Managed Care Outlook

2023

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Introduction

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We built our Managed Care Practice for you, the lawyers and business leaders looking for strategic legal partners who understand both the local backdrop and national perspective of our highly specialized industry.

This inaugural Managed Care Outlook is an extension of our covenant to share with clients and prospective clients our insights and observations on critical legal issues in the managed care marketplace.

As we survey 2023 and look beyond, we expect legal issues impacting managed care organizations (MCOs) to remain a focus of regulators, legislators and the plaintiffs' bar. As in prior years, familiar provider lawsuits, behavioral health issues, bad faith cases, ERISA matters and the like will continue to dot the managed care litigation landscape. As the 2022 elections move further into the rearview mirror, new areas of contentious litigation are likely to develop.

At the top of that list are attacks from post-*Dobbs* legislation, including civil and criminal prosecutions under those statutes. While some common wisdom has kept MCOs outside of the crosshairs of this legislation for now, the perceptions of deep pockets and causation for potential wrongful acts under the statutes may bring MCOs from the periphery into the line of fire. We are keeping a close eye on this issue. Those who subscribe to our Post-*Dobbs* Tracker have first access to thought leadership and innovative practice tools on this rapidly developing issue.

As the United States sets new records in Medicare and Medicaid enrollment, MCOs continue to expand into the government programs space. With expansion comes increased scrutiny. We expect growth in the number and variety of False Claims Act (FCA) cases and fraud and abuse investigations leveled against MCOs by governments. The amount of money at stake can be monumental, so we focus on risk assessment and mitigation strategies. While we often use our capabilities to defend against allegations asserted in FCA cases or to cooperate with the government in fraud, waste and abuse investigations, we prefer – as do our clients – to proactively identify and address issues that could lead to such actions before any action is taken. Proactive forethought can readily avoid significant business disruptions that accompany these sorts of matters. In other words, an ounce of prevention can prevent the need for pounds of cure.

With concerns about an economic downturn on the horizon, M&A activity in managed care likely will ramp up. This increased activity will bring more complexity to deal-making in 2023, with greater regulatory scrutiny, recession fears, the current inflationary environment and rapid changes in the health care industry. Even so, health care acquisition activity in 2023 is positive, although dealmakers will face increasing challenges that may require creative solutions.

This report reflects these and other highlights that we see on the horizon for the managed care industry. There is, of course, much more going on out there. Even as this report is going to press, the law in this space is moving at breakneck speed, with President Biden announcing a plan to end the COVID-19 emergency declarations, and courts delivering important decisions like the Ninth Circuit's ruling in *Wit v. United Behavioral Health*. To keep you up to date on the latest trends, we also offer a steady stream of webinars, alerts and subscriber services on all things managed care. Our mission aligns with yours: we strive to stay abreast of the latest legal developments and provide the most advanced legal thinking on the issues that impact our clients.

As is customary with our practice, I invite you to reach out and have a conversation with me or any one of our 60-plus attorneys dedicated to this field to discuss the issues we address here and what they mean for your organization. To that end, a call from you would be most welcome.

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Benefits issues and litigation

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2023 portends intensified regulatory and litigation spotlight on behavioral health

Takeaways

- Mental health is a compliance and litigation hot-button issue.
- Even with the overturn of *Wit v. UBH*, payors feel pressure to switch to non-proprietary medical necessity criteria.
- Funding for parity compliance increased in 2022, which will expose health plans to parity enforcement actions.

The spotlight on behavioral health issues intensified again in 2022 as our society continues to uncover the impact of the pandemic on mental health. This increased awareness has brought mental health issues to the forefront for legislatures and litigants alike. This trend will no doubt continue in 2023, as regulatory agencies have received funds to enforce the Mental Health Parity and Addiction Equity Act (MHPAEA), and individual health plan members feel more emboldened to seek reprieve for their denied mental health claims. Two areas are of particular note for 2023. First, 2023 will likely see further legislative efforts to codify the holding of the *Wit v. United Behavioral Health (UBH)* matter, even though the decision has been overturned by the Ninth Circuit. Second, this year will bring increased efforts to enforce compliance with MHPAEA, as evidenced by the massive funds earmarked for such efforts.

