.

The USAP case is of a piece with government and private actions to constrain the power of dominant hospital systems. Private plaintiffs successfully survived a motion to dismiss a putative antitrust class action brought by commercial and Medicaid health plan members against Hartford Healthcare in Connecticut. The allegations are that the defendant hospital system has monopoly power and uses anticompetitive tactics to maintain and grow it. The core anticompetitive tactic alleged is the use of "all-or-nothing" contracting – meaning that Hartford won't enter agreements with insurers for hospitals in which it has a monopoly and for which there are no alternatives unless the insurers also contract with Hartford's other hospitals. This case is much like the California attorney general and private plaintiffs' case against Sutter Health that resulted in a $575 million settlement in 2019 but also in a trial loss for one set of private plaintiffs in 2022. In similar cases against HCA Healthcare and others, all-or-nothing contract terms and anti-steering and anti-tiering provisions are at the heart of the allegations of anticompetitive conduct.

In the hospital merger space, states in the South have continued to pass Certificate of Public Advantage (COPA) laws to provide immunity to merging hospitals from federal antitrust scrutiny. Mississippi passed a COPA law in 2023, North Carolina is considering one for the UNC system and Louisiana passed a COPA for a $150 million hospital merger that sparked a challenge from the FTC. On September 27, 2023, the federal district court in Louisiana concluded that the merger was subject to the state action doctrine – because it was covered by the state COPA review process – and thus immune from the federal antitrust merger enforcement process. Under the state action doctrine, federal antitrust laws do not apply to anticompetitive restraints imposed by states as an act of government.

In 2023, countering that trend in Southern states, each of California, New York, Minnesota and Illinois joined 10 other states (Colorado, Connecticut, Hawaii, Massachusetts, Nevada, New Hampshire, Oregon, Rhode Island, Vermont and Washington) that previously had required advance notice and an opportunity to investigate even quite small transactions (e.g., as small as $10 million in revenues).

This year may also bring challenges to consolidation on the payor side of the market. In December 2023, Cigna and Humana announced (then quickly pulled back from) a possible merger that likely would have drawn an investigation and, potentially, a challenge, as proposed mergers of Anthem and Cigna, and Aetna and Humana did in 2017.

The very extent to which there are "provider" and "payor" sides of the market for antitrust purposes will also be subject to scrutiny in 2024. One aspect of antitrust in health care markets that remains to be tested is the extent to which managed care entities operate a two-sided platform as described in *Ohio v. American Express*, 138 S. Ct. 2274, 2283 (2018), such that any anticompetitive effects must be evaluated collectively in both the payor and provider side of the market. In 2020, in *In re Delta Dental Antitrust Litig., 484 F. Supp. 3d 627, 637 (N.D. Ill. 2020)*, the Northern District of Illinois addressed whether a dental insurer, Delta Dental, operated a two-sided platform at the motion to dismiss phase. The court concluded that the insurer was not a two-sided platform, as it lacked the "simultaneity of the exchange" of the credit card transactions at issue in *Ohio v. American Express*. However, the court noted that a two-sided market analysis could be used to evaluate indirect network effects, deferring the issue until after discovery. Defendants appear poised to test this theory in 2024 with a fuller record as the case moves out of discovery and into the class certification phase.



For more information on this article, please contact Will Sheridan, Daniel Booker and Leah Hungerman

Back to contents.

What's next for payor transparency compliance?

Takeaways

- Price transparency enforcement is on the rise
- Payors see problems expanding federally required member cost-sharing tool to all items and services
- 2024 marks the second attestation period for compliance with gag clause prohibition, but payors continue to grapple with compliance
- Employer plans may use gag clause rules to trigger investigations and litigation

2024 marks the first year in which payors must comply with each of the three recent transparency requirements: (1) publicly posting rate information in machine-readable files (MRFs), (2) providing a consumer engagement tool to estimate member cost-sharing, and (3) submitting attestations that no gag clauses appear in provider network contracts.

And in 2024, we will likely see increased enforcement and litigation under 2020 Transparency in Coverage (TiC) rules and the Consolidated Appropriations Act of 2021, which together significantly altered payors' disclosure obligations, a process that is being furthered by legislation pending since the end of 2023.

Federal requirements aimed at increasing health care cost transparency continue to vex payors. First, payors may come under scrutiny and may experience ramped-up enforcement if they lag behind in complying with complicated MRF requirements. Although MRFs containing contracted rates and out-of-network allowed amounts for medical services have been required since July 1, 2022, strict compliance with the regulations has been challenging, particularly for payors with unique contracting arrangements. Application to downstream contracts, such as those accessed through vendors or independent physician associations (IPAs), is also uncertain and may be operationally difficult to implement.

Regulators recently announced that the MRF requirements apply to prescription drug prices. Previously, application to prescription drugs had been deferred. This may cause payors to scramble to uphold their own compliance and enforce it on their pharmacy benefit managers as soon as possible.

So, although enforcement of MRF requirements has been minimal to nonexistent so far, we may see increased attention from regulators as we enter the third year of MRF requirements being in effect.

Second, in 2024, payors must now offer members an online cost-sharing lookup tool for all covered items and services. The TiC regulations first required payors to provide this lookup tool in 2023, but only for 500 identified items and services. Operational challenges plagued even this limited rollout, and many plans continued to adjust their lookup tool for regulatory compliance throughout the first year. Increasing its scope to all covered services will amplify compliance risks around compliant disclosures, non-traditional contracting arrangements or benefit structures, and application to downstream contracted rates through vendors and IPAs. If TiC compliance (including the MRF requirements noted above) ramps up in 2024, the member cost-sharing tool may come under regulatory scrutiny. Further, H.R. 5378, a federal bill pending since the end of 2023, would codify both the MRF and member cost-sharing tool requirements of the TiC regulations into federal statutes beginning in 2026.

Finally, payors must continue complying with the gag clause prohibition established by the Consolidated Appropriations Act of 2021. This statute prohibits plans and issuers from signing contracts that would restrict access to provider cost and quality information. It also requires annual attestations of compliance, with the first attestation having come due at the end of 2023. Payors must continue to ensure compliance with this provision and incorporate lessons learned from the first attestation period to submit accurate attestations at the end of 2024. For example, one area that created difficulties in the first attestation was ensuring downstream contracts' compliance with the gag clause prohibition, as payors may have limited visibility into contracts accessed through vendors or third-party administrators (TPAs). Thus, payors may implement processes to ensure that they more closely monitor downstream contracts.

The gag clause prohibition has also led to disputes between self-funded plans and TPAs, with plans arguing that the statute entitles them to broad access to the TPA's proprietary payment data. Some disputes have escalated to litigation or arbitration, and we expect the trend to continue in 2024. The disputes may be compounded by H.R. 5378, which, if passed, would strengthen self-funded plans' position in these disputes. This legislation would deem any contract between a plan and a TPA "unreasonable" under ERISA unless the plan can audit and review de-identified claims and encounter data without limitation within 60 days of a request. If a contract violates this provision, the TPA may be fined up to $10,000 per day of noncompliance. Further, H.R. 5378 proposes to amend the annual attestation to certify not only that contracts comply with the strengthened gag clause prohibition but also that claim and encounter information is available and provided upon request in a timely manner. If the information is not provided timely, then the plan's attestation must provide an explanation and describe its correspondence with the third party in attempting to obtain the information. If passed, this legislation could lead to increased employer plan data demands and could significantly complicate the attestation process for such plans, as employer plans typically delegated the attestation function to their TPA in the first attestation period.

For more information on this article, please contact Alex Lucas

Back to contents.

Interstate post-Dobbs issues that may impact MCOs in 2024 and beyond

Takeaways

- Many states banned abortion after the Dobbs decision, and Alabama's attorney general has pledged to enforce Alabama's abortion ban across state lines.
- Other states passed shield laws to protect people seeking, providing or assisting abortion care against interstate prosecution of abortion bans.
- MCOs should carefully administer abortion or related travel benefits for members residing in states with abortion bans.
- MCOs should also consider reviewing provider contracts and benefit plans to ensure that terms comply with abortion bans and shield laws.

In the Post-*Dobbs* landscape, some states have passed laws criminalizing abortion access and subjecting abortion providers who provide abortion care to potential civil and criminal liability and professional discipline, including licensure revocation. In response, other states have passed shield laws to protect people who perform and undertake such care against the possibility of prosecution. Both create exposure and compliance risk for managed care organizations (MCOs).

While many states have abortion bans, so far there is no reported instance of states enforcing abortion bans across state lines. However, there is continued risk that a state broadly prohibiting abortion services could attempt to prosecute out-of-state abortion treatment that is lawful in the state where it was performed. This could include prosecution of activity that would facilitate such abortion treatment, which for MCOs could implicate authorizing the out-of-state care, referring members to out-of-state abortion providers, or even approving benefits for the out-of-state care.

For example, Alabama has a statute that could be construed to criminalize aiding and abetting abortion. The Alabama attorney general has threatened to pursue criminal prosecutions under the state's general aiding and abetting or conspiracy statutes

against people who assist a pregnant person in traveling out of state to obtain abortion care in a state where the abortion was legal. In a statement, the Alabama attorney general noted that using abortion medication to end a pregnancy in Alabama is illegal, even if the medication was prescribed remotely from a state where the medication is legal. This position creates risk of criminal liability to MCOs with members residing in Alabama or other states with criminal abortion restrictions to the extent they facilitate the member's travel to another state for abortion treatment, such as through the provision of travel benefits, or facilitate prescription of abortion medication in another state (including through telehealth).

Some states have threatened **prosecution of abortion restrictions across state lines**, while nearly a dozen states have passed shield laws protecting against such prosecution.

The combined impact may create operational challenges and compliance risk for MCOs in coming years.

Key statistics

On the other hand, nearly a dozen states have enacted shield laws in response to states with abortion restrictions. These laws aim to protect not only patients who seek abortion care in a state where abortion is legal, but also those involved in the provision of the care. For example, many shield laws protect providers from out-of-state prosecution for providing abortion-related services, including via telehealth, when such services are provided from within a state where abortion is legal. Some of these laws, like Hawaii's shield law, protect the act of paying for abortion-related services as well.

While shield laws may protect payors from prosecution by states with abortion restrictions, they can also include provisions with operational impacts and compliance risks for MCOs. For instance, the Colorado shield law requires contracts between state-regulated insurance carriers and providers to guarantee that the carrier will not take "adverse action," such as refusing to pay claims, on the sole grounds that the provider is performing an abortion that is legal under Colorado law. In addition, many shield laws address the privacy of abortion-related protected health information (PHI). California's shield law, for example, prohibits any collection or retention of the personal information of someone located at or within the geolocation of a family planning center. It provides a private right of action to enforce this requirement and entitles plaintiffs to treble damages and attorneys' fees. California also requires PHI related to abortion and contraceptive care (as well as gender-affirming care) to be segregated from other information in the patient's medical record.

The contradicting laws enacted across the country have set the stage for potential interstate disputes around abortion services. In 2024, the Supreme Court is expected to rule on the FDA's regulatory approval of the abortion medication mifepristone, which could have a national impact on such interstate disputes. However, regardless of the Supreme Court's ruling on the regulatory approval of this medication, states that restrict access to this drug could still attempt to extraterritorially enforce the restrictions. MCOs should carefully administer benefits for abortion-related care or travel expenses from members residing in states with restrictions, since advising members regarding these benefits or possibly even approving benefits could create risk of extraterritorial enforcement from the member's home state. Even if a shield law applies to the MCO, the constitutionality of such laws is uncertain, particularly under the Privileges and Immunities Clause of the U.S. Constitution. MCOs should keep apprised of the position of attorneys general in states with abortion restrictions, particularly regarding interstate prosecution of abortion bans.

