McDERMOTT HEALTH 2023 ANNUAL REPORT

MANAGED CARE: 2022 YEAR IN REVIEW

McDermott Will & Emery

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SPECIAL REPORT

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INTRODUCTION

The managed care space saw a number of regulatory and legislative developments in 2022 that are shaping the sector as we move further into 2023. Against this backdrop, the healthcare sector itself has continued to transform in response to the demand for improved patient care at lower costs, heightened focus on health equity, and other social and economic issues. Here we review updates across important managed care issue areas—such as risk adjustment, prior authorization and marketing practices—and provide an overview of key market trends. Reviewing managed care developments from the past year can help organizations better understand the broader legal and policy environment and plan for a more productive and effective year ahead.

M&A TRENDS

After a period of pandemic-induced uncertainty followed by a flurry of merger and acquisition activity in 2021, healthcare payors continued to operate strategically to meet the ever-changing demands of regulatory requirements and market dynamics through M&A in 2022. Some of the key trends in managed care acquisitions in 2022 included:

- **Regional Consolidation**: Payors have continued to consolidate to increase or maintain their market share and to remain competitive in the market. We have seen a particular focus at the regional level, with smaller companies being acquired by larger regional payors. This appears to be driven in part by a need to achieve economies of scale in order for regional payors to remain competitive with larger national payors.
- **Diversification**: In recent years, payors have focused on diversifying their capabilities and revenue streams through acquisitions of other adjacent assets, including pharmacy benefit managers, third-party administrators, healthcare technology and provider entities. Payors are also using acquisition strategies to diversify their product offerings, such as expanding Medicare Advantage offerings, which is projected to see record enrollment numbers in the coming year.
- **Vertical Integration**: Amid growing financial pressures from rising healthcare costs, payors can better manage their costs and care coordination for members through the vertical integration of providers. Thus, payors are increasingly acquiring various types of healthcare providers, including home health agencies, physician practices and long-term care facilities. In recent years, joint ventures between payors and providers have also become increasingly common as a preferred alternative to mergers and acquisitions. More details on this trend can be found below.
- **Technology and Data**: As the industry transitions toward a value-based approach to care, digital health and telemedicine services are essential tools for success. Investing in and adopting technology and data capabilities is necessary to improve health outcomes, streamline care coordination and remain competitive in the payor market. Through acquisitions, payors have consequently expanded their capabilities in areas such as data analytics, population health technology, risk assessment and fraud detection to promote the optimization of care and administrative efficiencies. Further, telemedicine services in areas such as behavioral health, remote monitoring and management of chronic conditions offer members flexible and convenient care while simultaneously providing an opportunity for payors to save on costs of care.
- **Expansion into New Markets**: Larger payors continue to pursue expansion into new geographic markets through the acquisition of smaller payors. The benefits of this strategy are twofold – the larger payors not only increase their enrollment, but also build a presence in regions in which they previously did not have access. Large payors may also seek to strategically purchase smaller payors to break into new markets without facing the regulatory concerns of establishing *de novo* plans. In addition to regional market expansion, payors are also looking to adjust their focus between commercial and government business. As evident by a growing Medicare Advantage population and the uncertainty of a looming recession, some major payors have exited the commercial group market space altogether.

- **Private Equity Involvement**: Private equity firms continue to heavily invest in the healthcare industry. The robust provider platforms built by private equity firms give rise to significant M&A and partnership opportunities for payors. Private equity firms continue to view payors as a potential investment exit strategy, and some payors, who are finding themselves behind their competitors in terms of building up providers assets, have seen these platforms as a shortcut to staying competitive in comparison to a *de novo* strategy.

INCREASE IN HEALTH SYSTEM AND PLAN JOINT VENTURES

Continued healthcare transformation and the drive for higher-quality, more-affordable patient care is creating new rationales for payers and providers to rethink historically contentious relationships and to consider previously unexplored ways to work together. An example of this is the increasing number of health systems that are entering into health plan joint ventures, which aim to reduce costs and advance value-based care while generating additional patient volume and revenue for the health system.

