Managed Care Outlook

2025

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Future focus: Insights for managed care in 2025

As we step into 2025, managed care organizations (MCOs) face a dynamic and multifaceted landscape that demands strategic foresight and adaptability. The evolving regulatory environment, technological advancements, and shifting societal expectations are reshaping the managed care sector. This year's *Managed Care Outlook* delves into the critical issues and emerging trends that MCOs must navigate to thrive in this complex ecosystem. From regulatory compliance and litigation trends to innovations in care delivery and fraud prevention, this report provides a comprehensive overview of what lies ahead.

Regulatory and legal challenges

The regulatory landscape for MCOs continues to evolve, with significant implications for compliance and operational strategies. The U.S. Supreme Court's 2023 decision in *Students for Fair Admissions v. Harvard* has prompted organizations to reassess their diversity, equity, and inclusion strategies. MCOs must balance legal compliance with the imperative to foster inclusive environments that improve health outcomes and innovation.

Moreover, the implementation of the No Surprises Act and its independent dispute resolution process has led to a surge in litigation as providers seek to enforce independent dispute resolution awards. MCOs must enhance their payment processes and ensure timely compliance to mitigate legal risks. Additionally, the Mental Health Parity and Addiction Equity Act (MHPAEA) final rule introduces new requirements for 2025 and 2026, necessitating thorough preparation and data-driven approaches to ensure compliance and equitable access to mental health services.

With the recent change in administration, there is an anticipated shift in regulatory priorities and enforcement strategies. This transition is expected to bring about new regulatory frameworks and policies that MCOs will need to navigate carefully to maintain compliance and operational efficiency.

Litigation trends

Litigation remains a significant concern for MCOs, with several key trends emerging. The rise in class actions alleging disability discrimination because of the exclusion of weight loss medications highlights the need for careful consideration of coverage policies. Behavioral health litigation under ERISA and MHPAEA is also on the rise, with courts increasingly scrutinizing the adequacy of denial letters and requiring detailed explanations and references to medical records.

The Ninth Circuit's decision in *Bristol SL Holdings, Inc. v. Cigna Health & Life Insurance Co.* underscores the importance of ERISA preemption in protecting MCOs from state-law claims by out-of-network providers seeking additional reimbursement. MCOs must stay vigilant and proactive in addressing these and other litigation trends to minimize legal exposure and ensure compliance with evolving standards.

Technological advancements and AI governance

The deployment and use of artificial intelligence in managed care present both opportunities and challenges. The National Association of Insurance Commissioners' AI Model Bulletin provides a framework for AI governance, emphasizing the need for transparency, fairness, and accountability. MCOs must develop robust AI governance programs that include risk management controls, internal audits, and clear roles and responsibilities to mitigate regulatory and business risks.

Additionally, the use of third-party tracking technology for data-driven marketing continues to pose privacy risks. MCOs must align their use of this technology with public statements and privacy notices to avoid regulatory scrutiny and class action litigation.

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Fraud, waste, and abuse prevention

Fraud, waste, and abuse (FWA) remain critical issues for MCOs, with emergency department service disputes, molecular panels, and remote neuromonitoring identified as key areas of concern. Upcoding of evaluation and management codes in emergency services, inappropriate billing of molecular panels, and excessive use of remote neuromonitoring require vigilant oversight and robust policies to prevent abusive practices.

Among other things, MCOs should look to ensure proper supervision and documentation of services to mitigate FWA risks. Aligning vendor incentives with accurate billing and quality care is also essential to reduce the risk of improper denials and legal challenges.

Strategic considerations for 2025

2025 presents both challenges and opportunities for managed care organizations. By staying informed and proactive, MCOs can effectively manage risks, improve operational efficiencies, and deliver high-quality care to their members. The insights provided in this year's *Managed Care Outlook* will equip MCOs with the knowledge and strategies needed to thrive in an ever-changing landscape.

Our managed care practice is designed specifically for lawyers and business leaders seeking strategic legal partners who possess a deep understanding of both local nuances and the broader national landscape of our specialized industry. True to our Practice's tradition, I encourage you to connect with me or any of our more than 60 dedicated attorneys to discuss the matters we handle and their implications for your organization.

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Business and management

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Continuing positive impacts of DEI commitments on MCOs post-*SFFA v. Harvard*

Takeaways

- The Supreme Court's *Harvard* decision has led organizations to reassess and cautiously approach their DEI strategies
- MCOs benefit from DEI through better representation, understanding social determinants of health, and fostering innovation
- Strategies for MCOs to strengthen DEI include inclusive recruitment, continuous education, community engagement, and data-driven approaches

Introduction

In June 2023, the U.S. Supreme Court issued a landmark decision in the case of Students for *Fair Admissions v. Harvard*, which has had significant implications for diversity, equity and inclusion (DEI) initiatives across various sectors. More than a year later, companies, particularly managed care organizations (MCOs), continue to navigate the evolving landscape of DEI with renewed vigor and strategic focus. This article explores how MCOs can respond to DEI challenges post-*Harvard* and underscores the critical importance of maintaining an unwavering commitment to DEI. By embracing the business imperative of a diverse workplace, MCOs can better include diverse voices, understand social determinants of health and, ultimately, improve health care outcomes.

Impact of *Harvard* decision on DEI initiatives

The Supreme Court's *Harvard* decision has prompted organizations to reassess their DEI strategies. While the ruling primarily addressed admissions policies in higher education, its ripple effect has extended to corporate DEI programs. Companies are now more cautious in their approach to diversity initiatives, ensuring compliance with legal standards while striving to maintain inclusive environments.

MCOs and the business imperative of DEI

MCOs have a unique responsibility to foster DEI because of the pivotal role they play in health care. The business case for DEI in MCOs is compelling:

- **Representation of diverse communities**: MCOs serve diverse populations with varying health care needs. A diverse workforce ensures that the voices and perspectives of these communities are represented, leading to more culturally competent care.
- **Understanding social determinants of health**: Social determinants of health, such as socioeconomic status, education, and environment, significantly impact health outcomes. A diverse team is better equipped to understand and address these factors, leading to more effective and equitable health care solutions.
- **Innovation and problem-solving**: Diverse teams bring a variety of perspectives and experiences, fostering innovation and creative problem-solving. This is particularly important in health care, where novel approaches can lead to improved patient care and operational efficiencies.

Strategies for strengthening DEI in MCOs

In the wake of the *Harvard* decision, MCOs should consider adopting several strategies to reinforce their commitment to DEI:

- **Inclusive recruitment and retention**: MCOs should enhance their recruitment processes to attract diverse talent. This includes partnerships with minority-serving institutions, targeted outreach and inclusive hiring practices. Additionally, retention efforts should focus on creating supportive environments where all employees feel valued and have opportunities for growth.
- **Training and education**: Continuous education on DEI topics is essential. MCOs should invest in training programs that address unconscious bias, cultural competence and inclusive leadership. These programs help build a more inclusive workplace culture.
- **Community engagement**: Engaging with the communities they serve is crucial for MCOs. This includes collaborating with community organizations, participating in local events and seeking input from community members to better understand their needs and preferences.
- **Data-driven approaches**: Leveraging data to track DEI progress is vital. MCOs should use metrics to assess diversity within their workforce, patient populations, and outcomes. This data-driven approach helps identify gaps and areas for improvement.

The resilience of DEI in MCOs

Despite the challenges posed by the *Harvard* decision, a continued commitment to DEI initiatives in MCOs is vital. MCOs should maintain and strengthen their commitment to DEI not only as a moral imperative but also as a business necessity.

Conclusion

The continuing importance of DEI post-*Harvard* cannot be overstated, especially for MCOs. By leaning into the business imperative of ensuring a diverse workplace, MCOs can include diverse voices, better understand social determinants of health, and drive positive health care outcomes. As MCOs navigate the evolving DEI landscape, their commitment to DEI will be crucial in shaping a more equitable and effective health care system.

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Helping MCOs navigate compliance with pay transparency laws and salary history bans

Takeaways

- Statewide pay transparency statutes are spreading, with several effective in 2025, often paired with salary history bans to promote pay equity
- Compliance complexities increase for multistate employers due to varying state and local pay transparency laws and salary history bans
- Employers may benefit from compliance by improving perception, attracting diverse candidates, satisfying ESG investors, and reducing class action lawsuit risks

As of 2023, women who worked in full-time, year-round positions earned 84 cents to the dollar when compared to their male counterparts; for racial minorities, the discrepancies were even more stark, with Hispanic and Black women taking home roughly 59% and 66%, respectively, of the weekly earnings of White men. More recently, the movement to rectify historical gender- and race-based pay gaps has devolved to the states and local municipalities which complicates hiring practices for managed care organizations with operations in multiple locations.

Following a wave of salary history bans that went into effect in the years preceding the Covid-19 pandemic – almost two-thirds of states now prohibit private employers like managed care organizations and their subsidiaries from asking applicants about their salary history. Similar bans have proliferated at the local level, with advocates of pay equity now pushing for laws that require employers to disclose salary ranges and other compensation and benefits information in job postings.

While significant progress has been made to reduce characteristic-based salary differences, pay transparency laws are the latest resource for prospective employees to level the playing field. Although only a handful of states and local municipalities currently require such disclosures, at least four statewide laws in Illinois, Massachusetts, Minnesota and Vermont will come online in 2025. Whereas some states, such as Connecticut, require only that an employer disclose the position's salary range upon an applicant's request or before or at the time of an offer, other states, including California and New York, require employers to list this information on job postings, even when hiring is outsourced to third-party employment agencies. Payors that operate within these states should review hiring practices and educate their recruiting teams to ensure that they are within compliance.

While a nationwide pay disclosure mandate or salary history ban does not currently exist, the winds of change may be coming, as multiple bills have been put forward and rules proposed over the last two years. For instance, the federal Department of Labor's Office of Federal Contract Compliance Programs issued guidance in 2024 underscoring the agency's position that wage history is not a legitimate, job-related factor that could justify race- or gender-based salary differences. Perhaps most notably, a bill was introduced in the 118th Congress that would amend the Fair Labor Standards Act to require employers to provide salary ranges to job applicants and divulge pay scales to current employees for their role. Although the Salary Transparency Act remains in committee, it is representative of a broad shift in policy priorities that may one day culminate in a national standard.

Given this legislative trend is yet in its infancy, managed care organizations should strive to to understand the practical application of pay disclosure requirements and the consequences of non-compliance across jurisdictions. For example, Vera Whole Health, an advanced primary care provider, was recently sued by an applicant in a putative class action for technical violations of Washington's job posting requirements. The unsuccessful applicant – who had not been offered an interview or engaged in salary negotiations – alleged that he "lost valuable time" applying for jobs for which the salary range was not disclosed and was unable to evaluate, negotiate, or compare that pay to similar available positions. The federal court granted Vera Whole Health's motion to dismiss for lack of standing, finding no actual or material risk of harm to "nominal" applicants such as the plaintiff. However, the question of non-compliance remains, as the case was remanded to Washington state court.

Health plans not only face mounting legal obligations at the local, state and possibly federal levels, but also pressure from investor groups who demand corporate action on environmental, social and governance (ESG) objectives. A majority of companies listed in the S&P 500 now include at least one ESG metric in executive compensation incentive plans, While many ESG groups have attempted to force corporations to disclose data on demographic pay gaps through shareholder proposals, some managed care organizations have begun to self-report. These health plans may benefit from improving company perception, attracting more qualified and more diverse talent from an applicant pool progressively focused on social issues and mitigating the risks of litigation.

As the momentum behind pay equity policies continues to gather across the country, payors must pay ever closer attention to how this evolving landscape affects their hiring practices, as noncompliance comes with potentially significant penalties and exposure to litigation. Managed care organizations may also be wise to use this watershed moment to broadly examine how compensation decisions are made and address any existing pay discrepancies within their workforce.



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Current Delaware governance considerations in an acquisitive managed care environment

Takeaways

- Validity of governance arrangements in agreements with stockholders was addressed in updates to the Delaware General Corporation Law this year
- Criticism of the scope of these updates suggests the use of stockholders' agreements to address certain governance rights may be subject to additional judicial challenge
- When negotiating governance rights in stockholders' agreements, minority holders should consider additional protections to ensure they receive their bargained-for rights

Organizations in the managed care industry planning to engage in joint ventures or investment transactions – where parties often negotiate specific stockholder rights – should take into account recent changes to Delaware law when evaluating stockholders' agreements. Delaware has codified the right of a Delaware corporation to enter into contracts with current or prospective stockholders that include broad stockholder protections or approval rights through the adoption of section 122(18) of the Delaware General Corporation Law (DGCL). Many growth stage companies seeking investment money are incorporated in Delaware, and Delaware remains a frequently preferred jurisdiction for corporate formation.

It's crucial for managed care organizations to carefully consider the legal implications of joint ventures and investments, and to ensure that appropriate agreements are in place to protect the rights of all parties involved. This includes understanding the impact of section 122(18) of the DGCL and how it may affect governance rights negotiated with stockholders. Proper legal evaluation and strategic planning are essential to navigate the complexities of these transactions effectively.

Moelis decision and introduction of Senate Bill 313

Company founders and other significant stockholders in the managed care industry have traditionally negotiated governance protections in stockholders' agreements, such as requiring certain approvals before the corporation takes specific actions, for example, entering into a significant transaction or hiring or firing the corporation's CEO. Prior to the Delaware Court of Chancery's decision in *West Palm Beach Firefighters' Pension Fund v. Moelis & Co.*, C.A. No. 2023-0309-JTL (Del. Ch. Feb. 23, 2024), many believed that Delaware corporations were free to enter into contractual governance agreements with their stockholders.

The *Moelis* case challenged the validity of certain provisions in a stockholders' agreement that, among other things, required the prior written consent of the corporation's founder and majority stockholder for the corporation's board of directors to take certain actions. The court determined that certain provisions in the stockholders' agreement violated section 141(a) of the DGCL by delegating to the stockholder certain management rights that are traditionally held by a corporation's board of directors. Section 141(a) of the DGCL provides the fundamental principle of Delaware corporate law that the "business and affairs of every [Delaware] corporation . . . shall be managed by or under the direction of a board of directors, except as may be otherwise provided [in the DGCL] or in the [corporation's] certificate of incorporation."

The *Moelis* court acknowledged that its decision would impact commonly used stockholders' agreements that typically "contain extensive veto rights and other restrictions on corporate action." The court noted that the Delaware General Assembly could enact a provision stating what stockholder agreements are permitted to do. Responding to this suggestion, the General Assembly proposed and passed Senate Bill 313 (S.B. 313) just a few months after the *Moelis* decision. S.B. 313, which added subsection (18) to section 122 of the DGCL, was signed into law on July 17, 2024, and became effective on August 1, 2024.

Opponents of S.B. 313 criticized its broad scope, predicting that it would erode fundamental principles of corporate law and lead to unintended consequences due to its rapid enactment and lack of thorough evaluation. On the other hand, proponents argued that the amendments provide needed flexibility to boards to achieve their goals without limiting directors' fiduciary duties. While the merits or lack thereof of section 122(18) are beyond the scope of this article, the focus here is to evaluate section 122(18) as it exists and raise considerations for parties investing in Delaware corporations.