MCOs should additionally review and ensure compliance with all requirements of shield laws that apply to the MCO or their members. If the shield law mandates terms in MCOs' contracts, MCOs should consider reviewing provider contracts and benefit plans to ensure that their terms also comply. MCOs should also be mindful of data privacy requirements around abortion-related PHI. Finally, MCOs should continue monitoring any litigation concerning these protections, especially if states prohibiting abortions challenge the constitutionality of shield laws.

Reed Smith's proprietary Post-*Dobbs* Tracker provides a solution to monitoring abortion law updates relevant to MCOs. Please contact the authors for more information or a demonstration of this tool.

For more information on this article, please contact Alexandra Lucas and Kelsey Hill

Back to contents.

Bipartisan group in Congress moves to boost False Claims Act collections

Takeaways

- FCA settlements and judgments, primarily in health care, are at near-record levels.
- Post Escobar, bipartisan group of senators has introduced bill that would amend FCA's materiality requirement, stating government's decision to continue paying claims despite knowledge of fraud is not dispositive if "other reasons" exist for continued payment.
- Enactment of proposed legislation could increase FCA enforcement, heighten discovery disputes and prolong litigation, particularly in health care matters.

In 2022, "[t]he government and whistleblowers were party to 351 settlements and judgments, the second highest number of settlements and judgments in a single year." Notably, "health care fraud remained the leading source of False Claims Act settlements and judgments[.]"Insurers should be aware that an effort is underway in Congress to further boost FCA enforcement. The False Claims Amendments Act of 2023 (FCAA) would amend the FCA's "materiality" requirement in a way that could pose challenges for managed care organizations.

Background

The FCA prohibits, in part, a misrepresentation of compliance with a statutory, regulatory or contractual requirement that is material to the government's payment decision See *Universal Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 192 (2016). The FCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *See* 31 U.S.C.

§ 3729(b)(2)(4). The Supreme Court's 2016 landmark decision in *Escobar* emphasized a "rigorous" approach to materiality because the FCA should not serve as a catchall anti-fraud statute or penalize minor breaches of contractual or regulatory provisions. The Court articulated several factors to determine materiality, including whether the government explicitly designated the requirement in question as a condition of payment; whether the violation was minor or substantial; and (relevant here) whether the government continued to pay or did so in the "mine run" of cases despite knowledge of the violation.

In FY 2022, the Justice Dept successfully recovered

over $2.2 billion

through FCA cases.

Key statistics

Post-*Escobar*, courts have grappled with application of this last factor. Many courts, relying on *Escobar*'s statement that continued government payment is "very strong evidence" of non-materiality, assign great weight to the government's decision to pay a claim despite knowing of the alleged falsity. There, courts have dismissed FCA claims for want of materiality. *See Gharibian ex rel. United States v. Valley Campus Pharmacy, Inc.*, No. 21-56253, 2023 U.S. App. LEXIS 1009, at *5 (9th Cir. Jan. 17, 2023) (upholding dismissal of complaint where there were no allegations that payment would have been withheld based on knowledge of falsity). Other courts, however, view the government's decision to pay a claim while being aware of the alleged falsity as only one non-dispositive factor among many. *See United States v. Anthem Inc.*, No. 20-cv-2593 (ALC), 2022 U.S. Dist. LEXIS 180298, at *12 (S.D.N.Y. Sep. 30, 2022) (finding materiality despite no refusal to pay because refusal to pay "is materiality's ceiling, not its floor").

Proposed FCAA

The FCAA, introduced by a bipartisan group of senators, seeks to address what they see as a loophole *Escobar* created. Namely, the proposed legislation will remove the argument that continued government payment provides "very strong evidence" regarding the lack of materiality. Accordingly, the proposed legislation states that continued government payment despite knowledge of falsity "shall not be considered dispositive if other reasons exist for the decision of the Government[.]" Its focus is to clarify that the mere continuation of government payments should not shield a company from FCA liability.

Potential impact

The FCAA would require courts to ascribe less deference to continued government payment as "very strong evidence" of non-materiality and instead consider undefined "other reasons" for continued government payment. Further, the FCAA's "other reasons" language suggests courts will be less amenable to motions to dismiss, which will in turn lead to increased discovery and increased litigation over FCA materiality. For instance, even if the government continues payments on its claims with full knowledge of the facts, the FCAA could enable arguments by the government that ongoing payment serves policy rationales, such as ensuring continued care for underserved communities. It remains to be seen whether this also opens up discovery avenues into these "other reasons" that expand the scope of discovery for the government too.

Current status

The FCAA was introduced as Senate Bill 2466 in July 2023 and was referred to the Judiciary Committee. Reed Smith will continue to monitor the status of the Bill.




For more information on this article, please contact Michelle Cheng, Daniel Ahn, Steve Hamilton and Zach Kizitaff

Back to contents.

Potential liability for MCOs under criminal gender-affirming care laws

Takeaways

- MCOs in some states might suffer derivative liability for facilitating care that's proscribed under bans on gender-affirming care.
- MCO-employed clinicians may have greater risk.
- State laws criminalizing gender-affirming care may have extraterritorial reach, implicating potential liability for MCOs even when they operate outside of the state.
- Shield laws may protect MCOs in some states from extraterritorial reach of other states' criminal bans.

Since 2022, five states – Alabama, Idaho, Florida, North Dakota, and Oklahoma – have enacted laws criminalizing the provision of gender-affirming care (GAC) to minors in the form of puberty blockers, hormone therapy, and/or surgery. Each of these bans is being challenged in either state or federal court. Although each of these bans targets the performing provider and carries a low risk of direct criminal liability for managed care organizations (MCOs) and their employees, the bans' broad language and the respective states' derivative criminal liability statutes could potentially create criminal exposure for MCOs operating both in and out of the state. On the other hand, some states have enacted shield laws that could protect MCOs from a criminal ban's extraterritorial reach.

While other states' civil statutes prohibiting GAC may also impose potential liability on MCOs aiding in the provision of GAC, this article focuses solely on states with criminal statutes and the challenges to and implications of those statutes.

Legal battles

All five states with criminal gender-affirming care bans – Alabama, Idaho, Florida, North Dakota, and Oklahoma – face lawsuits challenging the enforceability of the bans. Challenges to the criminal bans (and often other states' non-criminal bans, such as those with medical licensure consequences) predominantly rely on the U.S. Constitution's Due Process and Equal Protection Clauses. Frequently, these suits allege that the ban violates the fundamental right of parents to make decisions concerning the care of their children under the Due Process Clause and that it discriminates on the basis of sex and transgender status in violation of the Equal Protection Clause. The Eleventh Circuit has been at the center of these challenges since its jurisdiction includes two states with criminal GAC bans (Florida and Alabama). Citing to Dobbs, the Eleventh Circuit reversed a preliminary injunction on Alabama's GAC ban because it did not consider that the plaintiffs had a high likelihood of prevailing on their constitutional challenges. Notably, the Circuit applied a rational-basis standard of review, whereas the district court had applied a heightened standard of scrutiny. However, despite the Circuit's ruling, Alabama's ban remains partially enjoined while the Eleventh Circuit considers plaintiffs' request for en banc review. The criminal ban in Indiana is currently on appeal in the Seventh Circuit, which may reach the opposite conclusion. Thus, the question over the constitutionality of GAC bans may soon reach the U.S. Supreme Court. As a result of these challenges, including those at the district court level, some GAC criminal bans are enjoined in whole or in part. Still, MCOs must evaluate their potential liability under each of these bans until and unless a court decides to permanently enjoin the criminal GAC laws.

Nearly half of U.S. states have enacted bans on GAC, including bans that make the provision of GAC a crime. In response, **15 states have enacted shield laws or executive orders** that, among other things, protect residents of the state from enforcement of other states' GAC bans.

Key statistics

Liability risks

The broad language and state derivative liability laws of GAC bans potentially implicate MCOs. The criminal GAC bans are notably vague. Although some of these bans impose criminal liability solely on the doctors providing the care, other statutes potentially apply directly to MCOs. For instance, Alabama's GAC ban states that "no person shall… cause" GAC to be performed on a minor. The ban, however, does not define "cause" or limit the definition of "person." Thus, this ban could implicate referring members to providers of GAC or providing case management to a minor undergoing GAC treatment. But even when MCOs are not directly liable under a GAC ban, they could still be subject to liability under the states' derivative criminal liability laws. For example, although North Dakota's GAC ban imposes criminal liability only on health care providers, the state's criminal facilitation law imposes liability on any individual who "knowingly provides substantial assistance to a person intending to commit a felony and that person, in fact, commits the crime contemplated, or a like or related felony, employing the assistance so provided." Under statutes such as these, MCOs could be liable if they knowingly facilitate illegal GAC or even provide reimbursement for illegal GAC.

Cross-border challenges

GAC bans may have extraterritorial reach, but shield laws reduce their risk of being enforced that way. Should a GAC criminal ban apply to MCOs, MCOs acting in states that do not have such bans may still be held liable. In Florida, for example, criminal statutes can apply to out-of-state conduct when the out-of-state conduct causes a crime to occur in Florida. Under the state's GAC ban, a criminal result occurs when a minor receives GAC. If an MCO facilitates the provision of GAC in Florida, for example by providing a prescription delivery program with GAC drugs to a Florida minor, an MCO could be criminally liable under Florida's ban even if the MCO never set foot in Florida. States elsewhere, however, are enacting shield laws to combat any potential extraterritorial reach of a GAC ban. Currently, 14 states plus the District of Columbia have shield laws or executive orders protecting GAC. In general, these laws provide protection against the consequences and enforcement of GAC bans by prohibiting local law enforcement from cooperating with out-of-state prosecution related to GAC and by protecting practitioners from legal actions taken against them for providing GAC.

Conclusion

In 2023, more states passed gender-affirming care bans than ever before. There is no indication that legislatures will slow down in 2024, and MCOs must stay up to date with GAC bans to protect themselves from criminal and civil enforcement. For more information, we recommend that you consult your Reed Smith representative to learn more about the firm's GAC Tracker.



For more information on this article, please contact Alex Lucas, Rizzy Qureshi, and Katie Goetz

Back to contents.

How to write denial letters in 2024

Takeaways

- Tenth Circuit opinion sets a new standard for denial letters because in defending litigation, claims administrators would be limited to the information contained in denial letters
- Tenth Circuit's position could spread to other parts of the country
- Most denial letters do not meet the standard set forth by Tenth Circuit

2023 was a rough year for denial letters. The Tenth Circuit – the hotbed of behavioral health litigation – upended familiar and standard ERISA principles, opting to require claims administrators to provide robust denial letters, including detailed accounts of members' medical records, in support of medical necessity denials and specific counterarguments to those raised by members' providers.

It's not yet clear if this phenomenon will spread, but there are lessons to be learned that may benefit members and will certainly bolster claims administrators' ability to defend their medical necessity decisions, particularly in cases with sympathetic plaintiffs where the court will scrutinize whether the member had a proper "full and fair review" under ERISA.

What happened in the Tenth Circuit?

Typically, under ERISA, courts have found that claims administrators have no duty to "explain a decision or to credit medical evidence that conflicts with the report of a treating physician." *Black & Decker Disability Plan v. Nord*, 538 U.S. 822, 834, 123 S. Ct. 1965, 155 L. Ed. 2d 1034 (2003). Further, ERISA case law has noted that courts should not impose on administrators a discrete burden of explanation when they credit reliable evidence that conflicts with a treating physician's evaluation. *Id.* at 824. Of course, claims administrators cannot arbitrarily refuse to credit a claimant's reliable evidence, including the opinions of a treating physician. *Id.* at 834. However, such administrators have not been required to accord special deference to the opinions of treating physicians.