Legislating medical necessity criteria

Medical necessity criteria is an area of great interest in lawmaking and litigation. In a published decision that was released on January 26, 2023, the Ninth Circuit recently bolstered its 2022 decision overturning the high-profile *Wit* decision involving a challenge to the propriety of medical necessity guidelines in light of generally accepted standards of care (GASC). The district court had found that UBH breached its fiduciary duties under ERISA to insureds by denying their mental health claims as a result of allegedly flawed medical necessity criteria that the court concluded are not consistent with GASC.

The Ninth Circuit found that the district court had misapplied the abuse of discretion standard of review by substituting its own interpretation of the health plan language at issue for UBH's interpretation. The Ninth Circuit noted that the plans exclude coverage for treatment inconsistent with GASC but do not require coverage of treatments that are consistent with GASC. As a result, the Ninth Circuit found that UBH's interpretation did not conflict with the plain language of the plans and reversed the district court's judgment that UBH had wrongfully denied benefits to the named plaintiffs based on the court's finding that the guidelines had "impermissibly deviate[d] from GASC."

Despite that the Ninth Circuit overturned the district court's ruling, legislatures have wasted no time trying to codify the district court's holding that medical necessity criteria must be based on GASC. California, Illinois, and others have such laws. Further, in 2022, the Congressional Research Service recommended that Congress go so far as to amend ERISA to require payors and plan administrators to use medical necessity criteria that are based on GASC. Even though the well-known and clinically sound proprietary medical necessity criteria long used by major payors around the country are based on GASC, these legislative efforts have narrowed the criteria payors may use to those developed by certain community organizations. These community organization-developed guidelines include LOCUS, CASII, ASAM and others. Thus, even if *Wit* remains overturned, these laws and potential other legislative actions may restrict payors to using these community organization-developed guidelines.

Increased compliance funds will fuel regulatory efforts

The U.S. government budget for 2023 and the passage of the Consolidated Appropriations Act both strengthened MHPAEA enforcement. These fiscal measures added several line items relating to mental health parity, including:

- Sunsetting of provisions of the Public Health Service Act such that large, self-funded state and local government plans can no longer opt out of MHPAEA and those that already opted out may not review that election upon its expiration.
- State eligibility for grants from a pool of $10 million available for five years to bolster enforcement activities, including requesting and reviewing health plans' comparative analyses.
- Department of Labor (DOL) being earmarked $275 million over 10 years to do audits on health plans to ensure they comply with parity laws and to fine those out of compliance.
- States being designated $125 million over five years to enforce parity rules.

These measures will fulfil promises legislatures have made to increase MHPAEA compliance efforts in 2023. More than ever, health plans need to be ready for MHPAEA enforcement actions. Having comparative analyses and robust documentation to support those analyses will go a long way toward staving off any potential MHPAEA-related action or litigation.

For more information on this article, please contact Rebecca Hanson

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ERISA managed care litigation trends and 2023 outlook

Takeaways

- Multiple circuits are addressing arbitration and class action waiver clauses in plans.
- Views on the scope of ERISA discovery are changing.
- The Mental Health Matters Act further signals a potential sea-change in ERISA litigation.

The special rules and procedural requirements that have long applied to Employee Retirement Income Security Act (ERISA) benefits litigation have always had their detractors, who have argued that such requirements tend to benefit plans at the expense of plan participants. In 2022, there were some victories for those detractors, with more courts prohibiting arbitration and class action waiver clauses in ERISA plans and another circuit court permitting full discovery in certain ERISA benefits litigation. Congress also attempted to pass legislation that would have swung the pendulum even further, such that ERISA benefits litigation would proceed like any other type of litigation.

While the results of the 2022 mid-term elections have paused any action by Congress for the time being, in 2023 the courts may continue their trend of questioning (and potentially rolling back) the unusual procedures that have long characterized ERISA benefits litigation.

Circuits address arbitration and class action waiver clauses

The question of whether ERISA benefit plans may require participants to arbitrate disputes and waive their right to participate in class actions has been around for some time, and circuit courts have reached different conclusions in recent years. More circuit courts will weigh in in 2023, potentially creating a circuit split and making it more likely the U.S. Supreme Court will resolve the issue.