Key provisions of section 122(18)

Section 122(18) of the DGCL authorizes Delaware corporations to enter into agreements with stockholders even if those agreements may constrain the board's discretion, so long as the agreements do not violate the DGCL or the corporation's charter. These agreements can:

- **Restrict corporate action**: Require specific approvals before the board can proceed with certain actions
- **Mandate actions**: Stipulate that the corporation will take or refrain from taking particular actions
- **Grant governance rights**: Allow corporations to contractually provide governance rights to stockholders traditionally reserved for corporate boards without amending their charter

Importantly, section 122(18) does not eliminate the fiduciary duties of directors, officers or controlling stockholders, leaving open the potential for claims that challenge agreements with stockholders on that basis.

Considerations for stockholders in managed care

Majority stockholders in the managed care industry seeking governance rights under section 122(18) should be vigilant about changes in market practices and the potential for breach of fiduciary duty claims as the broad limits of section 122(18) are tested. To mitigate risks, a majority stockholder may:

- **Proactively place guardrails**: To best position itself to defend challenges, implement measures such as permitting the board to override stockholder protections upon unanimous approval of independent directors
- **Negotiate charter amendments**: Consider negotiating to include governance rights in the corporation's charter rather than seeking contractual rights

Minority stockholders should also consider seeking additional minority protections to ensure that the corporation does not agree to provide existing or future stockholders governance rights without obtaining relevant approvals, such as those required to amend the corporation's charter.

Impact on managed care organizations

In today's environment, the possibility of making smaller investments is particularly appealing to some managed care organizations. These organizations should be familiar with the limits that may circumscribe their ability to negotiate certain governance rights with other investing stockholders. The enactment of section 122(18) of the DGCL has opened the door to further flexibility in structuring such governance rights. However, managed care organizations must be cognizant of potential limits and pitfalls that can arise in connection with investments in Delaware corporations.

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NAIC's AI Model Bulletin: Insights for MCOs

Takeaways

- A formal AI governance program can significantly reduce regulatory and business risks arising from the deployment and use of AI technology by MCOs and their suppliers
- The NAIC's AI Model Bulletin provides a solid foundation for MCOs' AI governance programs (and may be required in some states)
- States that have adopted a version of the AI Model Bulletin have made clear their intent that AI governance includes participation across the organization, including the Board

Managed care organizations (MCOs), like most organizations, are inundated with information about how to deploy and use artificial intelligence (AI) in ways that reduce business and legal risk. Legal risk arises from federal, state and local laws and regulations. Current laws targeting AI are narrowly applicable to only parts of the insurance life cycle, including underwriting and pricing activities and medical necessity determinations in utilization management. Given AI use cases go beyond those limited areas and can impact product development, marketing, sales and distribution, policy servicing, fraud detection and other business operations, many state insurance regulators have adopted a version of the National Association of Insurance Commissioners' (NAIC) "Model Bulletin on the Use of Artificial Intelligence Systems by Insurers" (AI Model Bulletin). Even MCOs that are not licensed in one of the 19 or more states where the insurance regulator has adopted a version of the AI Model Bulletin should consider using the resource as a foundation for their AI governance program.

The AI Model Bulletin sets expectations and guidelines for insurers' deployment and use of "AI Systems," which are defined as "machine-based system[s] that can, for a given set of objectives, generate outputs such as predictions, recommendations, content (such as text, images, videos, or sounds), or other output influencing decisions made in real or virtual environments." This definition is consistent with other government publications related to AI. AI may (but does not need to) involve machine learning, and generative AI is a subset of AI Systems.

The AI Model Bulletin recommends:

Key statistics

At least **19** **states** including Washington, D.C., have adopted the NAIC AI Model Bulletin since its publication in December 2023

- **Adopting a tailored, written program for the responsible use of AI Systems (AIS Program)**. The AIS Program should address: (1) governance; (2) risk management controls; and (3) internal audit functions through the entire insurance life cycle and AI System life cycle. More specifically, the program should address and mitigate risks associated with violations of insurance regulatory standards and laws, such as unfair trade practice laws, that may arise from the MCO's use of AI systems.
- **Implementing a governance framework**. The AIS Program should include a documented framework for the oversight of AI Systems, which prioritizes transparency, fairness, accountability and respect for proprietary rights. Governance also includes involving subject matter experts in decision-making, personnel training, monitoring and auditing the operation and performance of AI systems, and documenting clear roles and responsibilities for those accountable for the AI systems. The AI Model Bulletin also suggests looking at the governance guidance set forth in the AI Risk Management Framework from the Department of Commerce's National Institute of Standards and Technology.
- **Performing risk management**. The AIS Program should include a documented risk assessment and internal controls that mitigate the risks. The risk assessment should cover the processes for evaluating and approving AI Systems; data use, quality, protection and retention practices; and management and oversight of predictive AI (i.e., those that involve "mining of historic data using algorithms and/or machine learning to identify patterns and predict outcomes that can be used to make or support the making of decisions").

- **Consumer transparency.** Insurers should develop processes and procedures to provide notice to impacted consumers that AI Systems are in use and provide access to appropriate levels of information about their use in the insurance life cycle.
- **Managing third-party AI Systems and data**. When using third-party AI Systems or data, an effective AIS Program should incorporate thorough supplier due diligence practices, contract terms with suppliers that require cooperation with audits and regulatory inquiries, and post-deployment audits.
- **Documentation**. In addition to documenting the various elements of the AIS Program, MCOs should consider documenting evidence of compliance with the AIS Program and its AI System oversight activities. For example, documentation should include policies and procedures, results of supplier due diligence and audit activities, and assessments of AI System and data quality and performance.
- **Involving the Board (or Board committee) in the AIS Program**. MCOs should vest the responsibility of the development, implementation, monitoring and oversight of the AIS Program to senior management, who should be accountable to the Board and/or Board committee. This approach promotes top-down accountability.

The regulatory and technical landscape relating to AI is rapidly evolving. MCOs that deploy and use AI technology, or work with subcontractors that do so, can help manage the risks arising from this evolution and comply with applicable laws and regulations by maintaining a flexible and strong AI governance program. The AI Model Bulletin sets forth some foundational elements MCOs can use to strengthen their AI governance programs. MCOs should be prepared to continue to monitor regulatory and technical developments and adjust their AI governance programs accordingly.

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Navigating privacy risks: Third-party trackers still pose challenges to MCOs

Takeaways

- Although a court vacated portions of OCR's guidance on third-party trackers, they remain a focus of regulators and class action plaintiffs
- MCOs should align third-party tracker use with public statements and privacy notices per recent FTC guidance
- Organizations should inventory third-party trackers to identify those with risks outweighing benefits

The use of third-party trackers to power data-driven marketing continues to present regulatory and class action risk for managed care organizations. A primary factor relating to increased risk for MCOs was the bulletin released by the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR), which described potential HIPAA noncompliance arising from the use of third-party trackers. In March 2024, OCR revised the bulletin, and part of it was vacated by a federal district court. But recent guidance from federal regulators indicates that risks remain. In light of this risk, managed care organizations should ensure they evaluate their use of third-party tracking technologies.

Why did OCR revise the bulletin?

The bulletin, originally released in December 2022, explained that impermissible disclosures of protected health information (PHI) can occur through routine tracking tools on websites made available by HIPAA-regulated entities, and that these disclosures could lead to breach-notification obligations under HIPAA. In particular, OCR took the position that PHI exists if a third-party tracker connects (1) an individual's IP address with (2) a visit to a regulated entity's unauthenticated public web page addressing specific health conditions or listing health care providers (the Proscribed Combination).

OCR issued a revised version of the bulletin in March 2024 that sought to clarify regulated entities' obligations with respect to the Proscribed Combination, but the revised bulletin appeared to suggest a standard that would be effectively impossible for companies to meet. Essentially, the revised bulletin suggested that whether the Proscribed Combination constituted PHI depended on the subjective intent of the web page visitor. According to the revised bulletin, if a student were writing a term paper on the changes in the availability of oncology services before and after the COVID-19 public health emergency, the collection and transmission of information showing that the student visited a hospital's web page listing the oncology services provided by the hospital would not constitute a disclosure of PHI, even if the information could be used to identify the student; but if an individual were looking at a hospital's web page listing its oncology services to seek a second opinion on treatment options for their brain tumor, the collection and transmission of the individual's IP address, geographic location, or other identifying information showing their visit to that web page would be a disclosure of PHI to the extent that the information was both identifiable and related to the individual's health or future health care.

In June 2024, the U.S. District Court for the Northern District of Texas vacated the portion of the bulletin related to the Proscribed Combination, finding that the bulletin "improperly create[s] substantive legal obligations for covered entities." HHS initially appealed that decision but then withdrew the appeal on August 29.

What does this mean for managed care organizations using third-party tracking technologies?

Even if the use of tracking technologies to connect an IP address with identifiable information doesn't constitute a HIPAA violation, it may implicate other privacy regulatory frameworks. Recent guidance from the Federal Trade Commission (FTC) explains that the Federal Trade Commission Act (FTC Act) applies to HIPAA-regulated entities. The FTC takes the position that disclosing individuals' health information for advertising purposes without their consent may be an unfair practice. The guidance specifically states that the use of "behind-the-scenes tracking technologies that share consumers' sensitive health data in contradiction of [the organization's] privacy promises" is "a violation of the FTC Act."

The class action bar has also continued to bring a significant number of putative class actions in connection with the use of common tracking technologies, often characterizing the tracking technologies as facilitating "eavesdropping" and "wiretapping" 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 Angie Matney and Rob Newman

Legal and regulatory challenges

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340B update: Inflation Reduction Act's pricing reforms may create pressure on rebate relationships

Takeaways

- Duplicative discounts for 340B drugs are a longstanding concern for manufacturers, but there has been no generally accepted mechanism to identify such claims
- The IRA's drug pricing reforms create new scenarios for duplicative discounts
- Drug makers are devising new ways to identify and dispute drug claims subject to duplicative discounts, in both government and commercial contexts
- MCOs should monitor the regulatory processes associated with the implementation of IRA drug pricing reforms and consider contractual changes to address the evolving industry regulatory landscape

Prescription drug benefit financing relies on manufacturer rebates to reduce plan costs, but that funding source may be under increasing pressure. The federal 340B drug discount program, which requires drug manufacturers to extend discounts to specified "covered entity" purchasers, has long carried the potential for manufacturers providing both a 340B discount and another form of discount or rebate on the same prescription (duplicative discounts). Several new Inflation Reduction Act (IRA) drug pricing programs, which are currently being implemented, have created a new impetus for drug manufacturers to identify and prevent duplicative discounts, particularly by reducing the plan rebates that they would otherwise provide.

The Minnesota Department of Insurance recently estimated that

85%

of 340B provider profit margins are funded by commercial insurance and Medicare Part D plans

Key statistics

Drug manufacturers provide 340B discounts on drug purchases by covered entities serving medically underserved populations, and those drugs are commonly dispensed through retail "contract pharmacies." Although many manufacturer rebate contracts exclude claims for prescriptions on which a 340B discount has been provided from eligibility for rebates, there is no commonly accepted way to identify such 340B claims. For example, in some cases claims for drugs dispensed by registered covered entities, based on those entities' provider numbers, are considered 340B claims, but this approach may be overinclusive by including prescriptions not dispensed to 340B patients and underinclusive by not capturing prescriptions dispensed through contract pharmacies billing under their own provider numbers. Further, few PBMs require pharmacies to identify 340B claims through information submitted through the National Council for Prescription Drug Programs (NCPDP) claims processing standard. Moreover, emerging state laws (including in Arkansas, Louisiana and West Virginia) may actually prohibit PBMs from imposing such requirements. As a result, whether particular drug claims are ineligible for rebates as 340B claims is a common topic of disputes under manufacturer-PBM rebate contracts.

The IRA created four new federal drug price regulation programs in the context of Medicare: (i) Part D manufacturer discounts; (ii) Part B inflation rebates; (iii) Part D inflation rebates; and (iv) "maximum fair prices" negotiated for "selected drugs" under Parts B and D. In each of the latter three programs, Congress directed the U.S. Secretary of Health and Human Services (HHS) to develop mechanisms to avoid duplicate discounts under the 340B program and the new program, and HHS has specified three completely different mechanisms to do so for those programs.

- With respect to Part B inflation rebates, since January 2024, providers must include a "JG" or "TB" claims modifier to identify 340B units for exclusion.
- With respect to Part D inflation rebates, the Centers for Medicare & Medicaid Services (CMS) has declined to require any mechanism to identify 340B claims. The agency initially proposed to reduce gross Part D utilization based on its estimate of the percentage of 340B sales of the drug relative to total sales of the drug. However, CMS subsequently elected not to proceed on that basis, and instead is "exploring" the establishment of a Part D claims repository which would collect four claims data elements from covered entities and their contract pharmacies, and CMS would use that data to administer the exclusion.
- Finally, in the context of maximum fair prices for selected drugs, which must be made available through a point-of-sale mechanism to pharmacies for Medicare Part D claims (beginning in 2026), CMS declined to require point-of-sale 340B claims identification and essentially left 340B claims identification up to manufacturers. Specifically, while Part D plans will submit all Part D utilization of selected drugs to a clearinghouse which will bill manufacturers for the difference between the selected drug's list price and the maximum fair price, manufacturers will be able to dispute such payments on 340B claims based on their own internal mechanisms for identifying 340B claims.

And indeed, manufacturers have been developing increasingly sophisticated and data-driven mechanisms to limit or identify 340B claims. For example, this past spring in *Novartis Pharmaceuticals Corporation v. Becerra*, the D.C. Circuit upheld one manufacturer's limitation on the number of contract pharmacies to which it would ship 340B drugs, and another manufacturer's requirement that covered entities must submit claims data as a condition to the shipment of 340B drugs to contract pharmacies. More recently, several manufacturers have proposed to implement a new 340B model under which covered entities would no longer receive 340B prices through up-front discounts on their purchases of drug inventory from wholesalers. Instead, they would be eligible to receive the 340B price through a back-end 340B rebate from the manufacturer based upon the submission of 340B claims data. The data generated under these programs can potentially be used by manufacturers to identify 340B claims and dispute their eligibility for plan rebates under manufacturer-PBM rebate agreements.

Consequently, managed care organizations should monitor the regulatory processes to implement the IRA reforms as they relate to 340B claims identification. Moreover, drug manufacturers, MCOs and their PBMs are likely to pay closer attention to contractual rebate eligibility and dispute terms in their contract negotiation and administration, and they may wish to consider new contract provisions to address the evolving industry landscape.

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Mental health parity rules: Forget 2025, start planning for 2026 now!