In short, claims administrators have not been required to explain all bases for disagreeing with a member's treating physicians in their denial letters and did not have to give any extra weight to the opinions of plaintiff's treating physicians, nor did they have a "discrete burden of explanation." *Id.* at 824. Indeed, courts have found that denial letters did not have to give the "reason behind the reason" and that claims administrators did not have to "pin cite" to the record in the letters. Instead, in other circuits, "[a] denial letter is substantially compliant with the regulations when the claimant is provided a statement of reasons that, under the circumstances of the case, permitted a sufficiently clear understanding of the administrator's position to permit effective review." *Morningred v. Delta Family-Care & Survivorship Plan*, 790 F. Supp. 2d 177, 194 (D. Del. 2011), clarified on denial of reconsideration (June 30, 2011), aff'd, 526 F. App'x 217 (3d Cir. 2013).

In some recent cases, the Tenth Circuit has set a new standard for denial letters because in defending litigation, claims administrators would be limited to the information contained in denial letters (and perhaps other information, so long as it was provided to the member during the administrative process). The court was hyper-focused on ERISA's requirement for a "meaningful dialogue," noting that administrators must "engage with" opinions of treating providers and discuss medical records/ history. The court has taken this principle a step beyond how it has been traditionally interpreted in the courts by essentially finding that information not shared with the member in the administrative process cannot be relied upon by the claims administrator in litigation. In short, the court found that denial letters must be "comprehensive" to establish a "meaningful dialogue" with the member.

The Tenth Circuit's position is troublesome for defending medical necessity decisions in litigation. In litigation claims, administrators often rely on clinical notes and medical records outside of the denial letters to defend medical necessity decisions. Under the Tenth Circuit's view, in order to demonstrate that a payor provided a "full and fair review," the only information the payor can point to is that which was provided to the member during the administrative process, and in most cases, that will limit payors to what is contained in the denial letter.

While the Tenth Circuit's position remains somewhat of an outlier as compared to other circuits' positions, it is not unreasonable to think that the Tenth Circuit's position could spread to other parts of the country. Cases with sympathetic plaintiffs, like behavioral health cases, provide fertile conditions for courts to depart from traditional principles in order to find in favor of the member. While not all denial letters will be scrutinized through litigation in the Tenth Circuit, it is a certainty that the plaintiffs' bar will attempt to get other courts around the nation to adopt the Tenth Circuit's reasoning, making it worthwhile for claims administrators to consider changes to their denial letters sooner rather than later.

How denial letters can be better

Most denial letters do not meet the Tenth Circuit's standard. While most of those letters likely do meet ERISA's "full and fair review" requirements, claims administrators might consider providing more detail to make the appeals process more transparent to members. Claims administrators can meet the twin goals of making the administrative process smoother for members and guard against the litigation pitfall embodied by the Tenth Circuit's precedent by bolstering their denial letters. Below, we provide some pointers for meeting the Tenth Circuit's standard, along with some additional thoughts on how to improve denial letters.

If the goal is to meet the Tenth Circuit's standard, claims administrators should consider the following tips:

- **Medical directors could address treating physician opinions in the denial letter.** This would include both providers with whom reviewers have peer-to-peer discussions and providers who provide medical necessity letters in support of the patient (which are often attached to appeal letters). Medical directors could provide an explanation for rejecting or not following these opinions.

- **Denial letters should include reasoning and references to evidence in the administrative record.** Under Tenth Circuit logic, the court does not need to look beyond the denial letter for support for the medical necessity decision. The court held that ERISA requires that denial letters be comprehensive and include requests for additional information, steps claimants may take for further review, and specific reasons for the denial. This practically means that the letter has to refer to evidence in the administrative record that supports the medical necessity decision, rather than a high-level summary of the member's condition. Here, medical directors might use more detail from the notes they make while analyzing medical necessity and refer to medical records for evidence.
- **Consider attaching internal case notes to denial letters.** The Tenth Circuit noted that the claims administrator's internal case notes were more thorough than the vague denial letters that were sent to plaintiffs. While these notes may not satisfy regulators' and accrediting bodies' reading level requirements for denial letters, the denial letters themselves could be written in a manner to satisfy these types of requirements and the notes could be attached as evidence. It may be worth reaching out to those that impose reading requirements to get their view on attaching the notes to denial letters. Note, however, that the internal notes themselves must be robust and contain specific references to the medical records and must grapple with treating providers' opinions. Further, it would be prudent to make denial letters themselves more robust than they currently are, even if attaching the internal notes.

Regardless of whether the goal is to meet the Tenth Circuit's standard, claims administrators should consider these tips:

- **Specifically mention the factors considered from the relevant medical necessity criteria.** The Tenth Circuit has found that a denial letter was sufficient where the letter discussed the specific factors from the relevant medical necessity criteria and why the member did not meet those factors. The court has found that letters that summarize the criteria used are sufficient, insofar as they accurately capture the essence of the decision-making points. Further, where the reason for denial is the absence of symptoms that meet those criteria, claims administrators are not required to point to medical records. Thus, mentioning the criteria and explaining what evidence there is (or is not) to support the criteria will help bolster arguments that the denial letter provides a sufficiently "full and fair review."
- **Denial letters should align with internal notes and records.** Regardless of whether more information will be included in the denial letter, claims administrators should take care to ensure that statements made in the denial letter are not contradicted by internal notes and records. For example, if the denial letter indicates that the member does not require residential treatment level of care because the member had no self-harm, but the medical records indicate there was some degree of self-harm happening, the courts will reject the reasoning provided in the letter. Statements about the member's condition should be nuanced to indicate that the intensity of the member's symptoms (which should be identified specifically) do not require the level of care requested, rather than making absolute statements about the absence of such symptoms, particularly if the records indicate they are present to some degree.
- **Care should be given to harmonize decisions across time.** Decision-making should make sense across time and facilities. For example, in the case where a member goes directly from one facility to another, if the claims administrator denied coverage for the last part of treatment at the first facility, but allowed coverage for care at the second facility, care must be taken to show why the decision was made to allow coverage.
- **Denial letters should address all diagnoses and concerns**. Courts have criticized denial letters that do not address a diagnosis, such as when a denial focuses on the member's depression or other mental health condition, but ignores substance use disorder issues that are raised by the provider. A review of admission reasons and treatment plans can be useful in ensuring that all relevant issues are included in the denial letter rationale.

- **Medical directors should be careful to explain why the member's symptoms do not warrant the level of care being sought and should not appear to be "cherry-picking" the record.** Laypersons like judges do not readily understand that mental health care is provided on a continuum of intensity of services and that mental health symptoms vary in terms of their intensity, as well. Judges are often swayed by statements made by members that they suffer from suicidal ideation, without understanding that such symptoms are not always severe enough to be treated in an intensive setting like a residential treatment facility. Medical directors should take care to explain why the member's current symptoms are not severe enough to warrant the level of care being sought. Further, because mental health symptoms can change significantly over time, it is important to provide context. For example, a member may be admitted because they have intense suicidal ideation, but over time the member may improve to where they only have passive thoughts of suicide. The denial letter should explain the improvement by citing evidence in the record and should not ignore the fact that suicidal symptoms still persist, while including context to explain that one does not have to be free of suicidal thoughts to be treated on an outpatient basis outside of a 24-hour setting.

An additional item to consider

While claims administrators are considering changes to their denial letters, it is worth considering adding information about any **contractual limitations** on filing a lawsuit. A number of circuits have disallowed arguments in litigation about contractual limitations clauses if the limitation is not included in the denial letter. Providing notice of the limitations period in the denial letter will allow claims administrators to argue that the case should be dismissed in instances where the limitations period was not met, which might help resolve cases at the pleadings stage.

For more information on this article, please contact
Rebecca Hanson

Back to contents.

Plan sponsors face key decisions as major Part D statutory changes approach

Takeaways

- MCOs in some states might suffer derivative liability for facilitating care that's proscribed under bans on gender-affirming care.
- MCO-employed clinicians may have greater risk.
- State laws criminalizing gender-affirming care may have extraterritorial reach, implicating potential liability for MCOs even when they operate outside of the state.
- Shield laws may protect MCOs in some states from extraterritorial reach of other states' criminal bans.

The Inflation Reduction Act of 2022 (IRA) made important changes to Medicare Part D. While media coverage has largely focused on provisions requiring the Centers for Medicare and Medicaid Services (CMS) to negotiate "maximum fair prices" for certain drugs (which are applicable beginning in 2026), some of the most significant changes to Part D take effect beginning in plan year 2025.

Consequently, Part D plan sponsors will soon need to determine how to design their benefits and formulate their bids for 2025, which must be submitted to CMS in the second quarter of 2024. Given the magnitude of the changes, there may be a shakeup not only in benefit and formulary designs, but also in the Part D competitive landscape.

Subsidy changes

Beginning in 2025, the largest source of federal subsidies to Part D plans – catastrophic reinsurance subsidies – will be dramatically reduced.

Since 2006, catastrophic reinsurance subsidies have been covering **80 percent** of the costs (net of average percentage manufacturer rebates and other price concessions) paid for Part D drugs that are dispensed in the catastrophic phase, which enrollees enter after reaching an "incurred cost" threshold of the benefit design. Beginning in plan year 2025, this subsidy will be reduced to:

- **20 percent** of such costs for "applicable drugs" (branded drugs, biologics and biosimilars); and
- **40 percent** of such costs for non-applicable drugs (generic drugs).

In 2022, catastrophic reinsurance subsidies totaled $56.8 billion. The Medicare trustees estimate that this change, together with other changes made by the IRA, will bring catastrophic reinsurance subsidies for 2025 down to $21.9 billion.

Plan sponsors will likely increase their bid amounts to make up for some of that reduction in funding. While the IRA capped the annual increase in average Part D enrollee premiums due to higher bids to 6 percent per year (under a formula that results in higher "direct subsidies" to make up the difference), individual plan premiums can increase by more or less than that 6 percent amount, depending upon the level of the plan's bid compared to the national average monthly bid amount.

Since enrollees are highly sensitive to plan premiums and premiums affect the eligibility of plans to receive auto-enrollment of Medicare/Medicaid dual-eligibles, the bids that sponsors submit in 2024 could have big impacts on plan enrollment – positive or negative. Moreover, sponsors will have to make judgments about the impact of various Part D changes and the levels at which their competitors are likely to bid – all of which create greater uncertainty than the Part D marketplace has seen in years.

New manufacturer discount program

The impact of that subsidy change will be mitigated somewhat by concurrent changes being made to the mandatory discounts that manufacturers of applicable drugs must pay to Part D plans for their products to be eligible for Part D coverage.

Currently, manufacturers of applicable drugs must pay "coverage gap discounts" equal to 70 percent of the negotiated price of drugs (i.e., the price paid by or on behalf of the plan to the pharmacy, excluding dispensing fees) dispensed to non-Low-Income Subsidy (LIS) beneficiaries in the Part D "coverage gap." However, beginning in 2025, the coverage gap phase is being eliminated, and the coverage gap discount program is being replaced with a new "Manufacturer Discount Program."

Under that program, beginning in 2025, manufacturers of applicable drugs generally must pay mandatory discounts to plans in both the initial coverage and catastrophic phases of the benefit, on prescriptions dispensed to both LIS and non-LIS beneficiaries, after the beneficiary has incurred costs equal to the defined standard deductible for the year, as follows:

- **10 percent** of the negotiated price (including dispensing fees) for applicable drugs dispensed in the initial coverage phase.
- **20 percent** of such negotiated price for applicable drugs dispensed in the catastrophic phase.