From the health system perspective, ownership in a health plan offers an opportunity to drive additional patient volume to the system. Health systems, which have been facing continued revenue strain due to the pandemic, also are viewing an equity stake in a health plan as an opportunity to diversify their revenue streams and to share in the premium and administrative income earned by the plans. Further, ownership in a health plan allows the health system a seat at the table when the plan is deciding on product expansion, entering into new markets and targeting local employers for plan contracts.

> Using a joint venture model helps limit risk for the health system and drastically increases the speed of entering the market.

Many health systems have tried previously to own and operate their own health plan, but doing so requires standing up significant administrative operations and an often-large capital investment. In contrast, a joint venture with an existing payer provides an experienced partner with existing capability and spreads the risks and costs of the venture.

Payers, on the other hand, are looking for collaborative approaches to working with providers to further align quality and financial incentives. By sharing in the success of the joint venture, health systems are further incentivized to provide efficient, quality care and to eliminate unnecessary services. Payers also see value in leveraging the health system brand that may already have patient loyalty, giving the joint venture plan credibility and a source of members in an increasingly competitive market.

Health plan joint ventures are on the rise because they often make strong business and clinical sense. With effective up-front planning by health system boards and senior leaders, these joint ventures can increase the likelihood of success.

LEGISLATIVE AND REGULATORY DEVELOPMENTS

In late 2022, the Centers for Medicare & Medicaid Services (CMS) released several notices and proposed rules that could have important implications for Medicare Advantage Organizations (MAOs) and Part D sponsors. First, CMS postponed, but then finalized, a rule that will have a significant effect on MAOs' liability for recoupment of overpayments. Additionally, CMS issued a series of proposed rules in December 2022 that include important proposed changes to Medicare Advantage (MA) prior authorization practices—including a general prohibition on the use of unpublished, proprietary guidelines for coverage determinations and requiring that MAOs establish a utilization management committee to ensure consistency with traditional Medicare coverage guidelines.

Risk Adjustment. On November 1, 2022, CMS published a Federal Register notice that again postponed, until February 1, 2023, the deadline for finalizing a November 2018 proposed rule on MA Risk Adjustment Data Validation (RADV) audits. CMS's 2018 proposed rule included significant changes to the MA RADV regulations and the extrapolation methodology that CMS previously adopted in 2012. Under the 2012 methodology, CMS determined that a so-called fee-for-service (FFS) adjuster would be applied as an offset before finalizing an audit recovery. This approach would have allowed for a permissible level of payment error and would have limited audit recoveries to payment errors beyond that established threshold. The 2018 proposed rule sought to walk back this approach and, instead, proposed that CMS extrapolate the findings of RADV audits without applying the FFS adjuster and that such extrapolation apply retroactively, beginning with payment year 2011. CMS extended the deadline for finalizing the proposed rule multiple times.

Then, on January 30, 2023, CMS finalized the rule, eliminating the FFS adjuster from its methodology for extrapolating audit findings but limiting extrapolation to plan years 2018 and beyond. For audits conducted between 2011 and 2017, CMS will only collect non-extrapolated overpayments identified. CMS may collect extrapolated overpayments identified in either CMS RADV or Department of Health (HHS) Office of Inspector General (OIG) audits for the 2018 plan year and later. CMS estimates that this approach will produce a total estimated recovery amount of $4.7 billion between 2023 and 2032. Other notable provisions in the final rule include the following:

- *Contract-wide versus sub-cohort*. The final rule gives CMS authority to use any statistically significant sampling and extrapolation methodology. This could include contract-wide samples or "sub-cohort" samples (e.g., beneficiaries with an assigned diabetes hierarchical condition code), with extrapolation to the population from which the sample was drawn.
- *Selection of MA plans to audit*. CMS does not specify how many MA plans will be selected for each year's RADV audit, only that CMS will select MA plans that "through statistical modeling and/or data analytics, are identified as being at highest risk for improper payments."
- *Process for pending audits*. CMS intends to finalize and make recoveries for the currently pending RADV audits on a rolling basis beginning April 1, 2023. These audits will not be extrapolated, as all pending RADV audits are for years prior to 2018.