Takeaways

- Ensure coverage of core mental health treatments based on independent standards
- Use unbiased and objective factors and evidence to justify limits on mental health benefits
- Collect and evaluate data on NQTLs impact on access and outcomes and address disparities
- Prepare for fiduciary certification and quick response to comparative analysis requests

The long-awaited final rule for Mental Health Parity and Addiction Equity Act (MHPAEA) compliance came out earlier this year, bringing both good and bad news for those tasked with mental health parity compliance. While there is some relief that the Departments of Labor, Health and Human Services, and Treasury dropped the "mathematical test" for non-quantitative treatment limitations (NQTLs) after receiving over 10,000 comments, much uncertainty remains. Managed care organizations (MCOs) should already be ready to roll out their comparative analyses to meet the new 2025 "design and application" and other new requirements, but the requirements that go into effect in 2026 are going to take some time to implement. Below, we suggest steps to take in 2025 to prepare for those requirements.

What's in store for 2026?

MCOs should use 2025 to address the more challenging parts of the new rule, including the meaningful benefits standard, the prohibition on discriminatory factors and evidentiary standards, the relevant data evaluation requirements and the related outcome-focused requirements in the new rule's comparative analysis provisions. These changes apply from the first day of the first plan year beginning on or after January 1, 2026.

Meaningful benefits. While the final rule maintains that MHPAEA is not a benefits mandate, the new rule states that plans and issuers must provide at least one "core treatment" for each covered condition in a relevant benefits classification where medical/surgical benefits are offered, to meet the "meaningful benefit" requirement under the new rule. Core treatment is defined as "standard treatment or course of treatment, therapy, service or intervention indicated by generally recognized independent standards of current medical practice."

Takeaways:

- Review plan benefits to determine if the plan offers a "core treatment" for covered conditions. For example, ABA therapy for autism spectrum disorder and coverage of nutritional counseling for eating disorders are specified as core treatments. Plans also need to cover medications for opioid use disorder if they cover substance use disorder.
- From the "core treatment" language in the final rule, we understand that services like wilderness therapy are not required to be covered because residential treatment qualifies as core treatment for mental health in the intermediate classification of benefits.

Prohibition on discriminatory factors. As part of the new design and application requirements for comparative analyses, the new rule prohibits plans and MCOs from using discriminatory factors and evidentiary standards in designing NQTLs that apply to mental health benefits. Under the new rule, a factor or evidentiary standard is discriminatory if the information or sources on which it is based are biased or not objective in a manner that discriminates against mental health benefits as compared to medical/surgical benefits.

Takeaways:

- Consider whether the information and sources they use are based on independent professional medical or clinical standards, which the new rule considers unbiased and objective.
- Prepare for challenges to medical necessity criteria from private companies, as opposed to criteria developed by independent community organizations.

Relevant data requirement. Under the new rule, plans and MCOs are required to collect and evaluate relevant data that shows the impact of each NQTL on access to mental health and medical/surgical benefits. This data must be examined to determine if, in the aggregate, the NQTLs contribute to material differences in access. Such differences will be considered strong indicators of a parity violation. Plans/MCOs are required under the new rule to take "reasonable action" to address any material differences.

Takeaways:

- Develop a plan to document "reasonable actions" to mitigate material differences.
- Start collecting and evaluating data now, and make adjustments before incorporating it into comparative analyses.
- Consider adopting two different strategies:
  - Collecting recent data on prior authorization, claims denials and network issues to show the NQTL's impact on access to mental health benefits.
  - Implementing a monitoring process to assess reasonable actions taken to address material differences in outcomes.
- Start with network-related data – although the rule did not codify the "Special Rule on Network Composition," the Departments made clear that network composition and access are areas that must be analyzed under the new NQTL rules and will be a compliance priority.

- Consider:
  - Collecting data on whether providers are accepting new patients.
  - Conducting member surveys on reasons for selecting out-of-network providers.
  - Tracking in-network exceptions.
  - Collecting data on percentage of urban versus rural providers in networks.
  - Collecting data on both dollar value and number of provider claims submissions for in- and out-of-network claims.
  - Strengthening recruitment efforts for out-of-network mental health providers. Consider creating automated requests for providers to join the network when you receive an out-of-network claim, and ask members why they went out of the network. Create a process for analyzing the results of these efforts.
  - Streamlining the credentialing process to reduce barriers to network participation.
  - Expanding telehealth options to increase participation.
  - Ensuring the process for updating provider directories is effective – get the directories in order ASAP!

Longer term, MCOs should analyze variations in access to mental health benefits when compared to access to medical/surgical benefits. Are there studies discussing whether mental health providers join networks at different rates than medical/surgical providers? What role do reimbursement rates play in network participation? At bottom, MCOs need to prepare to respond to questions about why people are choosing out-of-network mental health providers. MCOs can take steps now to contract with new providers and track these efforts to demonstrate reasonable efforts to address any material differences in access.

Additional MCO considerations for 2025 and 2026

Fiduciary certification. The final rule does not require a fiduciary to certify the accuracy of comparative analyses. However, an ERISA plan fiduciary must certify that the plan engaged in a prudent process to select qualified service providers to perform and document a comparative analysis for NQTLs that apply to mental health and substance use disorder benefits under the plan in accordance with MHPAEA and its implementing regulations, and fulfil the duty to monitor those service providers. This requirement goes into effect in 2025, but MCOs and plans are likely to engage in discussions over who is a fiduciary of the plan for MHPAEA purposes throughout the year.

Steps to take

- Check administrative services agreements now to see who is listed as a fiduciary and prepare for ASO partners to engage in discussions about this issue.

Timing expectations. Despite requests for more time to address comparative analyses, plans and issuers must still respond to requests within 10 business days. The Departments expect these analyses to be ready even if the requested topic isn't on the final rule's "non-exhaustive" list of NQTLs.

Steps to take

- Get various stakeholders engaged and aware of turnaround times, so when requests come in, they have a plan of attack.

For more information on this article, please contact Rebecca Hanson and Taylor Marcusson

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Medication abortion and increasing compliance challenges for health plans

Takeaways

- Since states began introducing abortion restrictions following the Supreme Court's *Dobbs* decision, medication abortion via telemedicine has enabled those in restrictive states to access related care
- The rise in telemedicine for medication abortion has led to legal challenges, posing compliance risks for MCOs
- Despite FDA approval, state laws significantly impact the availability of medication abortion, with some states imposing strict in-person requirements

In the post-*Dobbs* landscape, there has been a renewed focus on medication abortion as an option for expanding access to abortion care for people residing in states with abortion bans or restrictions. Given the increased availability of medication abortion throughout the U.S. via telemedicine, this area has attracted several legal challenges that could create exposure and compliance risk for managed care organizations (MCOs).

The two-drug combination of mifepristone and misoprostol is the most common medication abortion regimen in the U.S. and can be safely used until up to 10 weeks of pregnancy according to the U.S. Food and Drug Administration (FDA). The FDA first approved mifepristone, the primary drug used in medication abortion, in 2000; since that time, reliance on the mifepristone and misoprostol regimen has increased steadily as it has become more accessible through telemedicine. In 2023, medication abortion accounted for more than 63% of all abortions nationwide, up from 53% in 2020.

Since 2000, the FDA has repeatedly expanded the availability of medication abortion and broadened the use of telemedicine dispensing. For instance, in December 2021, the FDA removed the in-person dispensing requirement for mifepristone, and in January 2023 it approved a rule to expand the certification program to allow retail and mail-order pharmacies to fill prescriptions for the drug. Before that latest rule change, a pregnant person had to receive mifepristone directly from a physician or by mail via a telemedicine appointment.

The FDA has approved mifepristone as safe and effective, but the availability of medication abortion is largely dependent on state law. Following the *Dobbs* decision, some states have attempted to restrict access to medication abortion via telemedicine either by mandating an in-person visit with a physician, requiring a state-mandated in-person counseling session or ultrasound, imposing a requirement for in-person dispensing, or requiring medication abortion to be provided by a physician. For example, in addition to the 14 states currently enforcing a near-total ban on all abortion, five states where abortion is permitted until at least six weeks of pregnancy restrict access to medication abortion via telemedicine—Arizona, Nebraska, North Carolina, South Carolina and Wisconsin require that a patient being prescribed medication abortion have an in-person visit with a physician, and Arizona and North Carolina also ban mailing abortion-inducing drugs to a patient.

Key statistics

More than **10** **states**

require at least **one trip** to an abortion clinic before being prescribed medication abortion, effectively banning the use of telemedicine to access

The expansion in access to and use of medication abortion via telemedicine has been the subject of recent litigation in federal court. Shortly after the *Dobbs* decision, an anti-abortion group sued in the Northern District of Texas challenging the FDA's approach to regulating mifepristone. The case, *Alliance for Hippocratic Medicine (AHM) v. FDA*, went all the way to the U.S. Supreme Court, which ultimately found that the original plaintiffs lacked standing to sue, and therefore, unanimously agreed to maintain the FDA's eased access to the drug. Despite the Supreme Court's ruling, however, the case has recently re-emerged in the

same federal district court in Texas. The revised lawsuit was filed in October by three intervenor states – Idaho, Kansas and Missouri – attempting to circumvent the standing hurdle, and if successful, could reverse the ability of a nurse practitioner or other health care provider to prescribe mifepristone, remove the ability for a retail pharmacy to dispense the medication, and require an in-person visit with a prescriber.

Unlike the original lawsuit, Idaho, Kansas and Missouri take aim at the growth of "shield laws" that have been increasingly enacted in abortion-friendly states to preserve abortion access and protect those who provide or assist abortion care from out-of-state prosecution. In the revised lawsuit, they argue that the FDA's decision to remove the in-person dispensing requirement "enabled a 50-state mail-order abortion drug economy" and led to the proliferation of shield laws, which they claim violate their state sovereignty by allowing abortion medication to be prescribed through telemedicine and then mailed into states that ban or sharply restrict abortion.

Regardless of the immediate outcome of the revised *AHM v. FDA* case, other disputes and efforts to restrict access to medication abortion via telemedicine will likely continue to escalate, especially given the uncertainty of the change in administration. Further, while the revised lawsuit references the role of shield laws with respect to telemedicine, there has been no known instance of states directly challenging the constitutionality of such laws in court. Accordingly, a potentially significant area to watch going forward will be whether other states proceed with challenging shield laws in light of that case, and importantly, whether such challenges are successful. If so, that result would not only have a direct impact on states that have enacted shield laws but would also drastically curtail access to mifepristone in abortion-hostile states. In fact, the Texas attorney general recently filed a lawsuit, alleging that a New York physician violated Texas' abortion ban by providing abortion medication to a Texas resident via telemedicine. The lawsuit, *State of Texas v. Carpenter*, is likely to be the first test of shield laws, as New York has a statute protecting physicians from out-of-state prosecution.

While the constitutionality of shield laws is currently uncertain, MCOs should stay apprised of the positions of the new administration and states' attorney generals on medication abortion and mifepristone in particular. For instance, the FDA may move to restrict access to or remove mifepristone from the market, making any legal challenge to the FDA's regulatory approval of the drug moot. Accordingly, MCOs should monitor litigation regarding mifepristone, as well as whether more states decide to challenge the use of telemedicine in prescribing and mailing medication abortion and the role of shield laws in that area. Finally, MCOs should consider reviewing contracts and benefit plans to ensure that their terms comply with coverage requirements with respect to abortion, especially medication abortion, and continue to carefully administer benefits for abortion-related care for members residing in states with abortion restrictions and bans, particularly as they relate to the use of telemedicine.

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.

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2025 Outlook on gender-affirming care

Takeaways

- Supreme Court's decision in *U.S. v. Skrmetti* will significantly influence gender-affirming care laws and federal regulation
- Biden administration's section 1557 final rule prohibits discrimination based on gender identity, but its enforcement is currently enjoined nationwide
- Twenty-four states have enacted laws restricting gender-affirming care, creating a complex and conflicting legal landscape for health care providers and insurers

The health care landscape for gender-affirming care stands at a pivotal moment as the country awaits the Supreme Court's decision in *U.S. v. Skrmetti*, slated for mid-2025. The complex interplay between the Biden administration's section 1557 final rule, competing state-law gender-affirming care bans and the pending Supreme Court decision adds to ongoing uncertainty around health care discrimination protections for transgender individuals and health care providers' obligations under federal and state law.

Whether section 1557 prohibits discrimination on the basis of gender identity remains unsettled

On May 6, 2024, the Biden-Harris administration, through the Department of Health and Human Services (HHS) Office for Civil Rights (OCR) and Centers for Medicare & Medicaid Services (CMS), published a final rule implementing section 1557 of the Affordable Care Act (ACA). The final rule explicitly classifies discrimination based on gender identity as a form of sex-based discrimination. Although the rule does not require coverage of specific services, it prevents discriminatory exclusion of

categories of care, and therefore prohibits ACA-covered entities from denying or limiting coverage for gender-affirming care, such as hormone therapy, surgeries and other treatments related to gender transition, solely based on an individual's gender identity.

Although the final rule was supposed to be enforceable starting in 2025, there is currently an injunction on its enforcement due to the Southern District of Mississippi's ruling in *Tennessee v. Becerra*. On July 3, 2024, the district court invoked the U.S. Supreme Court's recent *Loper Bright* decision (which overruled the principle of *Chevron* deference to agency interpretations) to decline to defer to HHS's interpretation of section 1557 and, thereby, issued a nationwide injunction enjoining the Biden administration from "enforcing, relying on, implementing, or otherwise acting" under the final rule's gender identity provisions. Notably, the district court stayed the effective date of the regulations nationwide as to specific parts of the non-discrimination provision, in so far as they extend "discrimination on the basis of sex" to include discrimination based on gender identity. This includes the final rule's provision that covered plans cannot deny or limit coverage to patients based on gender identity or sex assigned at birth, adopt or apply a categorical exclusion or limitation for health care services sought for the purpose of gender transition or other gender-affirming care, or otherwise deny or limit coverage or impose additional cost sharing for such care.

State-level restrictions continue to compete and create a patchwork of conflicting gender-affirming care laws

Meanwhile, 24 states have enacted laws restricting access to gender-affirming care, creating tension between state law and any protections that exist in section 1557 or otherwise. For example, Tennessee's SB 1 has emerged as a focal point of the gender-affirming care debate. The law, which went into effect on July 1, 2023, bars providers from knowingly performing or offering to perform gender-affirming care on minors, through telehealth or otherwise. SB1 also prohibits any person, including but not limited to providers, from knowingly providing illegal hormones or puberty blockers to minors. A provider that violates the general ban may have their license revoked, and the Tennessee attorney general can fine anyone who violates SB1 up to $25,000 per violation. A challenge to the constitutionality of SB 1 under the Equal Protection Clause and Fourteenth Amendment has made its way through Tennessee's district court, which granted a preliminary injunction against enforcing the law, and the Sixth Circuit, which stayed the injunction. It is now slated to be heard by the Supreme Court.

U.S. v. Skrmetti

On June 24, 2024, the U.S. Supreme Court announced that it will review the Sixth Circuit's decision and address "whether Tennessee Senate Bill 1, which prohibits all medical treatments intended to allow 'a minor to identify with, or live as, a purported identity inconsistent with the minor's sex' or to treat 'purported discomfort or distress from a discordance between the minor's sex and asserted identity,' violates the equal protection clause of the 14th Amendment." On December 4, 2024, the U.S. Supreme Court heard oral arguments in *U.S. v. Skrmetti*.