There are exceptions to these requirements. Most significantly, in 2025, a manufacturer that qualifies as a "specified manufacturer" or "specified small manufacturer" may pay only 1 percent of the negotiated price on utilization of its applicable drugs (by LIS enrollees in the first case and by all enrollees in the second) during both the initial coverage and catastrophic phases. (The discount percentage increases in later years.)

Manufacturers qualify for these "phase-in" discounts based primarily upon expenditures for their drugs under Part D and Part B during 2021, and they must submit certain ownership information to CMS by March 1, 2024 to enable it to make the relevant determinations. After that, CMS will publish guidance to enable Part D plan sponsors to determine which drugs are subject to the lower discount percentages.

Presumably, plans will consider the combined mandatory manufacturer discount and any rebates the manufacturer makes available voluntarily in determining what drugs to cover and prefer on their formularies. Consequently, some specified manufacturers or specified small manufacturers could decide to pay higher voluntary rebates to make up for all or a portion of the reduced mandatory discounts they will pay due to such status.

Benefit changes

Beginning in 2025, there will be a new cap on Part D enrollees' out-of-pocket costs for covered Part D drugs, equal to $2,000. After reaching that level, beneficiaries will enter the catastrophic phase, where they will have no cost sharing, in contrast to the 5 percent co-insurance that non-LIS beneficiaries generally paid in that phase through 2023. Effectively, the new $2,000 limit will lower the incurred cost threshold that beneficiaries previously were required to reach to enter the catastrophic phase.

Consequently, more beneficiaries are likely to enter the catastrophic phase, and since they will have zero cost sharing once they are there, they are more likely to continue using Part D drugs during that phase. Plans will bear a much higher percentage of the cost of drugs covered in that phase due to the combined effects of all the changes described above.

Additionally, beginning in 2025, enrollees will have the option to spread out their cost-sharing obligations during a given month over the remainder of a plan year. For example, a member who has incurred out-of-pocket expenses of $200 and is prescribed an expensive specialty drug in March for which a single month's cost sharing would be $1,800 could instead decide to pay that cost sharing in installments of $180 per month over ten months. This will further increase the likelihood of beneficiaries using such expensive drugs, for which the plan will bear the costs.

Conclusion

One of the policy rationales for the changes made by the IRA was a concern that plans did not bear sufficient risk for drug costs in the catastrophic phase between the 80 percent reinsurance subsidy and enrollees' 5 percent coinsurance, as well as the impact of LIS cost-sharing subsidies. Advocates contended that by shifting more of that risk to Part D plans, plan sponsors would have greater financial incentives to manage catastrophic phase drug costs.

As the implementation of those statutory changes in 2025 approaches, plan sponsors will be evaluating potential benefit changes they can make to reduce costs. Options may include such actions as narrower formularies that could generate higher rebates from manufacturers and/or increased use of lower-priced specialty generics and biosimilars. Plan sponsors may be challenged to balance the cost savings that such measures may produce against potential reactions by members and their physicians facing greater limitations on the drugs for which coverage is available under their plan.

For more information on this article, please contact Robert Hill and Joseph Metro

Artificial intelligence, technology and data privacy

Back to contents.

Retaining control of data and learnings in agreements with AI developers

Takeaways

- Despite fears, sophisticated AI developers are generally not trying to take their customers' data.
- MCOs should focus on operational steps that can be taken to protect data and trade secrets in addition to executing strong contractual protections.
- A mature AI governance program should incorporate standard contracting principles with AI developers as well as operational safeguards for data shared with AI developers.

Managed care organizations (MCOs) should implement and maintain both operational controls and contractual safeguards to prevent artificial intelligence (AI) developers from receiving and using personal information and other proprietary and confidential information for unintended purposes.

Technology that uses AI will not reach its potential if the individuals using and affected by the technology do not trust it. We see this lack of trust cited in statements by politicians, the media, and individuals (in lawsuits) in connection with the use of AI. One contributor to this perspective is the perception that companies lose control of large amounts of data to AI developers when they develop, train, and use AI models. This article highlights six considerations to help retain control of data when engaging an AI developer. It assumes the reader has some foundational knowledge of AI terminology and characteristics.

Rights to MCO's datasets and subsets, compilations and derivatives

AI developers typically will not assert ownership over datasets provided by an MCO to develop, train or use an AI model and will agree to limit their rights to such data. However, MCOs should contractually protect the datasets and also all subsets, compilations and derivatives of the datasets. In other words, the contract should be drafted to reduce the risk that an AI developer will argue that it has created net-new data (that it owns) when the AI developer processes the dataset. For example, an AI developer may perform significant processing of datasets to convert the data into a form usable by the AI (i.e., a derivative of the original dataset) or the AI developer could combine an MCO's data with other data (i.e., a compilation) for AI development and training purposes.

80% of respondents

believe companies will lose control over personal information used with AI-based solutions, according to a survey by the Pew Research Center.

Key statistics

Access to MCO's datasets

MCOs can take additional operational steps to protect their datasets. Even if the contract assigns ownership of data to an MCO, identification and prevention of data misuse by an AI developer may be difficult or impossible. To help counteract this concern, many of the more sophisticated AI developers have bifurcated their AI solution so that the foundational pre-trained AI model runs in the developer's environment, and an MCO's datasets used to train the AI model remain in the MCO's environment. MCOs should ask about operational steps the AI developer can take to limit or prevent access to MCOs' datasets and contractually require compliance with those limits.

Rights to fine-tuned weights

To improve the quality of AI models, MCOs will likely want to train (e.g., customize or fine tune) the pre-existing, out-of-the-box AI models provided by AI developers. Industry terminology is inconsistent, but commonly AI developers describe the part of the AI model that is customizable for customers through training/fine tuning as the set of "weights" within the model. Therefore, "fine-tuned weights" are the aspect of an AI model that has been customized using an MCO's datasets and will reflect the MCO's business practices (and may be trade secrets). Regardless of terminology, an MCO should ensure that contracts do not grant AI developers ownership of or the ability to use the fine-tuned weights for anything other than providing the AI solution to the MCO. Even if an MCO grants some rights to the fine-tuned weights, MCOs should contractually prohibit using or sharing fine-tuned weights with competitors.

Access to fine-tuned weights

AI developers typically do not grant ownership to fine-tuned weights to customers. Further, as with an MCO's datasets, identification and prevention of misuse of the fine-tuned weights by an AI developer could be difficult. Many AI developers have built their AI solutions so that the pre-trained weights can remain in an MCO's environment and are not available to an AI developer. Thus, an MCO should ask how the developer limits or prevents non-MCO access to its fine-tuned weights and contractually require compliance with those limits.

Rights to know-how

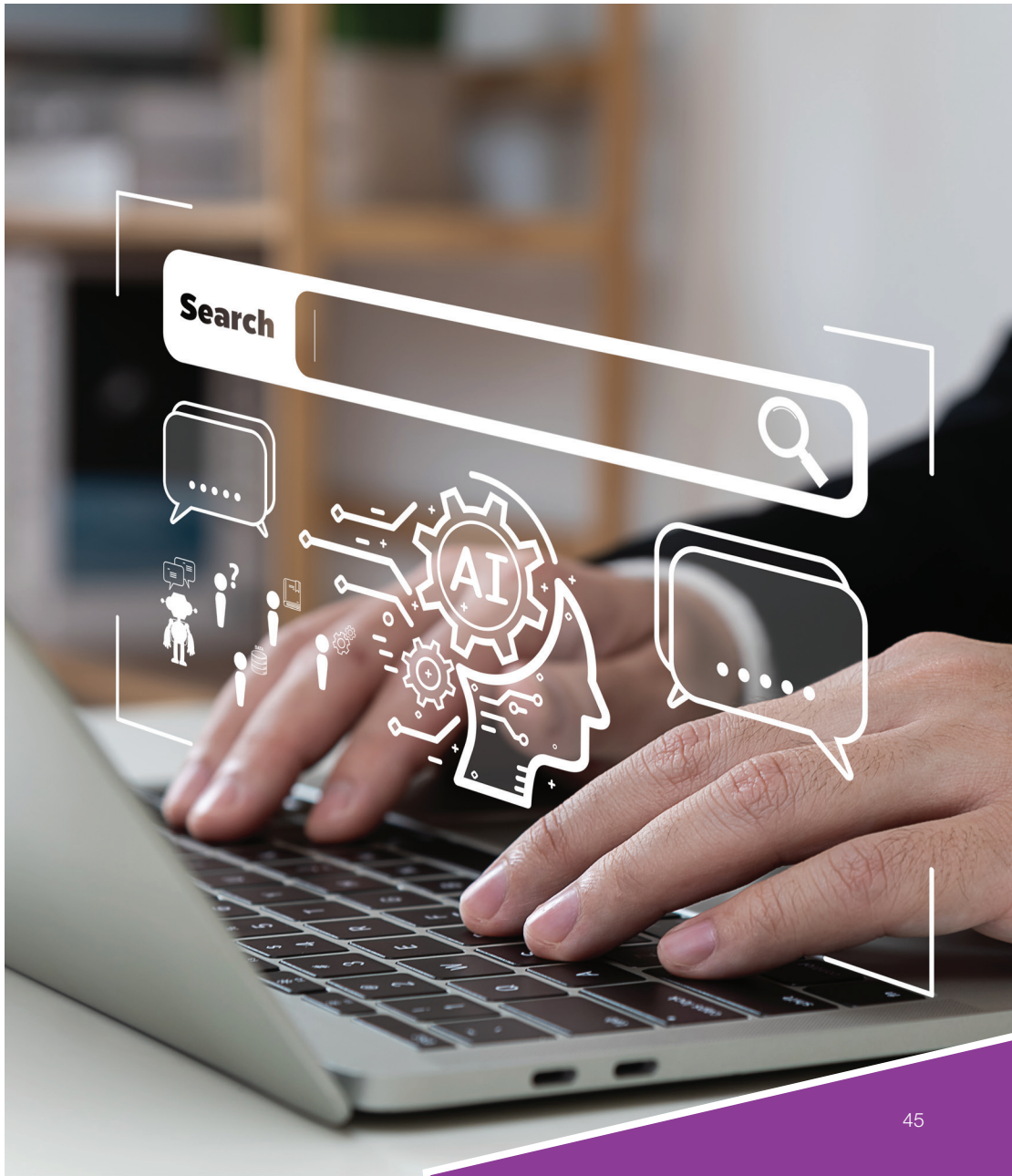
MCOs that interact with AI models provided by AI developers will likely gain knowledge that will be useful when developing their own models or deploying other AI models. For this reason, an MCO should ensure it contractually retains the rights to the know-how it gains when working with AI developers so that it does not unnecessarily limit its ability to use its know-how to build or use other AI models.

Rights to prompts and outputs

An MCO should contractually assert ownership over the inputs/prompts submitted into AI models and the outputs generated by AI models and obtain a commitment from the AI developer that inputs/prompts and outputs will not be stored by the AI developer (unless requested by the MCO) or used by the AI developer for any purpose other than providing the service to the MCO.

We have previously discussed that organizations should maintain an AI governance program to help manage the unique characteristics of AI. AI is dynamic and data driven, and the technology creates additional risk of data leakage if not governed appropriately. A mature AI governance program includes consideration of the protection of the data and limiting the rights of third parties that handle that data.

For more information on this article, please contact
Wendell Bartnick



AI regulations and their potential impacts on managed care organizations

Takeaways

- Federal legislation and rules warn health plans against relying excessively on AI in decisions about care.
- State-level actions are also expected to scrutinize MCOs' usage of AI and automated claims-processing tools.
- Increased scrutiny from government sources is likely to spur litigation over MCOs use of AI.