Prior Authorization. In December 2022, CMS issued several important proposed rules addressing prior authorization, with stakeholder comment deadlines in February and March 2023. On December 6, 2022, CMS first released a proposed rule that would require certain payers—including MA plans—to implement an electronic prior authorization process, shorten the timeframes to respond to requests, and establish policies to make the prior authorization process more efficient and transparent. Most of the proposals, if finalized, would take effect in 2026. The Trump administration previously proposed a similar rule in December 2020 that excluded MA plans. The Biden administration rescinded that proposed rule in 2021, and the new proposals now include MA plans.

On December 14, 2022, CMS issued the contract year 2024 MA and Part D policy and technical changes proposed rule, an important annual update to these programs. Comments on this proposed rule were due on February 12, 2023. The proposed rule includes significant proposed changes to utilization management and prior authorization regulations, among other proposals, including changes to the Quality Rating System, changes to the Program of All-Inclusive Care for the Elderly (PACE), proposals to advance health equity, proposals to expand access to behavioral health providers and services, and changes to current marketing rules (the marketing-related proposals are outlined in more detail below). For a more detailed summary of this important proposed rule, see our additional analysis here. Key proposed changes to prior authorization regulations that would apply to Medicare Advantage Organizations (MAOs) include the following:

- *Generally prohibiting MAOs from using unpublished, proprietary guidelines to make coverage determinations.* Generally, the proposed rule would require that MAOs follow published standards (including Medicare National Coverage Determinations and Local Coverage Determinations) when determining whether an item or service is covered. The proposed rule also generally prohibits the use of unpublished, proprietary guidelines for making such determinations. However, when there is no applicable Medicare statute, regulation, National Coverage Determination or Local Coverage Determination, MAOs may develop internal clinical coverage criteria based on current evidence in widely used treatment guidelines or clinical literature made publicly available.
- *Limiting MAOs' discretion to require the use of alternate services or settings*. Under the proposed rule, when care can be delivered in more than one way or setting, and a contracted provider has ordered or requested Medicare-covered items or services for an MA enrollee, the MAO may only deny coverage of the services or setting when the ordered services fail to meet regulatory criteria.
- *Requiring appropriate expert review of prior authorization requests*. The proposed rule would require that coverage determination requests be reviewed by health professionals with relevant expertise.
- *Establishing a transition period for new enrollees*. For enrollees undergoing an active course of treatment, the proposed rule would require a minimum 90-day transition period when the enrollee switches to a new MA plan, and would require that a prior authorization approval remain valid for the enrollee's full course of treatment.
- *Establishing a utilization management committee.* The proposed rule would require that MAOs establish a utilization management committee, which would review the MAO's prior

authorization policies annually and ensure consistency with traditional Medicare coverage guidelines.

Finally, on December 21, 2022, CMS also released a proposed rule that would adopt a set of technical standards for the electronic exchange of clinical and administrative data to support prior authorization requests and claims adjudication. The most technical of the three proposed rules discussed here, this proposed rule aims to support healthcare claims and streamline prior authorization transactions. Comments on this proposed rule are due on March 21, 2023.

Congress continues to consider legislation that mandates MA plans establish electronic prior authorization processes and requires MA plans to report certain information (e.g., approval, denial and overturn rates), among other requirements. The bill passed the House by voice vote in 2022. However, the bill stalled after the Congressional Budget Office (CBO) released costly implementation estimates in September 2022 and ultimately was not included in the 2022 end-of-year omnibus spending package. While Congress could take up the bill again in 2023, the policies included in CMS's three proposed rules would achieve many of the key reforms included in the legislation, making it less likely that Congress will devote time and resources on the legislative effort.