Although the case does not directly challenge whether SB1 violates the ACA, the Court's ruling could have far-reaching implications for similar state laws and potentially impact the federal government's ability to regulate gender-affirming care under section 1557. First, the Court's interpretation of equal protection in the context of gender identity could establish a new constitutional framework for evaluating similar laws nationwide. Importantly, if the Court decides that laws such as SB1 warrant heightened scrutiny, challenges to state gender-affirming care bans may see more success. Conversely, if the Court applies the rational basis test or more permissive standard of review, states defending their gender-affirming care bans or seeking to enact the same will likely have a stronger pathway forward. Second, a Supreme Court decision in favor of gender-affirming care bans could impact the federal government's ability to regulate gender-affirming care through section 1557. Setting aside speculation on what section 1557 may look like under a Trump administration, if the Court finds that gender-affirming care bans are constitutional, it could undermine the ability of any administration or federal agency to enforce federal protections over gender identity.

Conclusion

The outcome of *U.S. v. Skrmetti* and any future enforcement or amendment to the Section 1557 regulations could significantly impact the future of gender-affirming care access and coverage in the United States. Managed care organizations must continue to navigate this complex legal landscape while maintaining compliance with both federal and state requirements. In-house legal teams should stay abreast of developments using tools like Reed Smith's award-winning, proprietary Gender-Affirming Care Tracker to make real-time informed decisions that mitigate their client's risks.


For more information on this article, please contact Alexandra Lucas and Katie Goetz

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From "Just Say No" to emerging therapies: How three different reform initiatives could change the future for cannabis and psychedelics in U.S. health care

Takeaways

- Schedule I controlled substances face significant hurdles to accepted use in treatment in the U.S.
- Through state led initiatives, private innovation and direct appeals to the federal government, cannabis and psychedelics are increasingly seen as a potential treatment for various medical conditions
- While managed care companies face little risk refusing coverage for Schedule I drugs, they should continue to monitor the landscape to understand their coverage obligations

Despite a challenging legal landscape, cannabis and psychedelics have emerged as potentially legitimate treatment options in the U.S. This article explores how that happened and what it means for managed care companies.

Legal landscape

The U.S. regulates controlled substances through the Controlled Substances Act (CSA) and the Food and Drug Administration (FDA). The CSA allocates drugs in five schedules based on their medical use, potential for abuse, and safety and risk of dependence. Schedule I drugs include heroin, cannabis, psilocybin and MDMA. According to the CSA, these drugs have no currently accepted medical use and a high potential for abuse.

Any drug listed on Schedules II through V is eligible for FDA approval. The FDA reviews clinical trials and peer-reviewed studies to determine the safety and efficacy of a substance for a particular purpose. Once approved by the FDA, the drug

may be manufactured and distributed in interstate commerce. Although FDA approval is limited to particular dosages, forms and/or indications, providers may still prescribe FDA-approved drugs “off-label” in a manner that has not been approved by the FDA.

Schedule I substances face many hurdles to accepted use in treatment, including research and funding restrictions and limitations on substance access and supply. Consequently, Schedule I drugs tend to stay on Schedule I indefinitely.

Three approaches to reform

Cannabis, psilocybin and MDMA have been Schedule I drugs for decades. That could be changing as soon as this year through three different approaches to reform.

Cannabis has followed a state-led path to legalization. Beginning in the late 1990s, through voter-led ballot initiatives and legislation, states began passing laws permitting the use of cannabis for specified medical purposes, despite federal prohibitions. By the early 2010s, the federal government clarified through the Cole Memorandum and the Rohrbacher-Farr amendment that it would not enforce or fund enforcement against state-sanctioned cannabis activities. In 2024, at the recommendation of the Department of Health and Human Services, the Department of Justice (DOJ) proposed a new rule that would reschedule cannabis as a Schedule III drug under the CSA, which would recognize its potential for currently accepted medical uses in treatment and provide a pathway for eventual FDA approval.

Ketamine has relied on innovation in the private sector. The drug is currently FDA approved for anesthetic uses. However, over the last 25 years, physicians began prescribing ketamine for off-label uses, including to treat depression, anxiety and post-traumatic stress disorder (PTSD). Now, physician-owned ketamine clinics are prevalent across several states. While ketamine clinics have treated thousands of patients, the path to more widespread acceptance through FDA approval remains unclear.

A third path was pursued for psychedelics: direct appeals to the federal government. The FDA recently rejected an application to use MDMA to treat PTSD but left open the possibility of future approval. Separately, the 2024 Defense Authorization Act authorized research on the effects of psilocybin, MDMA and other psychedelic therapies on veterans suffering from PTSD. The U.S. spends about $230 billion annually on PTSD treatments; these studies may show that psychedelics are a safe and more cost-effective alternative to current treatments.

Studies predict that if medical cannabis were legalized at the federal level, U.S. health care expenditures would decrease by

$29 billion annually

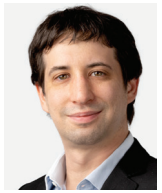
Key statistics

Coverage considerations

Coverage for drugs involves several considerations. First, plans generally require that the drug is medically necessary. Second, most plans only cover drugs approved by the FDA. Third, most plans maintain drug lists that identify drugs covered by the plan; drugs not on the plan’s drug list require prior authorization. Fourth, some plans expressly exclude specific drugs like cannabis. Generally, plans face little risk refusing to cover Schedule I drugs; they are not medically necessary under the CSA, they are not approved by the FDA, and they are not on the plan’s drug list.

Still, advocates are already seeking insurance coverage for medical cannabis. Several states have compelled worker’s compensation insurers to cover an injured worker’s medical cannabis when authorized under state law, despite federal prohibitions. If the DOJ proceeds with rescheduling cannabis as a Schedule III drug, requests for coverage will continue to grow. Clinical research and legal developments with psychedelics may bring similar coverage requests in the future.

We recommend that managed care companies monitor these emerging therapies to understand the landscape, determine their coverage obligations and consider what they might cover in the future.



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Loper Bright: Reshaping the ERISA regulatory landscape

Takeaways

- Under *Loper Bright*, federal courts must now exercise independent judgment in deciding whether an agency acted within its statutory authority
- The holding in *Corner Post* expands the ability to challenge long-standing regulations and agency decisions, notwithstanding statute of limitation concerns
- *Loper Bright* is likely to be the basis for a number of challenges to DOL regulations in the highly-regulated ERISA space in 2025 and beyond

After 40 years of *Chevron* deference, *Loper Bright* is now the law of the land and requires federal courts to exercise independent judgment in deciding whether an agency has acted within its statutory authority. Under this new standard, the Department of Labor (DOL) is not accorded the same deference in interpreting the Employee Retirement Income Security Act (ERISA) as it had enjoyed previously. ERISA plans and their administrators are likely to feel the aftershocks of the Supreme Court's earth-shaking administrative law decision in 2025 and beyond.

Chevron v. NRDC (S. Ct. 1984) instructed federal courts to defer to reasonable agency interpretations of ambiguous federal statutes on the grounds that agency experts were better suited than federal judges to make such interpretations. The Supreme Court decision in *Loper Bright Enterprises v. Raimondo*, however, overturned *Chevron* and commands federal courts to exercise their own independent judgment in deciding questions of interpretation. Agency interpretations may still be treated as persuasive authority, however, especially regarding matters within the agency's expertise. Importantly for ERISA, *Loper Bright* is inapplicable where Congress has expressly delegated authority to a federal agency to promulgate regulations.

Loper Bright, along with another Supreme Court decision, *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, provides powerful tools for challenging agency actions, even decades after they occur. In *Corner Post*, the Supreme Court permitted a business that did not open until 2018 to challenge a Federal Reserve rule from 2011. In so doing, the Court held that a cause of action under the Administrative Procedure Act (APA) does not accrue until a party is injured, seemingly extending the APA's six-year statute of limitations.

Loper Bright and *Corner Post* are already changing how courts handle challenges to ERISA regulations.

The district court in *Fed'n of Ams. for Consumer Choice, Inc. v. DOL* (E.D. Tex.) applied *Loper Bright* to enjoin the effective date of a 2024 DOL rule that broadly redefines fiduciary under ERISA. Plaintiffs, insurance agents selling tax-qualified annuities, argued that DOL's redefinition of "investment advice fiduciary" would improperly make them fiduciaries, subjecting them to significant compliance burdens and potential liability under ERISA. The court stated that, under *Loper Bright*, it owed no deference to DOL's interpretation because DOL impermissibly reinterpreted the 50-year-old term and accepting DOL's interpretation would grant DOL unlimited power to rewrite ERISA.

While not citing *Loper Bright* explicitly, the district court in *Am. Council of Life Insurers v. DOL* (N.D. Tex.) agreed with the above analysis and enjoined the same rule. An industry group representing life insurance carriers brought the challenge in this instance. The district court found that the DOL rule expanded the meaning of fiduciary far beyond Congress's intent. Taken together, these cases illustrate *Loper Bright*'s effectiveness as a vehicle for challenging ERISA regulations.

However, *Loper Bright* is not without limits, as *Cogdell v. Reliance Standard Life Ins. Co.* (E.D. Va.) illustrates. In *Cogdell*, the district court rejected a facial challenge to a DOL regulation considering a claim administratively exhausted if no appeal decision had been rendered by the plan administrator within 45 days. The court noted that ERISA grants the DOL exceedingly broad power to prescribe regulations, including setting limits for administrative claim exhaustion. As such, the court found *Loper Bright* did not apply. In addition, the court held that the challenge was likely time-barred notwithstanding *Corner Post* because Reliance had faced the consequences of the regulation prior to the APA's six-year statute of limitations.

2025 should see additional *Loper Bright* challenges. For example, the DOL, along with the Departments of Health and Human Services and Treasury, released new regulations implementing requirements for the Mental Health Parity and Addiction Equity Act. Though the final regulations toned down some of the more controversial provisions from proposed rules, parity continues to be a focus in the industry and a point of contention between ERISA plans and the DOL. Another area to watch is the DOL's environmental, social and governance (ESG) rule, which is currently being litigated in the Fifth Circuit. The ESG rule permits ERISA fiduciaries to consider environmental and social factors when evaluating plan investment opportunities that are otherwise financially equal.

The *Loper Bright* era is still in its nascence but is already having a substantial impact in the ERISA space that should continue throughout 2025 and beyond.

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Risk management

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Denial letters likely to remain under fire in 2025

Takeaways

- Tenth Circuit's *D.K. v. UBH* decision set a new standard requiring detailed denial letters
- Other courts follow suit, with Fifth Circuit (and potentially the Ninth Circuit) adopting similar standards
- Trend of overruling denials based on inadequate denial letters broadens
- Substantiate denial letters by referencing medical records, providing detailed explanations and ensuring consistent rationales over time in response to appeals

As we reported in the last Managed Care Outlook, 2023 was a rough year for the managed care industry with respect to denial letters – and 2024 was no better. 2025 is likely going to continue the trend now that the Fifth Circuit has taken the Tenth Circuit's hard line on denial letters, and with the Ninth Circuit potentially following suit. If you haven't updated your denial letters with additional details as outlined below, now's the time.

Why 2024 was no better than 2023

As we reported at the end of 2023, the Tenth Circuit opinion in *D.K. v. UBH*, 67 F.4th 1224, 1240 (10th Cir. 2023) set the bar for denial letters by requiring them to provide detailed information about the reasons for denials of requests for coverage, including responses to issues raised by providers – and even non-treating "experts." Additional Tenth Circuit opinions followed this approach, burdening managed care organizations and health plans in defending lawsuits in that forum.

The *D.K.* line of reasoning spread beyond the Tenth Circuit in 2024. District courts around the country issued numerous opinions on denial letters, with some toeing the *D.K.* line in finding them insufficient. See, e.g., *Demarinis v. Anthem Ins. Co.*, 2024 U.S. Dist. LEXIS 66106, at *62 (M.D. Pa. Apr. 10, 2024) (finding the lack of explanations in the denial letters "troubling").

In late September, the Fifth Circuit, in *Dwyer v. United Healthcare Insurance Company*, 2024 U.S. App. LEXIS 23866 (5th Cir. Sep. 19, 2024), joined the Tenth Circuit in finding that denial letters must contain detailed information, such as references to medical records, to satisfy ERISA's "meaningful dialogue" standard. In coming to this conclusion, the Fifth Circuit engaged in similar reasoning found in *D.K.* in analyzing the denial letter, which stated:

> You were admitted for treatment of anorexia nervosa, restricting type. After talking with your doctor, it is reported that you have made progress and no longer need the type of care and services provided in this setting. You are better. You have achieved 100% of your ideal body weight. You are eating all of your meals. You are not trying to harm yourself. You are not trying to harm others. Your primary care physician is involved in your treatment. Your care could continue at the intensive outpatient level of care.

Dwyer, 2024 U.S. App. LEXIS 23866, at *12. The Fifth Circuit criticized phrases from the letter like "[y]ou are better" as they had "no medical significance," calling instead for "particularized evaluation" of a member's medical needs and alternative treatments to meet those needs. *Id.* at *16. The court further noted that claims administrators must "weigh the evidence" provided by plaintiffs in their appeals, including responding to "potential counterevidence from medical opinions" provided by treating providers. *Id.* at *21. The court did not consider that managed care organizations are hamstrung by accreditation requirements that limit the language level the industry can use in drafting these letters.

In what could portend bad news for 2025, a Ninth Circuit panel recently expressed concern during oral argument on appeal about a purported vague denial letter that the court surmised might fail to meet ERISA's meaningful dialogue requirements. A panel member asserted that the denial letter seemed to fail to elucidate what information the family needed to provide to perfect their appeal and questioned whether they had received a "meaningful dialogue" as required by ERISA.

Other Ninth Circuit district courts have raised similar concerns. *See, e.g.*, *Oksana B. v. Premera Blue Cross*, 2023 U.S. Dist. LEXIS 224983, at *26 (W.D. Wash. Dec. 18, 2023) (finding the claims administrator failed to provide sufficient detail in its denial letter as to why coverage for wilderness therapy treatment was not available under the plan); *Dan C. v. Anthem Blue Cross Life & Health Ins. Co.*, 2024 U.S. Dist. LEXIS 64811, at *19 (C.D. Cal. Apr. 9, 2024) (finding the denial letter did not engage with the "voluminous medical record" or treating physicians' positions).