Following the increased use of generative artificial intelligence (AI), the federal government's current and proposed regulatory and legislative efforts are likely to more directly impact the health care industry, including managed care organizations (MCOs), which are increasingly using AI to transform and improve various processes that benefit their members and health care providers. This article highlights trends and key developments, as well as their potential impact on MCOs going forward.

CMS rules for MA plans

On April 12, 2023, the Centers for Medicare & Medicaid Services (CMS) published a final rule governing what Medicare Advantage organizations (MAOs) must consider when making medical necessity determinations. Specifically, it requires MAOs to make medical necessity determinations based on factors including the enrollee's medical history, physician recommendations, and clinical notes. Although the rule does not directly regulate MAOs' use of AI, CMS advised that compliance requires MAOs to make medical necessity determinations "based on the circumstances of the specific individual…as opposed to using an algorithm or software that doesn't account for an individual's circumstances." Thus, to continue using AI in medical necessity decision-making processes, MAOs must understand "the external clinical evidence [the AI] relie[s] upon" and "how the evidence supports the coverage criteria applied" by the AI. Particularly, MAOs must reassess the various machine learning and software tools they employ to ensure such programs are using only the factors listed in the final rule to make medical necessity determinations.

Executive order on safe AI

On October 30, 2023, the White House issued a Fact Sheet and Executive Order (EO) on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence. The EO is one of the White House's first steps in providing high-level direction to federal agencies, including but not limited to the Department of Health and Human Services (HHS), regarding the responsible use and development of AI by its stakeholders. While the EO touches on many industries, it has the potential to directly affect health care based on its directives to HHS in particular.

Among other tasks, the EO directs HHS to advance several directives over the next year. Within 90 days, HHS must establish an AI task force or, by January 28, 2024 and within one year of its creation, develop a strategic plan that includes policies and frameworks – possibly including regulatory action as appropriate – on the responsible deployment and use of AI and AI-enabled technologies in the health and human services sector. The EO also asks HHS to evaluate the quality of oversight of AI tools and medical devices, as well as develop AI assurance policies to evaluate performance. HHS, along with other agencies, must also consider appropriate actions that prompt compliance with federal nondiscrimination laws.

Congressional efforts

After the release of the EO, Congress has also moved forward with several legislative efforts that have the potential to affect health care. For example, on November 8, 2023, the U.S. Subcommittee on Primary Health and Retirement held a hearing on the various policy considerations for artificial intelligence in health care. At the hearing, leading health care executives testified that Congress needs to build on the EO by providing HHS with the authority and resources to enact AI governance initiatives. Additionally, the House Energy and Commerce Subcommittee on Health held a hearing on November 29, 2023, addressing similar issues, exploring how hospitals, pharmacies, and others in the health care sector are using AI and what Congress should consider as AI continues to change. Though these efforts reflect significant progress by Congress over the past year to support and regulate AI, to date, none have become law.

State legislative and regulatory efforts

Individual states are also joining the fray in scrutinizing and warning insurers about the use of AI and algorithms for internal processes, particularly as it relates to the potential discrimination AI algorithms may perpetuate.

- **Pennsylvania**: Proposed legislation (HB1663) that would require MCOs to disclose how they use AI as part of their utilization review process (referred to committee on insurance on September 7, 2023);
- **Colorado**: Department of Insurance adopted a new regulation affecting life insurance policies' use of algorithms and predictive models (enacted on September 21, 2023);
- **New Jersey**: Proposed legislation (S1402) that would prohibit insurance companies from discriminating through the use of automated decision systems against any person who is a member of a protected class (introduced February 10, 2022);
- **California**: Proposed legislation (AB1502) that would prohibit health care service plans or insurers from discriminating on the basis of race, color, national origin, sex, age, or disability through the use of clinical algorithms in its decision-making (introduced on February 2, 2023). California's Insurance Commissioner also published a bulletin warning insurance companies that AI use can and has increased systemic bias and unfair discrimination in the insurance industry, including in claims handling and underwriting practices (June 30, 2022);
- **Other states**, such as New York, Connecticut, and Washington D.C., have published similar warnings against AI's role in the insurance industry and its potentially discriminatory impacts.

The authors will continue to monitor these and other states' actions with respect to AI.

Conclusion

Federal and state lawmakers likely will continue to evaluate, enact, and enforce new regulations impacting MCOs' use of AI in 2024. With the rise of such developments, we can expect more lawsuits relying on those regulations to support adverse actions against MCOs and those in the health care industry.



For more information on this article, please contact Michelle Cheng, Katie Goetz and Vanessa Perumal

Tracking tools and health care websites: Manage with care

Takeaways

- Federal and state regulators and class action plaintiffs are focused on privacy implications of third-party trackers.
- An organization cannot effectively evaluate and mitigate the risk from its use of third-party trackers if it does not have an accurate picture of the scope of their use.
- Practice good website and mobile application hygiene – evaluate whether each third-party tracker is providing benefit that outweighs risk.
- Protect patient data and prevent invasion of privacy with notice and choice options, improved procurement, and renewed vendor diligence.

Managed care organizations, like all marketers, often seek ways to leverage data to improve their marketing efforts. Most companies across industries use similar technologies to gather this data online. However, commonplace technologies that used to power this data-driven marketing have come under significant attack over the past 18 months. Managed care and other health care organizations have faced increased regulatory and class action risk in connection with the use of cookies, pixels, tags, and other common tracking tools on their websites, mobile applications, and related digital services.

What are tracking tools?

Most websites use code that allows vendors of advertising and analytics services to collect information from users' devices as they interact with websites. The code may include, for example, the use of third-party cookies, web beacons, or tracking pixels and session replay functions. The providers of these tools then process and analyze data collected via trackers for various purposes, such as providing user analytics and facilitating and targeting online advertising.

What is the risk?

In recent months, federal and state regulators and class action plaintiffs have targeted users and vendors of tracking tools. The managed care industry has not been immune.

In December 2022, The U.S. Department of Health and Human Services' (HHS) Office for Civil Rights (OCR), which is responsible for enforcing the Health Insurance Portability and Accountability Act (HIPAA), issued a bulletin describing potential HIPAA noncompliance arising from the use of third-party trackers. The bulletin focuses on educating HIPAA-regulated entities on whether the use of third-party trackers is an impermissible disclosure of protected health information (PHI) under HIPAA. It explains that impermissible disclosures of PHI can occur through routine tracking tools on websites made available by HIPAA-covered entities. In the event a HIPAA-regulated entity experiences an impermissible disclosure, it must analyze whether it has breach-notification obligations under HIPAA, which may lead to regulatory scrutiny and class actions.

Since the beginning of 2023, the Federal Trade Commission (FTC) has settled three separate cases alleging deceptive and unfair business practices under the FTC Act by digital health platforms based on their use of tracking tools. In addition, in the summer of 2023, HHS and FTC issued a joint letter to approximately 130 health care companies alerting them to the regulators' position about the risks that tracking tools pose to the privacy and security of consumers' and patients' health information.

State regulators and legislatures also recently increased their focus on monetization of health and other personal information. The California attorney general's first public enforcement action under the California Consumer Privacy Act involved a website's use of ad/analytics services, and regulators in several states have recently issued statements or entered into settlement agreements related to the sharing of health information with third parties for ad/analytics purposes by companies in the health care industry. Three states (Washington, Connecticut, and Nevada) have enacted laws specifically aimed at restricting or eliminating companies' ability to use or disclose consumer health data for advertising purposes. While these laws contain exemptions for certain data regulated by HIPAA and other health care laws, they underscore the heightened scrutiny to which tracking tools have been subjected in recent months.

Finally, the plaintiffs' bar brought a significant number of class action lawsuits in 2023 against users and vendors of tracking tools. Plaintiffs have used creative arguments, characterizing the tracking technology as "spyware" and claiming violations of federal and state wiretap laws, violations of health privacy laws, violations of the Video Privacy Protection Act, an invasion of privacy, and other torts or contract breaches. The complaints generally allege that the defendants did not provide the necessary notice or obtain the legally required consent (opt-ins, authorizations, or opt-outs).

For more information on this article, please contact Robert Newman and Angela Matney

ERISA health plan litigation: Meaningful dialogue, powers of attorney and use of AI

Takeaways

- Plans and administrators should expect new battles over ERISA disclosure requirements, greater use of powers of attorney by providers and challenges to plans' use of AI.
- They should implement best practices around a) communication with members; b) provider powers of attorney; and c) implementing stronger protocols around AI-assisted claims determinations.

In 2024, ERISA litigation will witness new battlegrounds emerging across three distinct areas.

Increased disclosure requirements

Courts may apply more stringent ERISA disclosure requirements in the wake of a recent 10th Circuit decisions.

In *D.K. v. United Behavioral Health, 67 F.4th 1224 (10th Cir. 2023),* the Tenth Circuit adopted a more stringent approach to an administrator's disclosure requirements under ERISA. The court held that administrators must offer detailed responses in appeal determinations to the medical necessity opinions of the member's providers to avoid a ruling that their decisions are arbitrary and capricious (when that standard of review applies). Expressed in the context of inpatient behavioral health services, the Tenth Circuit's opinion relied upon the notion that full and fair review under ERISA requires "meaningful dialogue" between the member and the administrator.

Our colleagues have discussed *D.K.* in the context of behavioral health in a separate part of this Outlook, but the decision may have important implications for ERISA cases generally. First, we anticipate that the opinion may gain traction in other circuits and in cases involving medical benefits, including for long-term inpatient medical care or complex courses of medical treatment. Because many district courts and several circuit courts have adopted the "meaningful dialogue" framework for understanding full and fair review, we expect that plaintiffs' attorneys will cite *D.K.* in ERISA cases in other circuits.

And *D.K.* may have other implications. Because the Tenth Circuit held it was appropriate to exclude the internal notes of the administrator's reviewers from the administrative record that the court reviews to make its decision, we anticipate that ERISA plaintiffs will urge the court to ignore internal records of an administrator's decision-making if the benefit determination letter it sent to the member did not include a fulsome explanation of the denial.

Out-of-network providers find new ways to assert standing

Increasingly, out-of-network providers have been obtaining powers of attorney from patients in lieu of or in addition to assignments of benefits. Out-of-network providers have been using powers of attorney because a valid power of attorney can permit a provider to appeal and sue on behalf of the member and, at least arguably, may not be barred by a plan's anti-assignment provision. Providers have run into some issues with this new approach, but its use is increasing, and some courts have permitted it. In late October 2023, in *Sorotzkin v. Emblemhealth Inc.*, 2023 U.S. App. LEXIS 28724 (2d Cir. 2023), the Second Circuit Court of Appeals found that an owner of a medical provider had standing when it relied on powers of attorney executed by members, marking an important development in this area. In 2023, we saw an increase in out-of-network providers using powers of attorney as a vehicle to establish standing, especially in the Second, Third and Fifth Circuits, and this trend may spread to other circuits.

Members and providers contest payor use of AI

Members and providers are increasingly bringing suits asserting that insurers, administrators and their vendors' use of artificial intelligence (AI) constituted a breach of ERISA fiduciary duties or was otherwise improper. Some of these cases appear to involve payors' use of traditional automated processing (and not true AI), but we expect more litigation in this area as health plans and their administrators adopt true AI applications to assist with claims administration. Given the fast pace of change associated with AI, managed care companies should understand the potential litigation risks it may bring, particularly when used in the performance of fiduciary duties under ERISA.