ENHANCED SCRUTINY OF MEDICARE ADVANTAGE MARKETING

Significant Proposed Changes to MA and Part D Marketing Rules. In the context of enhanced congressional scrutiny and increased enforcement activity surrounding MA and Part D marketing practices, CMS's recently released MA and Part D policy and technical changes proposed rule contains numerous proposed marketing regulation changes. With more than 20 proposed changes to the marketing regulations, many of the proposals focus on marketing activity conducted by Third Party Marketing Organizations (TPMOs), particularly focusing on entities that operate on behalf of more than one MAO/Part D sponsor and on advertising practices designed to generate leads. Key proposed changes to the marketing rules include the following:

- *Imposing additional requirements on TPMOs.* Under the proposed rule, TPMOs that develop marketing materials for more than one MAO/Part D sponsor would have to submit marketing materials directly to CMS, would be required to name the plans that have approved/opted into the marketing, and would be required to display the names of the sponsoring organizations, among other requirements.
- *Requiring plans to monitor agents, brokers and TPMOs*. MAOs/Part D sponsors would be required to establish and implement an oversight plan to monitor agent and broker activities and report identified non-compliance to CMS.
- *Prohibiting misleading uses of the Medicare name and related logos or information.* The proposed rule would prohibit the misleading use of the Medicare name, CMS logo, and products or information issued by the federal government (including the Medicare Card) in response to concerns that beneficiaries are erroneously led to believe that communications or advertising are disseminated or endorsed by Medicare or the federal government when such communications are being disseminated by MAOs/Part D sponsors (or entities operating on their behalf).

- *Regulating the use of superlatives*. CMS would prohibit the use of superlatives, such as "best" and "most," in marketing materials unless the marketing materials provide documentation to support the statement. The documentation must be for the current or prior year.

CONTINUED INTEREST IN CMMI MODELS

Despite strong criticism from some lawmakers and stakeholders, particularly progressive Democrats and single-payer advocates, value-based care models run by the Center for Medicare & Medicaid Innovation (CMMI) continue to attract interest and participants. In early 2022, Representative Jayapal (WA-07) sent a letter, endorsed by 50 lawmakers, urging the Biden administration to end CMMI's Global and Professional Direct Contracting (DC) model, a Trump-era Accountable Care Organization (ACO) model that allowed a broader range of model participants, including commercial insurers and for-profit entities. The letter called for the immediate termination of the DC model, citing concerns that participation of for-profit entities and health insurers would create perverse incentives that would lead to worse care for beneficiaries.

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In response to congressional skepticism, CMS redesigned the DC model to promote provider governance, health equity, enhanced participant vetting and increased transparency, renaming the model the "ACO Realizing Equity, Access, and Community Health" (ACO REACH) model. Despite the redesign of key elements of the model, Senator Warren (D-MA) and Representative Jayapal continued to urge CMS to end ACO REACH in December 2022, again raising concerns about certain ACO REACH participants and calling for further investigation of specified participants cited as having a history of fraud and abuse.

Despite continued questions from Congress throughout 2022, the ACO REACH model is progressing as scheduled, with the first performance year of the redesigned model beginning in January 2023. Given CMS' responses to these critiques thus far, it seems unlikely that CMS would terminate the ACO REACH model altogether. However, CMS may make additional changes to ACO REACH in future performance years to address any perceived problems that arise during the first performance period, and we anticipate robust and continued dialogue between CMS and stakeholders to make modifications to the model as needed.

DEVELOPING LAW ON ERISA PREEMPTION

For plans governed by the Employee Retirement Income Security Act of 1974, 29 U.S.C. §§ 1001-1461

(ERISA), the doctrine of federal ERISA preemption over state statutes, regulations or administrative schemes has been a central subject of litigation since the inception of the statute. In December 2020, the US Supreme Court issued a decision on the subject in *Rutledge v. Pharm. Care Mgmt. Ass'n*, 208 L. Ed. 2d 327 (2020).

In the short, unanimous opinion, the Supreme Court in Rutledge held that ERISA did not preempt an Arkansas statute that regulates pharmacy benefit managers' (PBM) drug reimbursement rates. Arkansas passed Act 900 in 2015 to regulate PBM reimbursement rates for pharmacies, which, in effect, established a reimbursement floor that requires PBMs to reimburse pharmacies at a rate that reflects the pharmacy's acquisition cost for the drug in question.

> …we anticipate robust and continued dialogue between CMS and stakeholders to make modifications to the model as needed.