Courts do remain split on the issue, however. Some courts have held denial letters to pre-*D.K.* standards, focusing on whether the letters provided sufficient information for an appeal without requiring the extensive detail mandated by the Tenth Circuit. For example, in *Carl A.B. v. Blue Cross Blue Shield of N.C.*, 2024 U.S. Dist. LEXIS 148193, at *32 (M.D.N.C. Aug. 19, 2024), the court found that the denial letter statements, which notably were not unlike those in *D.K.* and *Dwyer*, had "substantial support" in the administrative record and did not violate ERISA. *See also R.R. v. Blue Shield of Cal.*, No. 3:22-cv-07707-JD, 2024 U.S. Dist. LEXIS 141364, at *15 (N.D. Cal. Aug. 8, 2024) (similar); *W.H. v. Allegiance Ben. Plan Mgmt.*, No. CV 22-166-M-DWM, 2024 U.S. Dist. LEXIS 99272 (D. Mont. June 4, 2024) (similar); *E.L. v. Hartford Life & Accident Ins. Co.*, 2024 U.S. Dist. LEXIS 55546, at *78 (N.D. Cal. Mar. 27, 2024) (noting that the denial letter "reflected in plain language the reasons for its denial"); *Burris v. First Reliance Standard Life Ins. Co.,* 2024 U.S. Dist. LEXIS 24029, at *23-24 (D. Nev. Feb. 9, 2024) (similar).

In short, the *D.K.* rationale is spreading, albeit slowly, across the country, so if you haven't already reevaluated your denial letters, make it your New Year's resolution for 2025.

Possible de novo review exception

Not all of 2024's developments were negative. A district court in Utah found that the *D.K.* approach does not apply in *de novo* review cases. The court found that "[e]ven assuming [the claims administrator] failed to provide a 'full and fair review,' neither ERISA's implementing regulations nor binding precedent state that the court is required to simply order benefits, no matter the record evidence, when a court is reviewing a benefits decision *de novo*. Instead, the court is required to determine whether a plaintiff's claim for benefits is supported by a preponderance of the evidence based on the district court's independent review of the administrator's decision." *See S.M. v. United Healthcare Oxford*, No. 2:22-cv-00262-DBB-JCB, 2024 U.S. Dist. LEXIS 158498, at *39 (D. Utah July 26, 2024) The court then used the record – even though it was not referenced in the denial letter – to make its determination instead of focusing only on the denial letters, which it still found "inadequate" for a full and fair review. We hope to see other courts adopt this reasoning in *de novo* review cases in 2025, containing the impact of *D.K.* to the arbitrary and capricious standard of review.

What should you do?

If you haven't already improved your denial letters, now is the time. Most denial letters we've seen do not meet *D.K.*'s standard. Here is a brief summary of possible actions to improve your letters in 2025. For more detail, please refer to our 2024 Managed Care Outlook.

- Add an explanation for rejecting the reasons given by providers in medical necessity letters or peer-to-peer reviews.
- Reference medical records to support the denial.
- Attach comprehensive internal case notes and the administrative record to the denial letter, for reference in litigation.
- Take an analytical approach by addressing each decision point in the medical necessity criteria in the letter and explaining whether the member met the criteria.
- Ensure consistency across denial letters and appeals, explaining any changes in decisions made over time, and consider offering members additional appeal rights.

For more information on this article, please contact Rebecca Hanson

Payors face a growing number of lawsuits to enforce IDR awards under the No Surprises Act

Takeaways

- Provider lawsuits seeking to enforce IDR awards are expected to increase
- At least one appellate court will decide whether providers may enforce IDR awards under the No Surprises Act
- Congress may also step in to enhance enforcement of IDR awards

The No Surprises Act (NSA) was a landmark piece of legislation aimed at protecting patients from unexpected medical bills. One of the key components of the NSA is the independent dispute resolution (IDR) process, which allows medical providers and payors to resolve payment disputes through arbitration. The IDR process has generated hundreds of thousands of awards for medical providers, which has subsequently led to a rise in litigation against managed care payors. This article explores the reasons behind this surge, the current state of litigation, and the prospects for further legal battles in 2025.

Understanding the NSA and IDR process

Under the NSA, providers who are dissatisfied with the payment they receive can initiate negotiations with the payor concerning the out-of-network rate for certain surprise medical bills. If negotiations fail, either party can initiate the IDR process. The IDR process uses a blind, "baseball-style" arbitration where the provider and the payor each submit an offer to a certified independent dispute resolution entity (CIDRE). The CIDRE reviews the parties' offers and selects one party's offer as the out-of-network rate.

The NSA provides that the CIDRE's decision is "binding" and that payment "shall be made . . . not later than 30 days after the date on which such determination is made." The NSA further specifies that judicial review is only allowed under Section 10(a) of the Federal Arbitration Act (FAA), which permits a party to seek to vacate an arbitration award under limited circumstances. The NSA does not expressly provide a mechanism for prevailing parties to enforce IDR awards.

Increase in litigation by medical providers

As discussed in *"Strategies for enhancing payment processes for IDR awards – lessons learned from litigation,"* payors faced operational challenges timely paying awards. These factors and others led to a backlog of unpaid, underpaid and/or untimely paid awards.

In 2024, providers began filing a wave of lawsuits in state and federal courts seeking to enforce awards. Some providers file lawsuits concerning one award, while others aggregate dozens of unpaid awards in one proceeding.

Providers' theories of recovery include the following:

- **Violation of the NSA**: Providers allege that payors violate the NSA when they fail to pay IDR awards within 30 days.
- **ERISA benefits**: Suing as member assignees, some providers assert that failure to timely pay breaches ERISA plan terms.
- **Federal or state arbitration acts**: Some providers attempt to confirm awards under Section 9 of the FAA and/or state arbitration acts.
- **State law claims**: Providers also seek to confirm awards through a variety of state law claims, such as unjust enrichment.

According to the latest government data, medical providers initiated more than **677,000 disputes** through the No Surprises Act's IDR process in 2023. In disputes that reached a resolution, providers prevailed more than **78% of the time**.

Key statistics

Current state of litigation

Several district courts have issued relevant rulings, with most finding the provider lacks a right to confirm or enforce an award. The Northern District of Texas dismissed a case with prejudice, finding the providers had no private cause of action under the NSA or standing under ERISA and could not state a claim for *quantum meruit* . This case is currently on appeal, with the Fifth Circuit expected to render a decision in 2025.

Prospects for 2025

Looking ahead to 2025, this situation will continue to evolve:

- **Increased IDR litigation**: We expect this area of litigation to increase as more providers file lawsuits over unpaid IDR awards. The huge number of awards issued to date suggests the number of cases filed will be significant.
- **Changing legal landscape**: Additional court decisions will impact providers' ability to obtain relief in these lawsuits. While the drift to date has been against permitting providers to enforce IDR awards, that trend could change, especially if the Fifth Circuit issues a ruling that favors providers.
- **Congressional action**: Congress is already considering amendments to the NSA that would impose harsh penalties on payors who fail to timely pay IDR awards. While current proposals do not provide express provisions permitting enforcement under the FAA or otherwise, it is possible Congress will consider such changes in 2025 in light of providers' complaints that payors are not timely paying awards.

For more information on this article, please contact Tom Hardy and Jason Mayer

Strategies for enhancing payment processes for IDR awards – lessons learned from litigation

Takeaways

- Front-end process improvements can enhance outcomes, reduce delays and decrease risk of post-IDR litigation
- Payors should ensure more effective notice of IDR initiations by including notice address on provider communications and provider-facing websites
- Payors can employ strategies to avoid other issues that lead to payment delays and potential litigation

Payors face many operational challenges in managing an independent dispute resolution (IDR) process, but there are steps they can take to make their processes more efficient and effective and give themselves better defenses if and when providers take legal action for a payor's failure to timely pay an award.

Ineffective notice

According to CMS statistics for Q4 of 2023, payors defaulted in about 10% of all IDR arbitrations. For arbitrations involving air ambulance claims, the default rate is nearly 20%. We have found that a principal reason for these defaults is that providers often are not presenting proper notice of IDR initiation to the payors.

At least for now, federal regulation does not require providers to serve notice on a payor by any specific means. Instead, a provider may electronically serve notice to a payor by a method that it believes in good faith will be readily accessible to the payor. That gives the provider a lot of leeway to decide how to send notice. Providers often send notices to email addresses for payor employees with no role in the IDR process. If a notice fails to reach the right department, the payor defaults and the

provider's offer prevails in the arbitration. The problem is compounded when the payor fails to timely pay the IDR award within 30 days because the lack of effective notice left it without any record of the arbitration.

Payors may avoid this outcome by taking a few steps. First, they can include an email address for receipt of IDR notices on remittance communications with providers. Second, payors should include the email address on their websites in an appropriate location. Even if these measures do not guarantee proper notice, the communications may later provide a payor with a basis for a motion challenging a default award.

Operational challenges

IDR awards can present operational hurdles that complicate payment. Examples include:

- **Awards that exceed the charges billed on the original claim**. The IDR process does not provide any safeguards to prevent this and, in fact, the blind-bid, baseball-style arbitration process, where the arbitrator is prohibited from considering the provider's billed charge, arguably incentivizes it. Payors' systems often are not set up to adjust claims to pay in excess of charges.

  Arbitrators are prohibited from considering billed charges in deciding which party's offer to accept. Still, when facing providers who have obtained awards in excess of their billed charges, nothing explicitly prohibits payors from referencing the provider's charge in their submissions to the arbitrator with context, including that charges are arbitrary, non-market-based rates. Whether the arbitrator will notice that information and what they will do with it, if anything, is ultimately up to them. But including it cannot hurt and may decrease the odds of an award that exceeds billed charges.

- **Other financially responsible entities**. Some payors engage in IDR on behalf of self-funded plans or other payors who are actually responsible for paying an award, and this can introduce delay in payment. Payors should consider entering into agreements with such parties that eliminate approvals and other roadblocks to adjustments for paying IDR awards that may contribute to delays.

- **Claim-splitting**. Typically, providers file separate IDRs for different lines on a single claim, resulting in multiple awards for a single claim. Payors should ensure that their IDR process takes this into account and tracks arbitrations by dispute numbers rather than by claim.

High volume

Providers initiated over 677,000 disputes in 2023, prevailing in nearly 80% of those that reached a decision. Payors have been unable to keep up with processing payment of this sheer volume of awards within the 30 days required by law. When payors fall behind, providers are hiring counsel and seeking aid from the court. While many of these lawsuits end up being dismissed, payors assume the expense of hiring counsel to defend them.

Payors with a high volume of IDRs should ensure they have reliable and efficient processes for tracking and paying IDR awards, with a specialized and dedicated team, to minimize the potential for and cost of IDR litigation.

For more information on this article, please contact Tom Hardy and Jason Mayer

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Notable fraud, waste and abuse issues impacting payors in 2025

Takeaways

- Emergency department service disputes remain a hot issue with a primary focus on facility upcoding of E/M codes to enhance reimbursement
- Billing of molecular panels is another area warranting increased payor attention; payors should ensure strong medical and coverage policies to prevent abusive billing
- Remote neuromonitoring is also a continued area of concern

Three areas where intensive focus on payor fraud, waste and abuse detection and prevention efforts will pay significant dividends in 2025 involve reimbursement for emergency department facility services, molecular panels and remote neuromonitoring.

Emergency services

Emergency service disputes will again be a focal point for fraud, waste and abuse investigations, with a particular focus on facility (hospital/freestanding emergency room (ER)) upcoding of evaluation and management (E/M) charges and challenges to payor policies on the handling of high-level E/M codes.

Emergency facilities coding differs significantly from emergency provider coding. Emergency provider billing refers to the professional services rendered based on the complexity and intensity of such services. Emergency facility billing, by contrast, is based on the volume and intensity of resources required for the care.

Recent reports show a trending shift in how ER facility E/M codes are reported, with a decrease in lower-level codes (99282 and 99283) and a corresponding increase in the two highest-level codes (99284 and 99285). This has caused investigations into the reasons for the shift, policy changes by some payors and ongoing payor/provider disputes as a result.

The American College of Emergency Physicians (ACEP), although an organization for physicians, has developed guidelines providing a general framework for ER facility billing of E/M codes. However, there is no national standard for ER facility billing, and less guidance (and therefore more ambiguity) exists for ER facility coding than for provider coding. Moreover, ER facilities are more often using software or algorithms to assign E/M codes, which may lend themselves to upcoding.

Emergency facility use of the ACEP guidelines and certain algorithms have faced legal challenges, including allegations that they facilitate upcoding and/or do not properly account for variations (such as size, volume, staffing and equipment) among emergency departments. Discovery (including expert discovery) will focus on the use of programs and algorithms to assign coding.

On the payor side, there has been an increase in litigation and arbitrations challenging payor policies intended to ensure accurate coding of ER facility E/M codes. This includes disputes over payors' use of third-party vendors or software to flag certain high-level E/M claims for medical records and/or downcode high-level codes when certain criteria are met.

Such challenges require proactive steps. First, the payor should review and update its medical policies to educate providers and clarify the proper use of Level 4 and 5 facility services.

Second, the payor should set up routine requirements specifying whether and when records need to be submitted with claims to justify high-level coding.

Finally, it should consistently audit for trends in high-level E/M codes, particularly in cases where the patient is treated and released.

Of course, all the foregoing must be implemented consistent with any notice requirements in participating facility agreements.

Reimbursement for molecular panels

Molecular panels are laboratory tests that analyze multiple genes or biomarkers simultaneously to diagnose, predict or guide treatment for various diseases or conditions. Examples of molecular panels include genomic sequencing panels for cancer, pharmacogenomic panels for drug response and infectious disease panels for pathogen identification. Molecular panels can offer clinical benefits such as increased accuracy, efficiency and personalization of care, but may pose challenges for payors in terms of coverage, coding and payment policies.

One main challenge for payors is determining the medical necessity and appropriateness of molecular panels, especially when they include genes or biomarkers that are not well established, validated or clinically useful for the patient's condition. Payors also may face difficulties in applying consistent and transparent criteria for coverage and reimbursement of molecular panels, given the lack of standardization and regulation in the molecular testing industry. Furthermore, payors may encounter abusive or fraudulent billing practices by some laboratories or providers who perform or order unnecessary, duplicative or excessive molecular panels to inflate reimbursement. In many instances, providers are billing for molecular panels for routine urinary or wound care when there is no medical justification for these expensive tests that can cost thousands more than a routine urine collection and laboratory analysis. Related to this, there are concerns regarding laboratories courting professional providers to run tests in their offices in order to bypass payor policies that deny or limit reimbursement when performed by laboratories – particularly non-contracted ones.

To address these challenges, payors should consider implementing the following:

- Strong medical and coverage policies that clearly define the clinical indications, evidence requirements and limitations for molecular panels.
- Appropriate coding and payment methodologies that reflect the value and complexity of molecular panels, and discourage overutilization and unbundling of tests.
- Enhanced data analytics and audit capabilities to find outliers, trends and patterns in molecular panel billing and utilization, taking corrective actions when needed.

Remote neuromonitoring

Remote neuromonitoring (RNM) is a type of telehealth service that involves the continuous or periodic monitoring of a patient's neurological activity by a qualified professional located remotely from the patient. RNM can be used for various purposes, such as detecting seizures, assessing brain function, guiding neurosurgical procedures or managing chronic pain. RNM can potentially improve patient outcomes, reduce complications and lower costs by providing real-time feedback, diagnosis and intervention.