Best practices and conclusions

Insurers and plans should implement best practices that account for the developments discussed in this article. All managed care companies' in-house counsel should familiarize themselves with *D.K.* and consider changes to their appeal process for medical as well as behavioral health claims.

Regarding the growing use of powers of attorney, managed care companies should understand state laws governing powers of attorney to evaluate their validity when used in pre-litigation appeals, as well as in litigation, direct discovery at the powers of attorney in litigation to evaluate the propriety of the member's consent, and evaluate whether the case was properly initiated in the member's name.

Managed care companies should develop and adopt protocols to prepare for litigation arising from the use of AI, such as thoroughly documenting how AI-generated information is created and used and what safeguards are in place to ensure its reliability, exercise caution with AI products that touch benefit claims, and review their AI vendor contracts to understand their indemnification rights and their ability to explain the AI's decision-making to a court or regulator.

For more information on this article, please contact Tom Hardy and Jordan Fontenot

Verification-of-benefits phone calls and building a record for summary judgment

Takeaways

- CSRs should be trained to avoid implying that a given reimbursement amount is "reasonable," or that they have contracting authority, in initial phone conversations.
- Retain audio recordings of VOB phone calls for at least five years.
- Consider stipulating in written policies and job descriptions that CSRs lack contracting authority. Consider automatic prompts during calls disclaiming authority to modify plan benefits.

Out-of-network providers seeking additional reimbursements beyond those required by members' benefit plans may claim that pre-service verification-of-benefits (VOB) calls form the basis of implied or express contracts for billed charges or "reasonable value." While case law has developed regarding the pleading standards for oral or implied contracts in this context, recent cases illustrate that VOB calls can also play a central role at summary judgment. *See*, *e.g.*, *Aton Center, Inc. v. United Healthcare*, 311 Cal. Rptr. 3d 564, 572 (Ct. App. 2023) . With these new developments in mind, this article explores key considerations for insurers preparing for summary judgment on oral or implied contract claims – among other related claims – based on VOB calls.

Common fact pattern

Out-of-network health care providers place pre-service VOB calls to insurers to confirm out-of-network benefits. During these calls, providers typically seek to confirm whether payment will be based on the usual, customary and reasonable rate, maximum non-network reimbursement rate, Medicare rate or other allowed amounts. Then, when claims are paid pursuant to applicable plan benefits, a provider may sue, claiming, *inter alia*, a breach of oral and implied contract based on the VOB calls.

Preparing for summary judgment

With VOB calls playing an increasing role at summary judgment, insurers may take certain steps to bolster their chances of winning summary judgment motions. Case law places importance on the use of phrases such as "will pay" or "would pay" during VOB calls as indicating an offer See, *e.g.*, *Bristol SL Holdings, Inc. v. Cigna Health Life Ins. Co.*, No. SACV 19-00709 AG (ADSx). To guard against creating implied promises to pay, Customer service representatives (CSRs) should confirm benefits coverage but avoid advising that claims will pay at any specific rate or pursuant to any methodology; instead, they should emphasize that any information provided is for informational purposes only and that actual reimbursement is subject to plan benefits and limitations determined after claim submission.

To increase the chances of success, insurers should also underscore that CSRs lack contracting authority during VOB calls. This can be supported with written policies, job aids/descriptions and guidance demonstrating that CSRs lack contracting authority. Consider also automated disclaimers preceding VOB calls explaining that CSRs are not authorized to enter into contracts and train CSRs to obtain confirmation during the call that the provider representative understood the disclaimer.

Assuming CSRs avoid language denoting a promise to pay, recording VOB calls and maintaining the recordings for at least five years can serve as powerful evidence against a meeting of the minds necessary for oral or implied contract formation. Such recordings will likely carry more weight than a provider representative's affidavit or even the representative's contemporaneous notes and documentation. Further, such recordings may be used in pre-litigation discussions or in early litigation strategies (*e.g.*, exchanging with a provider's counsel early to request dismissal or, where possible, attaching recording transcripts as part of early pleading challenges to educate the court).

Conclusion

Insurers can develop a comprehensive strategy to defend against allegations of an implied contract arising during VOB calls. As VOB calls are central to summary judgment in these cases, insurers should take stock of the importance of clear communication and documentation supporting a lack of intent to enter into any binding agreement. By continued training of CSRs, adhering to best practices, and understanding and communicating the limitations of VOB calls to providers, insurers can navigate these complex disputes more effectively and build a strong record to defend against these claims.



For more information on this article, please contact Amir Shlesinger, Michelle Cheng and Zachary Kizitaff

Litigation and trends

Back to contents.

Back to contents.

Mental health parity – Get in compliance now for the likely 2025 rules

Takeaways

- Upcoming MHPAEA rules will define provider networks as non-quantitative treatment limits
- Plans' pay rates, in-network capacity, out-of-network usage, CMS and state time/distance standards, etc., will be scrutinized
- Plans must use data and research to defend themselves, and they should consider improving member access to in-network mental health providers

The Mental Health Parity and Addiction Equity Act (MHPAEA) poses a challenging compliance headache that isn't getting easier for payors any time soon.

To ensure you are best positioned for important federal rules due to appear in 2025, 2024 should be a year of data preparation.

Health plans face the challenge of having to prepare for major changes in the form of proposed rules, which will be published in 2024; we expect them to be finalized and take effect in 2025.

The proposed rules, which would codify the Consolidated Appropriations Act of 2021's requirement to perform and document comparative analyses for all non-quantitative treatment limitations (NQTLs) imposed on mental health/substance use disorder (SUD) benefits, are likely to impose a mathematical test on NQTLs, like the one currently imposed on quantitative treatment limitations and would impose the use of outcomes data to ensure parity in practice.

The comment period for the proposed rules is over, and we expect to see more guidance on how the proposed rules will be implemented starting early in 2024. It is clear now, however, that the new rules will treat network composition as its own NQTL and will require health plans to analyze in-network and out-of-network utilization rates, network adequacy metrics (time and distance data, number of providers accepting new patients, etc.), and provider reimbursement rates. Any disparity would require "reasonable actions" to approve any differences, although the new rules may provide safe harbor protections attributable to provider shortages or other conditions outside of the health plan's control.

Because all aspects of the inevitable new rules will be data driven, payors should spend 2024 developing valid data sources and analytic tools for using that data. Health plans should focus on the following data:

- Out-of-network utilization
- Percentage of in-network providers actively submitting claims
- Time and distance standards issued by CMS and states
- Number of network providers accepting new patients
- The proportion of providers in urban and rural areas who participate in the plan's network
- In-network and out-of-network utilization (total dollar value and number of claims)
- Reimbursement rates

Further, you should consider engaging in the following efforts to shore up any potential network inadequacies or material differences in access to in-network providers:

- Provide greater reimbursement or other inducements to mental health/SUD providers.
- Expand telehealth offerings.
- Expand efforts to help members find in-network providers, including clear and prominent language on websites and in brochures and benefit booklets.
- Conduct outreach to encourage mental health/SUD providers to join the network, including any time a member seeks preauthorization for a service from an out-of-network provider.
- Track exceptions where you provide an in-network level of benefits for out-of-network services.
- Conduct member surveys related to out-of-network requests that would help confirm that members use out-of-network providers for reasons other than inadequate networks.
- Conduct surveys asking members how often they forego treatment or pay out of pocket due to a lack of available in-network providers.
- Ensure that network directories are accurate and reliable.

Engaging in these efforts now will put you in the best position for 2025 and can only help strengthen your current mental health parity compliance efforts. Stay tuned for more details on the proposed new rules in the new year!

For more information on this article, please contact Rebecca Hanson and Kevin Tessier

Back to contents.

The next waves of Medicare Advantage litigation: 340B and the two-midnight rule

Takeaways

- MAOs face demands for make-up payments for 340B drugs and arguments over hospital admissions.
- Some hospitals are issuing demands in both areas; plans need to develop an enterprise-wide approach to responding.

In 2023, the Centers for Medicare & Medicaid Services (CMS) issued two final rules that create a significant risk of litigation for Medicare Advantage organizations (MAOs), with hundreds of millions, and potentially billions, of dollars at stake. Indeed, the storm has already begun. This article examines the two rules and provides insights into best practices for responding.

340B remedy payments

Historically, under the 340B program for Medicare hospital outpatient drugs, Medicare set payments at 106% of the average sales price (ASP). However, CMS revised the payments to ASP **less** 22.5% starting in 2018 in order to more accurately reflect the actual costs incurred by participating hospitals. At the same time, because CMS is required to make outpatient payments on a budget neutral basis, it increased payments for all other outpatient services to all hospitals.

The American Hospital Association challenged the rate cuts as inconsistent with the Medicare statute. In 2022, the Supreme Court found the ASP **less** 22.5% payment methodology to be contrary to law because CMS had failed to conduct a survey of hospitals' acquisition costs for outpatient drugs before reducing the reimbursement rate as required by the statute. The Court did not, however, vacate the prior rules and remanded the case to the district court for the determination of a proper remedy. On remand, the district court vacated the payment rules prospectively from September 28, 2022 and required CMS to start paying hospitals under the original methodology as of that date. At the same time, the district court did not vacate the regulations establishing the payment reductions for the period prior to September 28, 2022, and instead remanded the matter to CMS to determine the appropriate remedy.

In July 2023, CMS issued a final rule to address the remedy payments. Under the final rule, CMS will make lump sum payments to hospitals to remedy CMS's legal error and restore the hospitals to as close to the position they would have been in without this change to the reimbursement rate from 2018 through September 28, 2022. In addition, because CMS increased all outpatient payments to all hospitals, CMS will be reducing outpatient payments starting in 2026 for approximately 16 years. Importantly, CMS stated that the impact of the final rule on MAOs was outside the scope of rulemaking and CMS simply reminded MAOs that they need to pay non-contracted providers the same amount as original Medicare.

Some hospitals have already started to issue demands to MAOs for similar lump sum payments. Similar to sequestration, contracted plan providers need to analyze their contracts to determine if they have a contractual obligation to make these payments. For non-contracted providers, things get a little trickier, but plans still have arguments, including that their obligations are to make claims payments at Medicare rates and not lump sum payments to remedy a legal error by CMS. Other potential defenses against claims brought by non-contracted providers include exhaustion and preemption.

Finally, MAOs facing litigation need to consider potential counterclaims against hospitals for the increased outpatient payments, which CMS referred to repeatedly as a "windfall" during rulemaking.

Utilization management and the two-midnight rule

In April 2023, CMS issued new regulations regarding utilization management requirements relating to MAOs (see 88 Fed. Reg. 22120). Among other things, these regulations require MAOs to make medical necessity determinations based on coverage and payment criteria identified in original Medicare laws, including payment criteria for inpatient admissions, skilled nursing facilities, home health care and inpatient rehabilitation facilities. If coverage criteria are not fully established, MAOs may use their own internal criteria. Importantly, CMS emphasized during rulemaking that, specific to inpatient admission decisions, the two-midnight benchmark is applicable to MAOs – meaning that an inpatient admission is generally covered if the admitting physician expects the patient to require medically necessary care that crosses two midnights.

This rule not only creates operational challenges for MAOs, it also sets up the potential for litigation from hospitals. Indeed, hospitals have already started to ask that MAOs confirm they will be paying all claims as inpatient when the admitting physician expects the patient stay to span two nights, although it may not be appropriate to pay hospitals for certain services at an inpatient level. As a result, MAOs can anticipate litigation over inpatient claims, in which hospitals may argue that MAOs cannot "second guess" the admitting physician's determination of whether the admission is expected to exceed two nights. MAOs need to implement the new regulations in a compliant manner while monitoring for proper documentation to support billing as an inpatient stay, including developing oversight of inpatient claims. Of note, CMS has explained that the two-midnight presumption does not apply to plans, which is a presumption used by CMS contractors to not audit inpatient claims that span two nights, meaning that plans can still consider these claims in their audit programs.