The Court held that the Arkansas law amounted to a cost regulation that did not create an impermissible connection or reference to ERISA because, while it might have had the indirect effect of increasing costs for ERISA plans, it did not force plans to adopt any particular scheme of substantive coverage, and it applied to PBMs whether or not they managed an ERISA plan.

The Supreme Court's *Rutledge* decision left undisturbed the decades of bedrock preemption principles it relied upon, but does create a roadmap for states attempting to increase regulation of service providers (including PBMs) that help administer ERISA-regulated group health plans, including the regulation of drug pricing and reimbursement activities of various entities in the industry. And although Rutledge is still working its way through courts across the country, recent decisions provide some guidance on how courts will evaluate whether a state law is preempted by ERISA:

- If compliance with the state law applies to ERISA and non-ERISA plans alike, courts are likely to consider that a strike against finding the law preempted by ERISA.
- On the other hand, there will be strong arguments that the state law is preempted by ERISA if the state law does any of the following:
  - Dictates ERISA-governed plan terms
  - Requires a plan to adopt particular substantive coverage
  - Mandates that a plan administer claims in a particular way
  - Relies on plan terms.

For example, in *NEMS PLLC v. Harvard Pilgrim Health Care of Connecticut Inc.*, 2022 WL 2834608 (D. Conn. July 20, 2022), the plaintiff brought an action against Harvard Pilgrim Health Care of Connecticut Inc. alleging violations of the Connecticut Unfair Insurance Practices Act (CUTPA) and the Connecticut Unfair Insurance Practices Act (CUIPA), for failing to comply with the Connecticut Surprise Billing Law. The NEMS court rejected the defendant's arguments that the claims were inextricably tied to the plans and were preempted. The

court found that the claims were not preempted because the surprise billing law applied equally to all insurance plans (not only plans governed by ERISA) and at most merely increased the costs or altered incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage.

In *RHC Operating LLC v. City of New York*, 2022 WL 951168 (S.D.N.Y. Mar. 30, 2022), the City of New York had enacted a law generally requiring hotels that closed following the onset of the COVID-19 pandemic to pay laid-off workers $500.00 in severance pay for 30 weeks. The plaintiff argued that the severance law was preempted by ERISA, but the court rejected that argument, finding that the severance law did not obligate an employer to establish an employee benefit plan. The court explained that to be preempted by ERISA, the statute must compel an employer to establish an employee benefit plan—not merely give employee benefits—and that would only be the case where the employer was required to create an ongoing administrative program to deliver the mandated benefits.

The court in *Griffin v. Blue Cross Blue Shield Healthcare Plan of Georgia, Inc.*, 2022 WL 18110967 (N.D. Ga. Dec. 2, 2022) also provided helpful guidance. In that case the plaintiff argued that the holding in Rutledge meant that a Georgia state law banning anti-assignment clauses was not preempted. The Griffin court rejected the plaintiff's argument, explaining that precluding enforcement of an anti-assignment provision would require the plan administrators to follow specific rules for determining who can be a beneficiary under a plan. This would directly affect central matters of plan administration—which is precisely the kind of state law that ERISA preempts. For the Griffin court, Rutledge reinforced the core principle that state laws cannot dictate ERISA plan terms that Congress intended to be determined by the contracting parties.

As these recent cases show, courts and litigants will continue to examine the contours of the Supreme Court's Rutledge decision in the coming years.

All stakeholders would therefore do well to continue to monitor the latest developments in ERISA preemption, particularly if—and when—the issue is revisited again by the Court.

CHART YOUR PATH FORWARD WITH MCDERMOTT HEALTH

Our Managed Care team is focused on the regulatory and legislative changes shaping the managed care space, and helping our clients navigate the dealmaking, business and care delivery implications of those developments. For additional information, questions or to request assistance in responding to proposed regulatory changes, please contact our team.

For even more from the McDermott Managed Care team, meet us in Nashville this April for our inaugural Value-Based Care Symposium.

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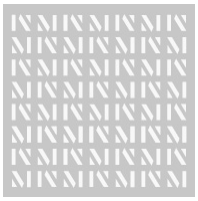

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