However, RNM is also an area of concern for payors as it may be subject to inappropriate or excessive use, billing or reimbursement. Some of the issues that payors may encounter with RNM include:

- Lack of clear medical necessity or clinical benefit in certain situations, such as routine or low-risk procedures, asymptomatic or stable patients, or prolonged or indefinite monitoring periods.
- Lack of proper supervision, credentialing or documentation of the RNM service by the remote professional, or lack of coordination and communication with the treating physician or facility.
- Improper coding or billing of RNM services, such as using incorrect or outdated codes, unbundling or upcoding of components, or double billing for the same service by multiple providers or facilities.
- Inflated or unreasonable charges or reimbursement rates for RNM services, especially when compared to similar or alternative services.

To prevent or mitigate these issues, payors should develop and enforce robust medical and coverage policies that specify the criteria, standards and expectations for RNM services. Payors should also verify the accuracy and validity of RNM claims, and ensure that they are consistent with the plan terms, coding guidelines and payment rules. Moreover, payors should monitor and audit RNM claims and providers for any signs of fraud, waste or abuse, and take appropriate actions to recover overpayments or prevent future violations.

For more information on this article, please contact Bryan Webster and Kate Katchen

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Management of third-party vendor utilization management, audits and post-payment claims reviews

Takeaways

- MCOs face legal risks from their vendors' decisions and compliance issues
- Payment/medical policies and plan terms must be current and adequately followed
- Risks of improper denial are lessened by aligning vendor incentives with billing accuracy and quality of care

Improper vendor decisions can endanger insurers

Health insurance companies often rely on third-party vendors to perform functions related to utilization management, preauthorization or claim audits. These vendors can add value in helping review claims for medical necessity, appropriateness and cost-effectiveness of health care services given their subject matter expertise and economies of scale. However, outsourcing these tasks to third parties may expose health insurers to legal risks, especially if the vendors use questionable methods, criteria or algorithms to deny or reduce coverage for care.

One of the primary legal risks for insurers is a lawsuit from health care providers or members who challenge the decisions made by vendors. For instance, vendors hired by managed care organizations (MCOs) to handle prior authorization requests have been accused of using improper claim algorithms to increase denial rates, thereby inappropriately cutting costs for MCOs. Both MCOs and vendors have been sued by providers and members alleging breach of contract, bad faith, negligence, fraud and violations of federal and state laws. In addition to the potential liability for alleged improper claim denials, MCOs also face potential penalties, punitive damages and attorneys' fees.

Another legal risk for MCOs is regulatory scrutiny or enforcement actions from federal or state agencies that oversee health insurance markets and consumer protection. For instance, the Centers for Medicare and Medicaid Services (CMS) has audited MCOs and vendors for compliance with Medicare and Medicaid rules and standards, and has imposed fines, sanctions or corrective actions for violations. Additionally, some states have enacted laws or regulations that impose specific requirements or limitations on the use of prior authorization, utilization review or claim audit processes by MCOs and vendors, such as disclosure, transparency, timeliness, accuracy and appeal rights.

On top of these litigation and regulatory risks are potential reputational harms to MCOs related to unfavorable publicity stemming from failure to properly oversee and manage vendors' claims review activities. As a result of these potential pitfalls, MCOs should carefully research, select and monitor their vendors, paying attention not only to cost savings achieved by partnering with them but also ensuring that they have adequate contractual safeguards, operational controls and quality assurance mechanisms in place. Our team has identified areas of concern and suggested actions to help minimize legal risk.

Strategies for mitigating the risks

Sources for claim review

Whose policy is being used? If the MCO has created its own medical policy, it will want to ensure the vendor uses that policy in its claim reviews rather than a competing policy created by the vendor.

Are the payment and medical policies that vendors use up to date? There is significant risk when: (1) the most recent medical and scientific literature is ignored in claims reviews and audits; and/or (2) the vendor fails to apply the current medical and scientific literature appropriately.

On the first issue, MCOs need to ensure that the vendor has appropriate procedures in place to identify current medical and scientific research, evaluate medical services and treatments, and understand the standard of care in the medical industry.

As to the second issue, many medical policies used to define benefit exclusions are based upon the application of research studies to validate the medical treatment. In particular, MCOs should be mindful of applying overly restrictive policies that deny a treatment for want of a specific research study when other generalized studies would support its efficacy.

A key example of where this debate has been at the forefront is coverage for proton beam therapy. MCOs may bear unnecessarily higher legal risk in taking a narrow or restrictive view of the efficacy of research studies. In many instances, a better approach may be to consider various studies as evidence of the treatment across different types of cancers where there are significant similarities between medical conditions.

For some MCOs, the issue regarding coverage of these treatments may be the cost of the care compared to other types of treatments. In the proton beam therapy context, this debate usually revolves around coverage of the services in comparison to intensity-modulated radiation therapy (IMRT). Coverage decisions regarding proton beam therapy may be restricted based on the view that IMRT produces equal (or perhaps better) results and is substantially less costly than proton beam therapy treatment. In such situations, a possible solution for reducing legal risk, and reducing abrasion with members, is for the payor to work with vendors by shifting these coverage determinations away from a medical policy determination and instead develop benefit plan terms in which these treatments are covered but only up to the cost of what the MCO believes is a comparable treatment. Thus, in this instance, instead of total exclusion of proton beam therapy treatments, the MCO can develop its benefit plans or work with its self-funded customers to cover these treatments through limited benefit plan coverage language, up to the cost of a similarly situated treatment, and any amounts beyond becoming the member's responsibility as an exception to an allowed amount determination.

Do the policies meet specific federal or state requirements? MCOs should ensure that the medical and reimbursement policies being used by vendors for these utilization management determinations or claims reviews are based on individualized patient circumstances rather than generalized datasets. This approach aligns with the CMS guidelines, which require that medical necessity determinations consider the patient's medical history, physician recommendations and clinical notes. By developing policies that prioritize patient-specific information, MCOs can reduce the risk of inappropriate denials and potential legal challenges.

Robust audits of the methods and criteria being used by vendors

A second critical aspect for MCOs to mitigate legal risks regarding the use of vendors is to employ robust audits and ensure adequate oversight of the vendor's reviews to guarantee accurate application of benefit plan terms and medical and reimbursement policies. These audits should assess the validity and fairness of vendor decisions based on a precise application of medical policies and consistent application of those policies across claims reviews without regard to the underlying benefit plan type. The following are a few best practices to consider:

- **Validate that there is equal and consistent application of plan terms and medical and reimbursement policies across plans.** This includes ensuring:
  - Equal and consistent application of reviews and policies between fully-insured plans versus self-funded plans.
  - Consistent application of reviews and policies across self-funded plan accounts to ensure there is no preferential treatment for certain accounts.
  - If algorithms or artificial intelligence platforms are used to make initial determinations, ensure that these tools are applied equally and consistently; if they generate pre-authorization or claim denials, then ultimate denials must be made by an appropriately credentialed person.
- **Secret shoppers**. The use of secret shoppers also can be an effective tool for MCOs to assess the performance of vendors and validate the member experience. Secret shoppers, posing as members, can evaluate various aspects of vendor services, including wait times, accessibility and the accuracy of medical necessity determinations. The use of secret shopper programs can be a helpful audit tool to test the process on the frontend and complements a robust audit program that focuses on claim reviews on the backend of the process.

Vendor compensation structures

Integrating the right compensation structures similarly can mitigate legal risks by aligning vendor incentives with the delivery of quality care and accurate payment of claims. Traditional contract arrangements, where vendors are incentivized to cut costs, can raise questions about inappropriate denials and potential legal challenges. MCOs should consider compensation structures that reward vendors for accurate adjudication or negotiate a flat rate service rather than merely shared savings. Similarly, if a shared savings model is employed, a hybrid approach should be considered in which payments are tied to additional metrics related to the validation of payments rather than being solely based upon savings derived from the denial of improperly billed claims or recovery of non-reimbursable services. The following chart illustrates potential vendor compensation models and their possible legal risk.

Approach	Compensation arrangement	Legal risk
Best	Compensation based on the number of claims reviewed and accurate evaluation of claims (confirmation that claims paid or adjudicated correctly).	Low
Better	Flat fee compensation structure where payments made to vendor are not tied directly to number of claims reviewed or outcome of claim review.	Mid
Good	Shared savings compensation structure where payments are tied to overall savings and accurate adjudication/validation of claims.	Mid
Fair	Shared savings compensation based solely on savings.	High

By aligning vendor incentives with the delivery of quality care and validation of accurate billing and payment of services, MCOs can reduce the risk of potentially inappropriate denials and subsequent legal exposure.

For more information on this article, please contact Bryan Webster and Eunsoo Choi

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Cyber breach response: Best practices to protect privilege in data breach investigations

Takeaways

- Establish proper processes in your company's breach response plan to enhance privilege protections
- Perform dual-track investigations: one for business operations, another for legal advice and defense at the direction of outside counsel, with separate reports for each
- Limit distribution of legal track communications and materials
- Maintain proper records from business track to determine facts of the data breach

In the realm of managed care, safeguarding privilege during a data breach investigation is paramount. Establishing and deploying best practices is essential to ensure your company's breach response investigation will be protected from disclosure.

A body of case law has emerged concerning the privilege of communications and materials related to data breach investigations. Courts are more likely to require adherence to these practices in future disputes.

By integrating these best practices into your breach response strategy, you can better position your company to protect sensitive information during a data breach investigation.

Breach response best practices

Two-track investigation. As a result of the case law that has developed in this area, it is best practice to conduct a two-track investigation in the event of a data breach – an ordinary business track and a legal track.

Courts have protected data breach investigative materials and communications under the attorney-client privilege and/or work product doctrine where there were two investigative tracks of a company's data breach response. *Maldonado v. Solara Med. Supplies, LLC*, 2021 U.S. Dist. LEXIS 258382, at *12-13 (D. Mass. June 2, 2021) (Work product and attorney-client privilege protections upheld for data breach investigation materials, in part due to the company conducting a two-track investigation).

Separate work streams for each track. One investigative track should handle the ordinary course of business investigation, which includes whether unauthorized activity within the systems environment occurred; whether it resulted in the compromise of sensitive data; the scope of such compromise; and remediation of the breach. *See Leonard v. McMenamins Inc.*, 2023 U.S. Dist. LEXIS 217502, at *9-10 (W.D. Wash. Dec. 6, 2023). The ordinary course of business track investigation should be limited to documenting technical information that likely is not protectable to determine what happened, culminating in a non-privileged report that can be used to help direct the response by IT and Privacy, remediate the data breach and comply with the law.

On the other hand, the legal track investigation should occur under the direction of outside counsel for the purpose of educating counsel about the data breach in order to provide the company with legal advice and prepare to defend the company against anticipated litigation/government actions, culminating in a separate privileged/protected report. To further preserve attorney-client privilege and/or work product protections, the tracks should not communicate with each other about the substance of the legal track investigation. *Id.,* at *9-11.

Retention of consultants by outside counsel. Courts are more likely to uphold attorney-client privilege and work product protections for investigative materials produced by consultants retained directly by outside legal counsel. For example, in *re Marriott Int'l Inc., Customer Data Sec. Breach Litig.*, 2021 U.S. Dist. LEXIS 124874, at *60-65 (D. Md. June 29, 2021) the court found investigative materials were not discoverable where the company entered into a three-party statement of work with its outside counsel and consultant, specifying that outside counsel engaged the consultant on behalf of the company to assist it in providing legal advice to the company.

Ideally, if possible, the company may use different consultants for each track. However, if the same consultant is retained by the company to conduct the investigations for both tracks, steps should be taken to ensure that a wall between the two tracks exists in order to maintain privilege and work product protections as to the legal track.

Specific statement of work for the legal track data breach investigation, separate and distinct from fact-based, ordinary course investigation or consultant's regular work for company. There must be a specific retention agreement for the legal track investigation of the data breach. The legal track investigation should be separated and be distinct from any other work that the company's regular network consultant may have previously agreed to conduct by entering a separate "statement of work" (SOW). The SOW should specifically state that the purpose of the investigation is to prepare for and obtain legal advice for anticipated litigation. In addition, the SOW should distinguish the scope of work to be performed to reflect that the legal track investigation is different from the ordinary business investigative work. Further, the consultant's fees and

expenses for the legal track should be designated and characterized as "legal" rather than "business" expenses.

These best practices are made clear by the developed body of case law on the protection of privilege. In *re Experian Data Breach Litig.*, 2017 U.S. Dist. LEXIS 162891, at *23 (C.D. Cal. May 18, 2017), the court found that an investigative report prepared by Mandiant in response to a data breach was protected work product over plaintiffs' objection. The court reasoned that Mandiant's previous work for Experian was separate from the work regarding this particular data breach.

Conversely, in *re Rutter's Data Sec. Breach Litig.*, 2021 U.S. Dist. LEXIS 136220, at *6-7 (M.D. Pa. July 22, 2021), the court concluded that a consultant's investigative report was not protected work product. The court reasoned that the SOW provided for ordinary business activities "to determine whether unauthorized activity within the Rutter's systems environment resulted in the compromise of sensitive data, and to determine the scope of such a compromise if it occurred."

Legal track investigative communications and distribution of materials must be limited appropriately. The fact-based, non-privileged report will be developed alongside and shared with the company's IT, security and privacy teams, as well as outside regulators, and to the extent you are providing updates to your Board of Directors regarding business, as opposed to legal, interests in response to the cyber incident. In contrast, the legal track investigative information, report and communications must be limited appropriately. Courts are more likely to uphold work product protections where a company limits access to legal track investigative materials to in-house and outside counsel and others who need to know for purposes of providing legal advice.

For instance, in *Experian*, 2017 U.S. Dist. LEXIS 162891, at *25, the court upheld work product protections for a report created by an outside consultant where the company limited the number of individuals to which it provided the report, which was not given to Experian's Incident Response Team or personnel working on remediation of the systems involved in the attack. In contrast, in *Wengui v. Clark Hill, PLC*, 338 F.R.D. 7, 12 (D.D.C. 2021), the court distinguished *Experian* noting that the consultant shared the investigative report "not just with outside and in-house counsel," but also with select members of the company's leadership and IT team, as well as the FBI.

Finally, the need to impose strict limitations is particularly critical in the event that applicable law applies the "control group" test to evaluate claims of attorney-client privilege in subsequent litigation regarding the data breach. In *Midwesco-Paschen Joint Venture for the Viking Projects v. Imo Indus.*, 638 N.E.2d 322, 329 (Ill. Ct. App. 1st Dist. 1994), the court noted that "distribution of otherwise privileged material to individuals outside of the control group destroys the privilege."

Ensure that non-privileged, fact-based forensic records are maintained. Courts have upheld work product protections when alternative avenues exist to evaluate factual information concerning the data breach, such as from the ordinary business investigative track. For example, in *Experian*, the court found that the plaintiffs, through discovery, could get the same information as produced in the outside consultant's report in discovery through their own expert. 2017 U.S. Dist. LEXIS 162891 at *24-25.

By adhering to these best practices, managed care organizations can maximize the protection of the communications and work product generated by the legal track from disclosure under the attorney-client privilege and/or work product doctrine, particularly in the context of subsequent data breach litigation or governmental actions.



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

Litigation and trends

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Medicare Advantage Stars: What's next now that the litigation floodgates have opened?