Conclusion

Both areas present significant potential litigation risk with hundreds of millions of dollars at stake. MAOs need to consider their pre-litigation and litigation strategies proactively and put their helmets on for years of disputes over MAOs' compliance with existing Medicare rules.

For more information on this article, please contact Steven Hamilton and Kevin Tessier

No Surprises Act litigation and enforcement in 2024

Takeaways

- We predict providers will file more lawsuits challenging late payor payments following IDR awards.
- Increasing provider demands for QPA disclosures may lead to litigation.
- Payors have opportunities to pursue litigation regarding misbehavior in IDR and challenging provider-friendly aspects of the law.
- Regulatory enforcement should remain low while QPA regulations are in flux.

While provider litigation regarding the No Surprises Act (NSA) could increase in 2024, payors may also pursue litigation, and regulatory enforcement of the NSA should remain low.

The NSA, which among other things, prohibits out-of-network providers from sending surprise medical bills to patients, has been the subject of frequent litigation since its enactment in December 2020. Providers have initiated several lawsuits against the federal government challenging NSA regulations. Most notably, the *Texas Medical Association (TMA)* lawsuits in the Eastern District of Texas vacated many aspects of the rules, resulting in a more favorable landscape for providers in the independent dispute resolution (IDR) process for resolving out-of-network billing disputes with payors. The August 24, 2023 *TMA III* decision upended the complex methodology for payors' calculation of the qualifying payment amount (QPA), which determines patients' financial responsibility and is a key factor in IDR. Providers have also pursued litigation against payors alleging violations of the law with respect to IDR awards and QPA calculations.

While providers' regulatory challenges may wind down in 2024, litigation against payors is likely to increase. Recent IDR activity indicates some providers are positioning themselves for litigation – for instance, by routinely seeking detailed disclosures regarding QPA calculations during the pre-IDR open negotiation process, and by challenging when payors allegedly do not pay IDR awards within the requisite 30-day period.

Payors have not pursued affirmative NSA litigation, but that may change. Providers' (and, in some cases, IDR arbitrators') conduct in IDR could provide grounds for payor lawsuits. For example, some providers many not comply with NSA requirements in the IDR process, such as by failing to follow the required open negotiation process, pursuing IDR (and obtaining enforceable awards) against incorrect payors, and withholding relevant information about IDR decision factors from payors while providing it to IDR arbitrators in confidential briefing. Payors have also experienced negligent decision-making by IDR arbitrators, who are overwhelmed by the unanticipated volume of IDR disputes and leave payors little recourse when they issue incorrect payment decisions (for example, when the services are clearly not eligible for the IDR process). Further, as a counterpoint to the *TMA* decisions, payors could assert more fundamental challenges to the NSA framework on a statutory or regulatory level. In particular, the structure and administration of the IDR process have arguably deprived payors of due process rights, and providers' overwhelming win rate (over 70% at last reporting) creates downstream economic burdens for the same patients the NSA intended to protect. Recently proposed revisions to the IDR rules may also be subject to constitutional challenges, though regulatory delays make the effective date of any revisions uncertain.

Regulatory enforcement risk should remain low in 2024. Regulators have already initiated the first round of NSA-required audits of payors' QPA calculation, but continued QPA enforcement is paused until at least May 1, 2024, while the agencies appeal the *TMA III* decision and wrestle with rewriting QPA rules in light of the decision. Regulators may also take a light touch in enforcing IDR compliance given the pending revised rules. Still, payors should continue to consider regulatory enforcement as an additional risk, and aim for NSA compliance to reduce their exposure to both.

For more information on this article, please contact Alex Lucas

Back to contents.

Coverage for cannabis? Expected change in federal drug laws brings new risks to MCOs

Takeaways

- While cannabis is currently illegal under federal law, the government signaled that cannabis may be reclassified as a drug with accepted medical use in treatment in the U.S. as soon as 2024.
- Multiple state courts have ordered worker's compensation insurers to cover the cost of medical cannabis, and consumers are likely to demand coverage under their health plans if the drug is reclassified under federal law as expected.
- Health plans should begin thinking about their approach to covering (or not covering) cannabis, including by reviewing plan designs and considering contracting and reimbursement issues.

There is quiet but strong momentum in Washington to reclassify medical cannabis under the Controlled Substance Act (CSA) from a Schedule I drug to a Schedule III drug in 2024. Reclassification would represent a monumental shift in federal cannabis policy and an express acknowledgement that there are accepted medical uses for the drug. Consumers are already seeking insurance coverage for medical cannabis, and the drug's expected reclassification may cause an explosion of coverage demands. Health plans should consider their policy toward cannabis now and prepare for the fallout.

Here, we provide background on the expected reclassification of cannabis as a Schedule III drug, an overview of existing litigation over cannabis coverage, and considerations for health plans as they navigate the expected change in federal policy toward cannabis.

Cannabis expected to be reclassified as a Schedule III drug

On October 6, 2022, President Biden directed the Secretary of Health and Human Services (HHS) "to review expeditiously" how cannabis is scheduled under federal law. Currently, cannabis is classified as a Schedule I drug under the CSA, meaning that the drug has "a high potential for abuse" with "no currently accepted medical use in treatment in the United States" and cannot safely be dispensed under a prescription. Heroin, LSD and peyote are examples of other Schedule I drugs.

American consumers are expected to spend more than

$33 billion

on cannabis in 2023.

Key statistics

Following President Biden's direction, on August 29, 2023, HHS recommended that the Drug Enforcement Agency (DEA) – which has the final authority to reschedule a drug – reschedule cannabis from a Schedule I to a Schedule III drug. A Schedule III drug has a lower potential for abuse than Schedule I or Schedule II drugs and "a currently accepted medical use in treatment in the United States." HHS based its recommendation on an extensive Food and Drug Administration (FDA) review of cannabis and related findings, although those findings have not been released to the public. Previously, DEA has testified during a congressional hearing that it is bound by FDA's recommendations on scientific and medical matters.

The upshot is that DEA is likely to reschedule cannabis to a Schedule III drug as soon as 2024, possibly before the upcoming presidential election.

Cannabis coverage litigation

Consumers and other cannabis industry participants have already successfully sued for insurance coverage for medical cannabis, despite its current prohibition under federal law. For example, the state Supreme Courts of New Hampshire and New Jersey and appellate courts in New Mexico have ordered state workers' compensation insurers to reimburse the cost of medical cannabis for injured workers. By contrast, the state Supreme Courts in Maine and Minnesota have held that the CSA preempts reimbursement for medical cannabis under their respective workers' compensation laws, relying on the drug's classification as a Schedule I drug under the CSA and principles of federal preemption. The latter cases may be decided differently if cannabis is rescheduled as a Schedule III drug.

In addition, there is at least one pending case filed by a putative class in New Mexico seeking coverage for medical cannabis from commercial and Medicaid health plans under state law. Cannabis reclassification under federal law could dramatically impact the health plans' arguments and defenses in such cases and lead to more coverage lawsuits against health plans throughout the country.

tThere are several steps that health plans can take to prepare for the likely reclassification of cannabis as a Schedule III drug. First, health plans should decide as a matter of policy whether to offer coverage for medical cannabis. Clients, consumers, and other stakeholders will have opinions regarding whether the plan should cover cannabis for medical purposes. Understanding these opinions and formulating coverage policies will help plans prepare for the drug's expected reclassification.

Second, health plans should review and conform existing health plan designs to their intended coverage policies. For example, many health plans currently rely on the lack of FDA approval to exclude cannabis from coverage. However, HHS relied on an extensive FDA review of the drug when recommending that DEA reclassify it, suggesting that FDA (and DEA) may approve of the drug for certain medical purposes if it is reclassified. Health plans that do not want to cover the drug should incorporate an express coverage exclusion for cannabis and related substances.

Third, health plans wishing to cover medical cannabis should consider contracting and reimbursement issues. The simplest method for coverage will involve reimbursement to members for medically necessary cannabis purchases, but plans that aspire to offer cost-efficient coverage could consider contracting with retailers or distributors at discounted rates.

The federal government's expected shift from an 85-year-old policy of cannabis prohibition brings many unknowns, but health plans that consider their approach to the drug now will be best suited to capitalize on its potential benefits and mitigate risk from lawsuits and coverage demands.

For more information on this article, please contact Jason Mayer

Trends in bad faith litigation: What to expect in 2024

Takeaways

- Health insurers can expect heightened court scrutiny of their handling of claims and member data.
- Increased reliance on technology to manage health care data and claims can create a minefield for health insurers and increase the risk of bad faith exposure.
- Data breaches are an ongoing concern and can trigger member lawsuits. Establishing safeguards for members' data can minimize the risk of costly litigation.

Bad faith litigation in 2022 and 2023 has brought heightened scrutiny of insurers' handling of claims and member data that can be expected to carry over into 2024. Key issues such as experimental or investigational treatment denials, the use of technology and data privacy have been significant topics in bad faith and other tort litigation in recent years and should be considered as part of health insurers' overall risk assessment strategies in 2024 and beyond.

Increased scrutiny on investigational/experimental claim denials

Investigational and experimental denials have come under particular scrutiny over the past few years. Last year, a Nevada jury rendered a large verdict in a bad faith case involving the denial of proton beam therapy to treat lung cancer on investigational and experimental grounds. Earlier this year, a putative class action involving the denial of proton beam therapy on investigational and experimental grounds was settled for up to $3.4 million. And in 2022, plaintiffs in two other proton beam therapy cases succeeded in reversing their claims denials, showing that courts will scrutinize and overturn experimental and investigational denials when clinical guidelines conflict with plan terms. Although in those two cases, the plaintiffs' claims were brought under ERISA,

the reasoning in both cases can apply with equal force in bad faith litigation that carries a risk of punitive damages. Given the potential for significant payouts to plaintiffs, insurers can expect to see new lawsuits alleging these issues in the coming year, and they should consider taking a closer look at their internal coverage guidelines and medical policies regarding investigational or experimental treatments.

Technology and data privacy concerns

Health insurers are increasingly relying on technology to manage health care data and claims, but with that reliance comes an increased risk of bad faith exposure. In late 2023, two bad faith class action complaints were filed challenging the use of an artificial intelligence (AI) algorithm to adjudicate claims for rehabilitative care to Medicare Advantage members. One such class action was filed in November 2023, in which members challenged the administration of extended care claims by using an artificial intelligence (AI) algorithm called nH Predict. A nearly identical class action lawsuit was filed in Kentucky on December 12, 2023. These two cases come on the heels of a similar bad faith class action complaint filed in California in July 2023 challenging the alleged use of an algorithm to administer benefit claims. With the increased use of these technologies in the health insurance industry, similar lawsuits are likely on the horizon.

Lawsuits over data privacy is another area of concern for the health insurance industry for the coming year. In the past few years, data breaches and the disclosure of members' protected health information have led to a number of lawsuits alleging bad faith and violations of state consumer protection laws. Most recently, a district court in the District of Columbia allowed certain claims to proceed against an insurer in a case that had initially been brought in 2015 as a putative class action stemming from a cyberattack and data breach in 2014. While the insurer managed to gut most of the case against it, it took eight years of protracted litigation to get to that point. *See Attias v. CareFirst, Inc*., No. 15-cv-882 (CRC), 2023 U.S. Dist. LEXIS 161800, at *4 (D.D.C. Sep. 13, 2023). Another case to watch is *Skuraskis v. NationsBenefits Holdings, LLC*, No. 23-CV-60830-RAR (S.D.Fl). That class action suit stems from a health care data breach in which information collected by NationsBenefits – a health benefits administration company that partners with managed care organizations to provide supplemental benefits, flex cards and member engagement solutions – was accessed by an unauthorized third party in early 2023, resulting in the disclosure of the personal health information of nearly 3 million people. Currently, the complaint asserts various contract and negligence claims arising from the data breach and is in its early stages of litigation.