Takeaways

- CMS has systemically made higher Stars more difficult to achieve, leading to lower ratings and reduced quality bonus payments
- In 2023-2024, Medicare Advantage plans sued CMS over Star Ratings, leading to higher ratings for 40 plans and $1.3 billion in bonuses
- Plans have sued over 2025 Star Ratings, a trend likely to continue due to their complexity and financial impact

For years, Medicare Advantage (MA) plans went through the process of receiving their Star Ratings, generally accepting them and moving on to the next year. However, in recent years, CMS has systemically tweaked the ratings methodology with the stated purpose of driving down the Stars Ratings and the corresponding quality bonus payments.

CMS's drag on ratings has resulted in a consistent decline of Star Ratings across the country, straining plan revenue and threatening member benefits. Starting in late 2023, plans went on the offensive against CMS, with Elevance and SCAN Health leading the charge, suing CMS under the federal Administrative Procedures Act for violating its own regulations in calculating Star Ratings. The result was a significant legal victory for the plans, and CMS ultimately changed the 2024 Star Ratings for all plans – leading to higher ratings for 40 plans and CMS paying an additional $1.3 billion in bonuses.

The 2023 Star lawsuits opened the floodgates to litigation challenging the Star Ratings. So far in 2024, at least five plans–UnitedHealthcare, Humana, Elevance Health, Centene and Blue Cross Blue Shield of Louisiana – have filed. The 2024 lawsuits are vastly different from the 2023 cases, as the theories advanced by each plan are wide-ranging and challenge various aspects of Star Ratings. For instance, United and Centene challenged a single phone call that impacted their Call Center measures, while Humana and Elevance Health have brought broader challenges to different aspects of how CMS calculates ratings.

What does this onslaught of lawsuits mean for the future of Star Ratings? Two items rise to the top of the list:

- **Plans will be forced to continue to challenge Star Ratings, but need to be creative in doing so**: Given CMS's systemic pushing down of MA payments overall, plans generally need Star Rating quality bonus payments to continue offering reduced premiums and supplemental benefits. We can anticipate that for the foreseeable future, plans will bring lawsuits each year that just miss out on quality bonus payments. The 2024 lawsuits show some insight on how plans can challenge specific CMS decisions, including in the call center measures where the facts are often limited and CMS's decision-making is opaque. Beyond the call center methods, plans can capitalize on the lack of statutory and regulatory foundation for Star Rating calculations and can be creative in developing theories.
- **CMS will probably take regulatory steps to reduce the likelihood of lawsuits**: CMS has already taken steps to reduce the impact of the Call Center measures by making Call Centers less important to the overall Star Rating. We can anticipate that CMS will continue to attempt limiting the variability in the Star Rating calculation process. For instance, CMS may continue to reduce the impact on the overall Star Rating of measures that require subjective interpretation of data, or it may revise their processes to be more transparent. Time will tell what CMS does, but we can be certain that it will do something and that the lawsuits will continue to mount.

In light of this foreseeable future, what can plans do to prepare for next year's Star Ratings? First and foremost, plans need to ensure that they improve their operations to position themselves for the best initial Star Ratings possible. Second, plans need to be extremely proactive during Plan Preview 1 and Plan Preview 2, which is when CMS allows plans to ask questions and raise challenges to data. We have repeatedly seen CMS change measure calculations during these Preview periods based upon plan challenges. Third and finally, plans need to consider litigation as an option to challenge Star Ratings that are lower than anticipated. Health plan counsel should engage their Stars team during the Plan Preview periods to appropriately raise those challenges and set the stage for possible litigation.

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Steve Hamilton

Health care: An evergreen area for antitrust enforcement

Takeaways

- Antitrust agencies will likely continue focusing enforcement resources on dominant market players despite the U.S. government switchover
- The Trump-Pence health care report emphasized competition and antitrust enforcement to manage health care costs, suggesting vigorous health care antitrust enforcement will persist in the new administration
- Information transfers among affiliated entities, out-of-network reimbursement calculators, and use of market power to steer self-referrals have been investigated

The change in control of the White House and the Senate that will take place later this month is expected to bring major shifts in federal antitrust enforcement. Commentators predict that the new administration will be more friendly to mergers but perhaps just as focused on reining in dominant tech companies as the Biden administration has been. Where does health care fall? The record of the first Trump administration and an active private plaintiffs' bar suggest that managed care companies should continue to take active steps to mitigate antitrust risk and monitor key case developments in 2025 and beyond.

At the outset of the Trump-Pence administration, the Departments of Health and Human Services, Treasury, and Labor and the Federal Trade Commission issued a joint report titled *Reforming America's Healthcare System Through Choice and Competition*. That report proposed managing health care costs by removing regulations and promoting competition, including through "vigorous" antitrust enforcement to prevent the accumulation of market power, particularly by health care providers. This is consistent with an evergreen approach to health care enforcement that persists across administrations and may set the tone for the Trump-Vance approach to enforcement.

As we transition to a new administration, antitrust enforcers may continue their focus on dominant players on both sides of the market. The FTC under chair Lina Khan targeted private equity roll-ups of providers, most publicly in the pending litigation against U.S. Anesthesia Providers in federal court in Texas. The Trump administration is unlikely to view private equity itself as a pernicious influence on health care, but it may well maintain the focus of the Trump-Pence administration on targeting dominant market participants regardless of whether or not they are backed by private equity. On the payor side, a health insurance company is currently under investigation for its firewall practices and the flow of potentially competitively sensitive information between its various affiliated entities. This is the sort of ordinary course antitrust enforcement that typically continues from administration to administration.

On the private enforcement side, the MultiPlan MDL will test whether plaintiffs will gain traction after some early setbacks with algorithmic price-fixing claims against payors that use third-party services in pricing out-of-network claims. A private company and a utility workers' union have filed putative class claims against a Blue Cross Blue Shield entity for allegedly leveraging monopoly power in the TPA market to force ASO customers to purchase stop-loss insurance. This presents a novel antitrust challenge to unilateral conduct that we will be watching closely.

Despite the change in government, antitrust scrutiny of market players' arrangements in the managed care space is unlikely to significantly recede in 2025.

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Developments in ERISA health benefit litigation

Takeaways

- Members are increasingly filing class actions alleging disability discrimination due to exclusion of weight loss medications, with more cases expected in 2025
- There is a rise in behavioral health litigation under ERISA and MHPAEA, with some courts requiring detailed denial letters, leading to divergent federal circuit views
- Laboratory providers continue to file claims against health plans for improper reimbursement of COVID-19 testing, with mixed success under various legal theories

The past year brought several trends in Employee Retirement Income Security Act (ERISA) health benefit litigation that should continue into 2025. Members filed a new wave of cases focused on coverage for obesity medication; they also filed behavioral health/mental health parity cases in increasing numbers; and laboratory providers brought a growing number of suits against health plans and administrators concerning COVID testing and other issues. In 2025, plans and administrators should be prepared to respond to these continuing trends.

Members allege obesity discrimination and seek coverage of weight loss drugs

In a surge of new cases, members filed class actions alleging that plans and administrators engaged in disability discrimination by excluding coverage for weight loss medications such as Wegovy and Zepbound. In these suits, plaintiffs allege that plans and administrators violated the Affordable Care Act's protections against discrimination by crafting and maintaining benefit exclusions

for medications used for weight loss. They assert a variety of theories, including intentional discrimination, disparate impact and proxy discrimination (i.e., that a "weight loss" exclusion targets obese members and only appears neutral). It remains to be seen whether these theories will withstand early motions. Because some members argue that an obesity diagnosis requires a holistic evaluation of the patient's clinical circumstances, courts may conclude that class certification would be inappropriate because individualized issues predominate over common ones. Managed care companies should expect additional filings in 2025, especially under ERISA, given the increase in prescriptions for these medications and the number of plans that are expected to restrict coverage for the drugs in 2025 given the drugs' high cost. Plans and administrators should consider the risk of litigation when determining whether to modify plan coverage terms for weight loss drugs.

Behavioral health cases abound

In 2024, members filed more suits concerning behavioral health under ERISA and the Mental Health Parity and Addiction Equity Act. An important development in this space occurred in September 2024 when the Fifth Circuit joined the Tenth Circuit in finding that denial letters must contain detailed information, such as specific references to medical records, to satisfy ERISA's "meaningful dialogue" standard. *See Dwyer v. United Healthcare Insurance Company*, 2024 U.S. App. LEXIS 23866 (5th Cir. Sept. 19, 2024). Other circuits will have the opportunity to consider adopting the same rationale in 2025. Due to these rulings, different federal circuits now have increasingly divergent views on how an administrator must communicate its determination to members, at least for behavioral health services. Whether courts will apply the Tenth and Fifth Circuits' rationale to denial letters for other types of services, such as inpatient medical care, also remains an open question. In this evolving environment, claims administrators should review their current practices for responding to appeals concerning behavioral health services. They should also consider modifying their appeal letters to either include or attach more detailed information regarding the bases for denials.

Labs file new cases around COVID testing

The uptick in claims brought by laboratory providers accelerated in 2024, and we forecast that 2025 will be similar. While laboratory providers asserted a host of discrete issues, COVID-19 testing looms large among them. Providers and medical laboratories have continued to bring claims against health plans regarding the plans' failure to properly reimburse COVID-19 testing services, typically asserting breaches of the Families First Coronavirus Response Act and the Coronavirus Aid, Relief, and Economic Security Act. Courts have generally held that providers do not have a private cause of action under either statute. *See, e.g.*, *Biodiagnostic Labs, Inc. v. Aetna Health Inc. (New York)*, No. 23-cv-9570 (BMC), 2024 U.S. Dist. LEXIS 110217, at *4 (E.D.N.Y. June 23, 2024) (collecting nine other cases). Providers have had more luck asserting claims under ERISA, as well as under state law theories like promissory estoppel, unjust enrichment or breach of contract. Few of these cases have produced rulings on the merits of these claims, so 2025 may bring a better indication of where this area of litigation is headed. To defend these types of cases, in-house counsel for managed care companies should understand their companies' practices for reimbursing laboratory services, including COVID-19 testing. They should also investigate whether they may have grounds for counterclaims, given that many COVID-19 testing companies have been sued for or charged with fraud.

Conclusion

The litigation trends discussed above present significant potential risk and expense to plans and their administrators. Managed care companies should pay attention to these areas in 2025 and consider some of the steps laid out above to enhance their ability to defend any suits filed against them.

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

How recent ERISA decisions may forecast trends in bad faith litigation

Takeaways

- Trends in recent ERISA decisions spotlight conduct that can subject plans to bad faith litigation
- New ERISA rulings hold that health plans breach their duties by sending denial letters that lack specific references to medical records, detailed explanations and particularized evaluations of the member's needs and by ignoring materials sent by providers during claims appeals
- By evaluating and addressing potential deficiencies now, health plans may be able to buttress their defenses to bad faith actions

Bad faith litigation represents a costly and constant financial burden on health plans. An aggressive plaintiff's bar increasingly exploits liberal discovery rules in state and federal courts seeking a smoking gun. Health plans frequently settle these actions in order to avoid the potential for an enormous – **nuclear** – award of punitive and emotional distress damages. Identifying and proactively addressing trending issues in ERISA litigation may prevent those trends from spreading to bad faith actions involving non-ERISA plans.

ERISA litigation is a highly active area of law, with thousands of cases filed every year by members seeking to recover benefits under employer-sponsored health plans. In contrast to non-ERISA actions, ERISA cases involve limited discovery, limited damages and bench trials. Consequently, ERISA disputes are fast-moving and involve risks limited to the value of benefits, costs of litigation and, potentially, plaintiff's attorney's fees. ERISA matters also frequently result in opinions that, when awarding benefits, can outline courts' views on the sufficiency of a plan's claims handling practices and its communications with members.

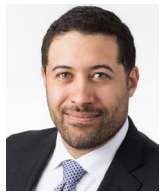
Most directly, because nearly all states have adopted some form of an Unfair Claims Settlement Practices Act, which generally lists various forms of conduct by a plan that may constitute unfair claims practices – such as misrepresenting policy terms, failing to conduct a reasonable investigation or not attempting to settle claims in good faith – ERISA decisions provide easy guideposts to plaintiffs' attorneys when probing for deficiencies in a plan's claims handling practices. As a result, ERISA litigation provides a testing ground for both health plans and plaintiffs to argue over the interpretation and application of contract provisions, clinical care guidelines and claims handling practices.

With this in mind, several recent trends in ERISA litigation may impact bad faith litigation. In particular, federal courts have increasingly scrutinized the content of denial letters. In 2023, the Tenth Circuit Court of Appeals ruled against a health plan, finding that the plan failed to engage in a "meaningful dialogue" with the member because the plan's denial letter did not inform the member of the rationale for the denial or address the specific points raised by the treating provider. (See related articles *Developments in ERISA health benefit litigation* by Tom Hardy and Jason Fontenot; and *Denial letters likely to remain under fire in 2025* by Rebecca Hanson.)

Other courts similarly rejected denial letters that defined a service as experimental or investigational without tying the decision to the health plan's definition of those terms or notifying the member regarding which component of the definition was not satisfied. Continuing this trend, in the fall of 2024, the Tenth Circuit adopted the Fifth Circuit's "meaningful dialogue" standard in finding that a health plan did not provide the member with a "specific reason" for the denial and lacked an explanation of the scientific or clinical judgment for the denial.

Each of these ERISA-based grounds may also form the basis of bad faith claims under state law, as they may indicate that the health plan acted unreasonably, unfairly or in bad faith in handling the claim. Indeed, we have recently seen a number of cases filed alleging bad faith against plans where the plaintiffs base their claims on misrepresentation of policy terms, failure to conduct an adequate investigation and failure to pay claims for which liability was apparent – all due to lack of detail in denial letters to members.

Plans should act proactively to prevent or minimize the impact of plaintiffs' attorneys adopting successful strategies from ERISA decisions by using these decisions as a guide to evaluate and improve their claims handling practices and policies, as well as their communications with members. Health plans should communicate clearly and accurately with their members regarding the basis and process of their decisions, and ensure they conduct a reasonable and thorough investigation of each claim that is documented in detail. By taking a few simple steps, plans may reduce the risk of bad faith claims, protect their reputation and financial interests, and better serve their members.



For more information on this article, please contact Robert Deegan and Adam Pullano

Notable court opinions deny class certification or strike allegations

Takeaways

- Comb the discovery record
- Don't forget typicality and adequacy issues
- Don't shy away from motions to strike class allegations

Oftentimes, class action defense counsel are faced with herculean challenges, such as plaintiff-friendly jurisdictions, red herrings in the discovery record and courts' reflexive tendency to dismiss motions to strike as a "rarity." But hope does spring eternal. This article summarizes five notable court decisions that push back on the plaintiffs' bar's plethora of putative managed care class actions.

Wit v. United Behavioral Health, 79 F.4th 1068 (9th Cir. 2023).

The Ninth Circuit Court of Appeals affirmed in part and reversed in part the district court's judgment in favor of plaintiffs who alleged that United Behavioral Health improperly denied coverage for mental health and substance use disorder treatment based on internal guidelines that were inconsistent with the terms of their ERISA-governed plans and state-mandated criteria.

The court held that the district court erred in certifying the denial of benefits classes without limiting them to those whose claims were denied based on the applicable challenged portions of the guidelines. Such certification violated the Rules Enabling Act, which prohibits the use of procedural rules to enlarge or modify substantive rights. The court also held that the district court erred in interpreting the plans

to require coverage for all care consistent with generally accepted standards of care (GASC), as the plans only required coverage for care that was consistent with GASC and met other conditions and exclusions.

Crosby v. California Physicians' Service, 498 F. Supp.3d 1218 (C.D. Cal. 2020).

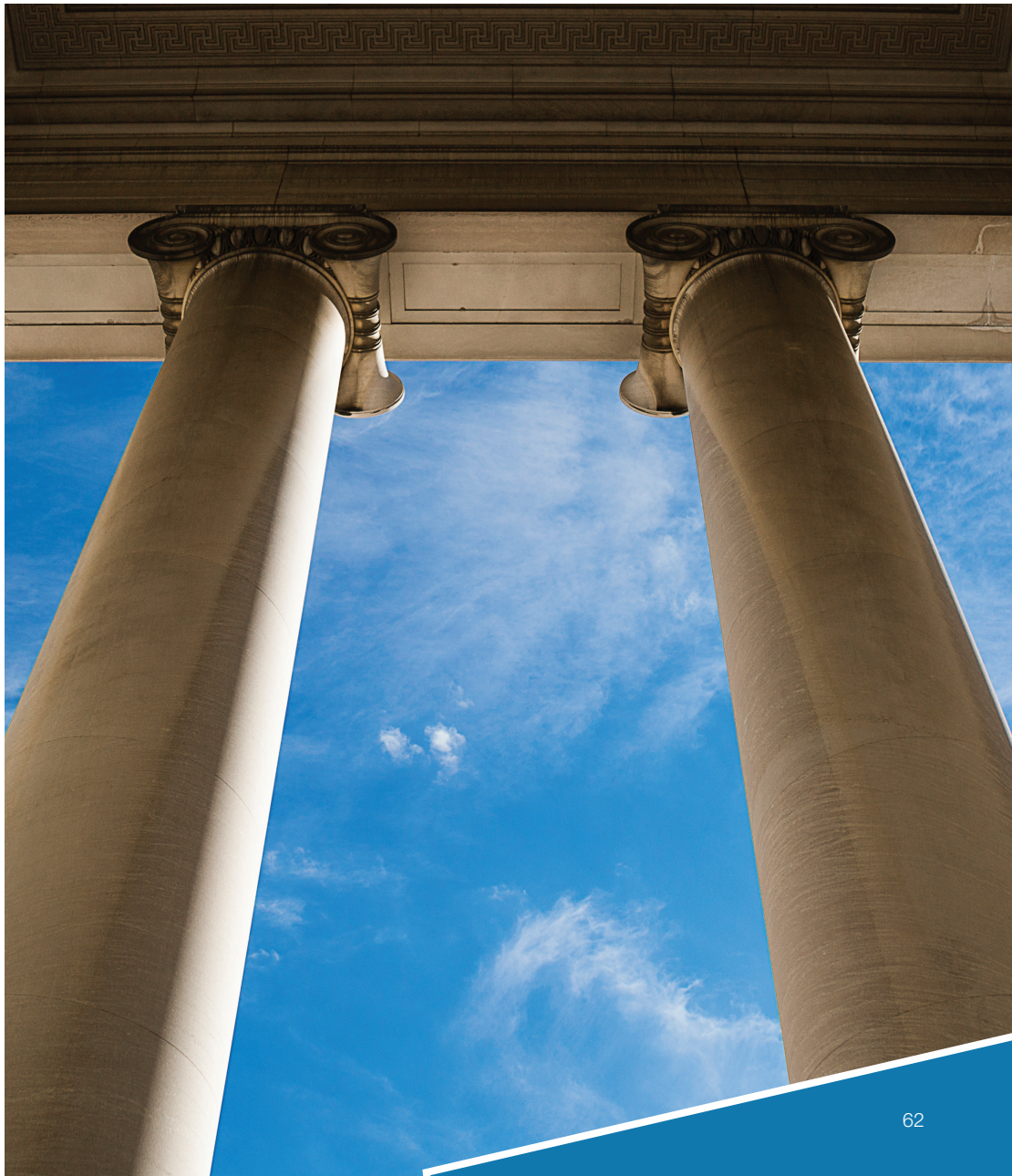
In *Crosby*, the court denied the plaintiffs' class certification motion. The plaintiffs alleged that California Physicians' Service improperly considered age and therapy history in medical necessity determinations for children with autism, which led to the denial, reduction or revision of coverage for applied behavior analysis (ABA) therapy.

The plaintiffs did not present data showing how many ABA users had their hours revised down, reduced, or denied based on medical necessity criteria, which was necessary to be part of the class. The court also highlighted procedural issues, including the plaintiffs having twice changed their proposed class definition and not describing the final proposed class in the operative complaint. The court concluded that the plaintiffs' claims were too individualized and that the involvement of ABA providers complicated the redressability of the plaintiffs' alleged harms, making class certification inappropriate.

Amy G. v. United Healthcare, No. 2:17-cv-00413-DN-EJF, 2020 U.S. Dist. LEXIS 101752 (D. Utah June 9, 2020).

In *Amy G.*, the court denied the plaintiffs' class certification motion. The case involved ERISA claims for benefits and equitable relief arising from the defendants' denial of insurance coverage for wilderness therapy.

The court grounded its decision on plaintiffs' failure to establish commonality. Plaintiffs admitted that the defendants did not apply the alleged uniform policy to all claims for coverage for wilderness therapy and acknowledged that the defendants' review of wilderness therapy claims varied. The putative class members' medical conditions, the wilderness therapy they participated in and the terms of their benefits plans also were too varied to satisfy commonality. The court concluded that these same reasons also precluded a finding of predominance and superiority.



Day v. Humana Ins. Co., 335 F.R.D. 181 (N.D. Ill. 2020).

In *Day*, the court struck the plaintiff's class allegations. The plaintiff, who was diagnosed with brain cancer, sued Humana and OSF Healthcare System Group Medical and Dental Plan for its denial of proton beam radiation therapy on the grounds of medical necessity and experimental treatment.

The court concluded that the plaintiff's class allegations failed to establish the existence of common questions of law or fact, in key part because plaintiff's class allegations "do not identify any 'glue' that unites 'the alleged reasons' for which Humana denied each putative class member's benefits claim." Additionally, the proposed class was deemed a fail-safe class, which is impermissible.

J.P. v. BCBSM, Inc., No. 18-3472, 2021 U.S. Dist. LEXIS 7462 (D. Minn. Jan. 14, 2021).

In *J.P.*, the court denied the plaintiffs' class certification motion. The plaintiffs alleged that BCBSM improperly applied offsets to their claims based on differing plan documents.

The plaintiffs' class theory lacked commonality, as they did not identify a common policy or practice that affected all class members in the same way. The plaintiffs' claims also lacked typicality, as they faced unique defenses based on their provider's lack of licensure and their failure to exhaust administrative remedies. Further, the plaintiffs were not adequate class representatives because they had conflicts of interest with other class members and did not demonstrate their knowledge of the case. The court then held that the plaintiffs failed the predominance and superiority requirements on similar grounds.

In key part, these five opinions illustrate that managed care organizations in similar putative class actions should not forget to dig into the discovery record, keep typicality and adequacy issues in mind and analyze the propriety of moving to strike class allegations where flaws in a plaintiff's class theory are plain on the face of their complaint.

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Ninth Circuit solidifies ERISA preemption of state "out-of-network provider" laws

Takeaways

- Federal appeals court declines to enforce state law holding plan to promises allegedly made in benefit calls, finding instead that ERISA governs the claim
- The Bristol decision bars providers from using state-law claims to challenge or circumvent the reimbursement rules and practices of ERISA plans and MCOs
- The decision has been followed by several district courts in the Ninth Circuit that have dismissed various state-law claims by out-of-network and in-network providers on the basis of ERISA preemption

The recent Ninth Circuit decision, *Bristol SL Holdings, Inc. v. Cigna Health & Life Insurance Co*., 103 F.4th 597 (9th Cir. 2024), provides a strong ERISA preemption defense for managed care organizations (MCOs) facing off against out-of-network (OON) providers who seek additional reimbursement beyond plan terms. This decision emphasizes that ERISA preemption is broad enough to enforce plan payment rates and methodologies, thereby limiting OON providers' ability to vary payment terms based on verification or authorization calls to MCOs.

Background

MCOs routinely face state-law claims by OON providers seeking to recover additional reimbursement based on statements made during preservice verification of benefit (VOB) and authorization calls. Historically, courts have ruled that these types of claims are not preempted by ERISA as they involve "independent" obligations unrelated to an ERISA plan. However, the Ninth Circuit's *Bristol* decision on May 31, 2024 changed this landscape.

The Ninth Circuit's opinion limited, if not foreclosed, OON providers' ability to seek reimbursement beyond plan terms based on VOB and authorization communications. In the published opinion, the Ninth Circuit held that ERISA preempts a medical provider's state-law claims based on the failure to pay the amount that the insurer said would be paid during VOB and authorization calls.

The holding in *Bristol*

Bristol, the successor-in-interest of a defunct OON drug rehabilitation and mental health treatment center, brought derivative state-law breach of contract and promissory estoppel claims against Cigna. Bristol aimed to recover reimbursements Cigna withheld after discovering the provider had been engaging in fee-forgiving, i.e., waiving member copayments and deductibles – a practice prohibited under the terms of the ERISA plans it administered. Bristol argued that a contract was created when Cigna indicated that it would reimburse the provider at a percentage of the usual and customary (UCR) rate during VOB and authorization calls. Bristol claimed Cigna breached the alleged contract by refusing to pay because of the provider's alleged fee-forgiving. After a lengthy procedural history, the district court granted summary judgment to Cigna, holding that ERISA preempted Bristol's state-law breach-of-contract claims.

Bristol appealed, arguing that the VOB and authorization calls to Cigna established independent contractual obligations between Cigna and the provider, unrelated to the ERISA plans at issue. The Ninth Circuit rejected this argument and affirmed the lower court's opinion. It held that Bristol's state-law claims were preempted, as they had a "reference to" and an "impermissible connection" with the ERISA plans Cigna administered.

The appeals court found that the state-law claims had a "reference to" an ERISA plan because Bristol's calls to Cigna were meant to determine whether reimbursement is available under the ERISA plans that Cigna administered. It noted that by attempting to secure payment for plan-covered services through state contract law, Bristol sought a remedy it could not obtain under ERISA.

The court found that Bristol's claims interfered with a central matter of plan administration. Specifically, allowing providers to create binding contracts through pre-treatment calls would risk undermining plan terms, which are not typically applied before treatment. The court explained that if providers could use state contract law to enforce insurers' representations during these calls, benefits could be governed by numerous calls and varying state laws, rather than by ERISA and plan terms – a scenario ERISA preemption is meant to prevent.

The court also distinguished its prior ruling in *The Meadows v. Employers Health Ins.*, 47 F. 3d 1006 (9th Cir. 1995), where the provider's state-law claims were based on misrepresentations that coverage existed when no ERISA plan was in effect. In *Bristol*, it was undisputed that the patients were eligible for coverage for the services at issue.

Post-*Bristol* decisions

Several district court have followed the *Bristol* precedent, dismissing a variety of state-law claims by OON providers based on ERISA preemption:

- *Keith Feder, M.D., Inc. v. Aetna Life Ins. Co.* (C.D. Cal. June 25, 2024): The court ruled that ERISA preempted a provider's state-law claims for promissory estoppel and negligent misrepresentation, which were based on Aetna's VOB call assurance that it would pay UCR rates. The court held that preauthorization communications could not create obligations conflicting with ERISA plan reimbursement rules and dismissed the claims with prejudice.
- *Healthcare Ally Mgmt. of Cal., LLC v. United Healthcare Servs., Inc.* (C.D. Cal. July 15, 2024): Interpreting *Bristol* broadly, the court held that state-law claims for reimbursement for medical services would be preempted unless they stem from a complete lack of ERISA plan coverage (on appeal).
- *Dedicato Treatment Ctr., Inc. v. Aetna Life Ins. Co.* (C.D. Cal. July 8, 2024): Following *Bristol*, the court found ERISA preemption for an OON substance abuse provider's claims for breach of contract, promissory estoppel, *quantum meruit* and unfair competition (on appeal).
- *Healthcare Ally Management of California, LLC v. Arup USA, Inc.* (C.D. Cal. Aug. 26, 2024): Another district court dismissed similar claims, granting a motion for judgment on the pleadings (on appeal).
- *Coast Surgery Center v. United Healthcare Insurance Co.* (C.D. Cal. Oct. 25, 2024): The court dismissed OON provider claims based on ERISA preemption, further solidifying the *Bristol* precedent.

Other courts have applied *Bristol* to dismiss state-law claims in different contexts. For instance, in *Cal. Brain Inst. v. United Healthcare Servs*. (C.D. Cal. Sep. 30, 2024), ERISA preempted state-law claims related to withholding payments from an OON provider as an offset for overpayments on a separate plan. The court ruled that these claims were preempted because they involved ERISA plan administration issues, including cross-plan offsetting.

In *THC-Orange Cty., LLC v. Regence Blue Shield of Idaho, Inc*. (D. Idaho Aug. 30, 2024), the court cited *Bristol* to find that ERISA preempted an in-network provider's state-law claims. The claims, based on alleged underpayment under a provider agreement, were preempted because, without the ERISA plan, the insurer would have no payment obligation.

Potential impact on state court cases

While the issue is not settled under state law, *Bristol* could have a significant impact on future state-law proceedings. Currently, there is conflicting California state appellate precedent that ERISA does not preempt a provider's contract claims based on VOB calls. In *Morris B. Silver M.D., Inc. v. Int'l Longshore & Warehouse etc*., 2 Cal. App. 5th 793, 805 (2016), the California Court of Appeal ruled that a provider's claims based on VOB calls were independent of the patient's ERISA plan and thus not preempted. However, *Silver* relied on the same Ninth Circuit cases that the *Bristol* court expressly distinguished, such as *The Meadows,* which the Ninth Circuit limited to situations where no coverage existed despite representations otherwise. This could place *Silver*'s holding in doubt following *Bristol,* leaving state law unsettled.

Key recommendations

MCOs should ensure reimbursement methodologies for out-of-network claims are memorialized and in compliance with ERISA plan benefits. All member- and provider-facing communications should also refer to plan benefits, instead of attempting to shorthand or characterize them in any way. By doing so, when faced with out-of-network claims seeking additional reimbursement based on VOB calls, MCOs will be better positioned to assert ERISA preemption under *Bristol.* Further, for cases brought in California state court, special attention should be paid to whether the case can be removed to federal court given the potential split in authority. Whether in state or federal court, MCOs would do well to assert this defense and draw supportive reasoning from *Bristol.*



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