For more information on this article, please contact Carol Lewis and Robert Deegan

Back to contents.

Why am I here? Challenging personal jurisdiction in provider pay disputes

Takeaways

- Recent court decisions in provider reimbursement cases give health insurers and TPAs a significant degree of protection when defending out-of-state lawsuits by dissatisfied providers.
- With the right facts, seeking early dismissal of an out-of-state lawsuit on personal jurisdiction grounds may be a valuable tool for reducing defense costs and minimizing the risk of litigating in unfriendly forums.
- As part of their defense strategy, insurers and TPAs should assess their contacts with the forum state and consider challenging personal jurisdiction.

Personal jurisdiction challenges are a useful but sometimes overlooked strategy to secure early dismissals in managed care litigation. Given that health plans typically provide coverage for health services rendered to members in any state, insurers and claim administrators routinely find themselves haled into distant and frequently unfriendly courts by providers seeking to challenge claim and payment decisions. In recent years, many courts have been reluctant to force nonresident insurers and claim administrators to defend payment disputes in the providers' home states, where there is little connection to the forum state beyond the place where the provider rendered the services or where the member resides.

Following the landmark decision by the U.S. Supreme Court in *Daimler AG v. Bauman*, 571 U.S. 117, 139 (2014), it is exceedingly difficult, if not impossible, for providers to establish general or all-purpose jurisdiction over nonresident insurers and claim administrators. Companies are subject to general jurisdiction only where they are "essentially at home in the forum state." As a general matter, for a corporation to be

sufficiently "at home," it must be incorporated in the state or have its "principal place of business" in the state. Thus, unless the company is domiciled in the forum state or has expressly consented to general jurisdiction as a condition of doing business, any jurisdictional challenge will likely turn on specific or limited jurisdiction.

Specific jurisdiction exists when a nonresident defendant (1) purposefully avails itself of the privilege of conducting activities within the forum state and (2) the plaintiff's claims arise out of or relate to the defendant's contacts with the forum.

Purposeful availment

Over the past few years, a good-sized body of case law has emerged rejecting the premise that an out-of-state insurer or claims administrator purposefully avails itself of the privileges of the forum state by preauthorizing, processing or paying claims for health care services rendered in the forum state. *See, e.g.*, *Beverly Hills Reg'l Surgery Ctr., L.P. v. Grp. Hospitalization & Med. Servs.*, *Inc.,* 2022 WL 1909550, at *5 (C.D. Cal. June 3, 2022) (a nonresident defendant's role in administering claims for a self-funded health plan with California-based members and phone calls with a California provider were not sufficient evidence of purposeful availment); *Physicians' Med. Ctr. v. Caresource*, 2020 U.S. Dist. LEXIS 39737, at *13 n. 7 (S.D. Ind. Mar. 6, 2020) (an insurer or third-party administrators (TPA) does not avail itself of the privilege of doing business in a particular state simply because the insured chose a provider in that particular forum and the insurer or TPA preauthorized treatment and paid claims); and *Matthews v. United Healthcare Servs.*, 2020 U.S. Dist. LEXIS 164082, at *13 (N.D. Tex. Sep. 9, 2020) (a nonresident insurer's processing of a patient's claims for treatment by Texas providers and communications with a Texas hospital that arose from the member's unilateral decision to seek medical treatment in Texas was not sufficient to show that the insurer purposefully directed its activities toward Texas).

'Arising out of' and 'relating to'

Previously, a strict causal relationship between the defendant's in-state activities and the litigation was required to satisfy this second prong. In 2021, the U.S. Supreme Court in *Ford Motor Co. v. Montana Eighth Jud. Dist. Ct*., 141 S. Ct. 1017 (2021), held in a products liability case that a strict causal connection was not required, so long as the defendant's activities in the forum relates to the plaintiff's claim. In *Ford,* the deciding factor for the Court was the extensive level of the defendant's marketing, sales and advertising in the forum state that led it to conclude that its forum-related activities were sufficiently "related to" the plaintiffs' claims. Although *Ford's* reach outside of products liability context is open to debate, its focus on an out-of-state company's ongoing activities within the forum state reinforces the broader point that a company's overall activities within the forum state is critical to the jurisdictional analysis and will be scrutinized on a case-by-case basis.

So, when should an insurer or claim administrator consider challenging personal jurisdiction? That depends on the facts and the nature of the claims in the complaint.

To start, if a provider pursues an ERISA claim under an assignment of the member's benefits, personal jurisdiction challenges are not a good option because ERISA provides for nationwide service of process and personal jurisdiction exists so long as the insurer or plan has sufficient minimum contacts with the United States.

For cases not brought under ERISA, however, challenges based on personal jurisdiction should be considered as part of the initial defense strategy, as such challenges are waived if not raised before the responsive pleading is filed. Fed. R. Civ. P. 12(b).

Among the factors that should be evaluated are the residence of the member to whom the disputed services were rendered and the type of plan in which the member is enrolled. For self-funded plans, a member's residence in the forum state is less likely to trigger specific jurisdiction because the relationship between the claims administrator and member is fairly attenuated. *Healthcare Ally Mgmt. of California, LLC v. Blue Cross Blue Shield of Minnesota*, 787 F. App'x. 417, 418 (9th Cir. 2019)(specific jurisdiction was not found where the California-based members' plans were self-funded, and the out-of-state health plan administered, but did not insure plan benefits). The same, however, cannot be said where a forum-based member is enrolled in a fully insured plan. *See ABC Servs. Grp. v. Health Net of Cal., Inc.,* 2020 U.S. Dist. LEXIS 78397, at *30 (C.D. Cal. May 4, 2020) (purposeful availment was found where the defendants "contracted to sell" insurance policies to California residents who then obtained treatment at a California facility).

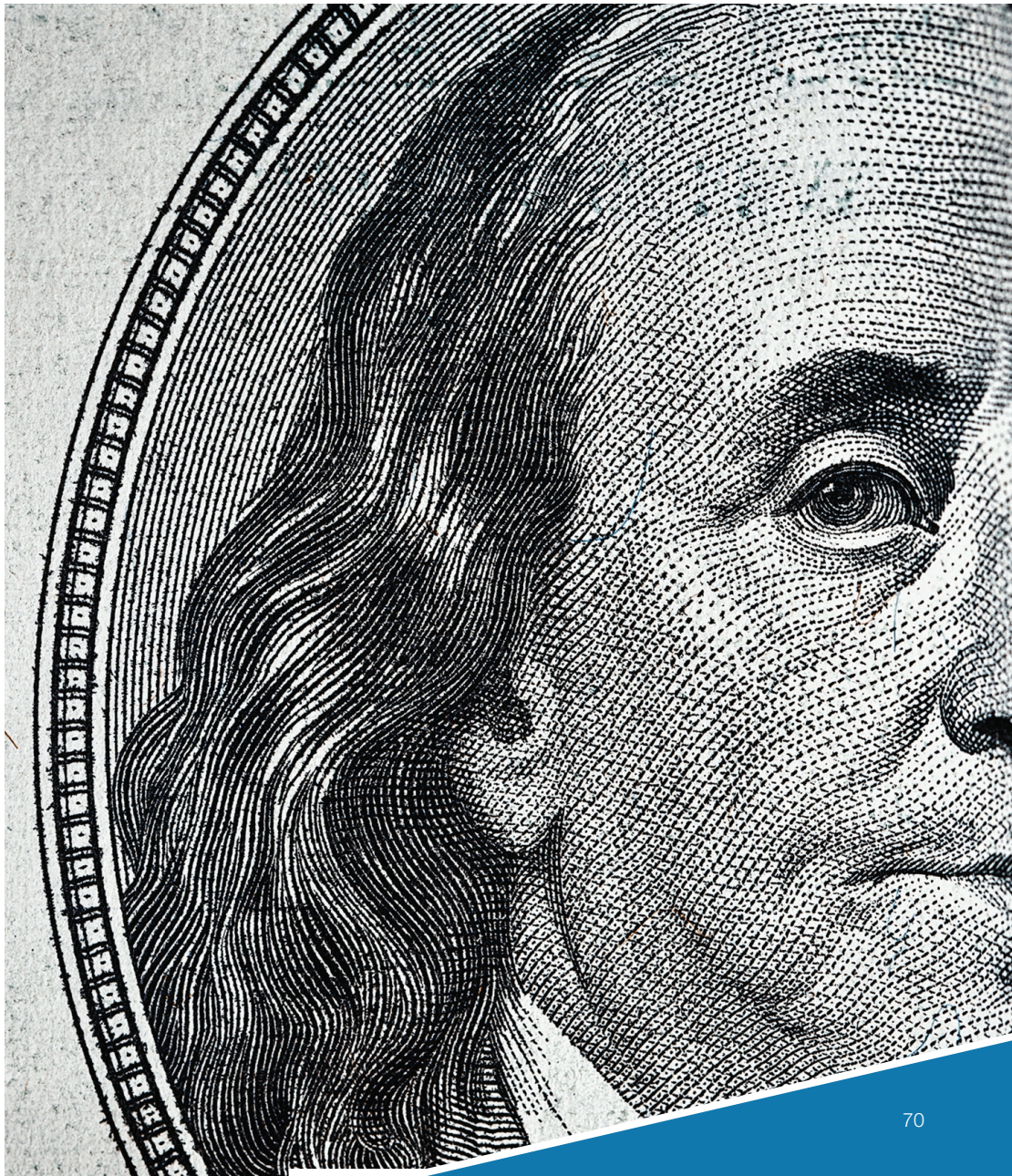
Another factor to consider is where the disputed claim was administered. Were there forum-based employees who performed utilization review or some other administrative function with respect to the claim? Were members directed or encouraged to seek treatment in the forum state? Has the insurer reached out to the forum state through marketing or advertising?

Another factor to weigh when considering a personal jurisdiction challenge is the likelihood that a court will permit the plaintiff to conduct jurisdictional discovery, which can be expensive and intrusive.

Conclusion

If the past few years are any indication of what's to come, insurers and TPAs can expect that in 2024 providers will continue their efforts to force them to defend themselves on the providers' home turf. Challenging personal jurisdiction is not a "get out of jail free" card. If successful, the provider can still refile its case in the insurer's or claim administrator's home state. But if there is an opportunity to avoid litigating in a jurisdiction where judges, jurors and/or procedures are less favorable to the defense, personal jurisdiction challenges should be evaluated as part of the initial strategy.

For more information on this article, please contact Carol Lewis and Lavinia Osilesi



Phone: +44 (0)20 3116 3000
Fax: +44 (0)20 3116 3999
DX 1066 City/DX18 London

ABU DHABI
ASTANA
ATHENS
AUSTIN
BEIJING
BRUSSELS
CENTURY CITY
CHICAGO
DALLAS
DUBAI
FRANKFURT
HONG KONG
HOUSTON
LONDON
LOS ANGELES
MIAMI
MUNICH
NEW YORK
ORANGE COUNTY
PARIS
PHILADELPHIA
PITTSBURGH
PRINCETON
RICHMOND
SAN FRANCISCO
SHANGHAI
SILICON VALLEY
SINGAPORE
TYSONS
WASHINGTON, D.C.
WILMINGTON

reedsmith.com