All courts that have addressed the issue have held that ERISA claims are generally arbitrable, but courts are split on whether a plan may require arbitration if it prevents a participant from "effectively vindicating" their statutory rights under ERISA. In 2019, the U.S. Court of Appeals for the Ninth Circuit affirmed the denial of a motion to compel arbitration in an ERISA benefits case but did not address the issue head-on. However, in 2021, the U.S. Court of Appeals for the Seventh Circuit held that an arbitration and class action waiver clause in an ERISA benefit plan was unenforceable, insofar as the clause limited the remedies available to plan participants under ERISA, and the Sixth Circuit issued a similar ruling in 2022.

As of the end of 2022, three different appeals are pending in the Second, Third, and Tenth Circuits that raise similar issues:

- *Dejesus Cedeno v. Argent Trust Co.*, No. 21-2891 (2nd Cir.)
- *Henry v. Wilmington Tr., N.A.*, No. 21-2801 (3rd Cir.)
- *Harrison v. Envision Mgmt. Holding, Inc. Bd. of Dir.*, No. 22-1098 (10th Cir.)

Employers and administrators of plans with arbitration and class action waiver clauses should keep an eye on these cases and other developments in this area.

Changing views on procedural requirements in ERISA benefits litigation

Procedure in ERISA benefits litigation is very different from other types of litigation. For instance, in ERISA litigation, discovery – and, as a consequence, the court's review – is typically limited to the administrative record, which consists of the information before the administrator when it made its determination. ERISA claims also are generally decided by the court using an administrative review-type procedure, without a jury, and plan participants typically must exhaust all mandatory appeals required by their plan before filing suit.

Many judges in recent years have questioned the continuing validity of these special procedural requirements, including exhaustion of administrative remedies prior to suit, disallowance of jury trials, and remand of cases back to the administrator, noting that these requirements are not found in ERISA's statutory language. Indeed, most of the procedural requirements for ERISA benefits cases, including limiting review to the administrative record, have been imposed by the courts, and the Supreme Court has only endorsed some of them. As a result, the circuit courts have the power in many cases to change course and make ERISA benefits litigation look more like ordinary litigation. While to date much of the questioning has occurred in non-binding dicta or concurring opinions, 2022 offered further evidence that some courts are increasingly inclined to roll back some of the requirements.

In most circuits, ERISA's discovery limitations apply whether the court applies an abuse of discretion standard of review or a de novo standard of review. However, a few circuits permit the parties to discover and the court to consider evidence outside of the administrative record when the de novo standard of review applies. Prior to 2022, the Third, D.C., and Eleventh Circuits had endorsed some version of that approach, though it was unclear whether the authority in the Eleventh Circuit was still good law. In 2022, the U.S. Court of Appeals for the Eleventh Circuit reaffirmed that a court's review is not limited to the administrative record in cases decided under a de novo standard of review, reasoning that such restrictions only make sense when the court's review is confined to whether the administrator's decision was reasonable based on what it had in front of it when it made the decision.

It remains to be seen whether the Eleventh Circuit's decision will influence other circuits, but there appears to be a growing chorus of judges who question the court-made procedure that governs ERISA benefits litigation. In 2023 and beyond, that chorus may continue to grow.

Plans and their administrators should be aware of both the current state of play and new developments in the circuits in which most of their members reside.

Mental Health Matters Act and ERISA procedure

As with the courts, members of Congress are also questioning why ERISA benefits litigation should work differently than ordinary litigation. On September 29, 2022, the U.S. House of Representatives passed the Mental Health Matters Act, H.R. 7780, which, among other things, would prohibit arbitration, class action waiver, and discretionary clauses in ERISA benefit plans. The bill stalled in the U.S. Senate prior to the mid-term election and did not pass before the end of the Congressional term.

If passed, the Act would have barred ERISA plans from giving their administrators the discretion to interpret the plan and apply its terms. In determining whether to apply the deferential abuse of discretion standard in ERISA benefits cases, courts look at whether the plan contains such a grant of discretion. If it does not, the court reviews the non-deferential de novo standard of review. The Act would have dictated that courts apply de novo review in all cases and would have eliminated abuse of discretion review.

Most of the judicial decisions that have produced ERISA's unusual procedural requirements are based on the courts' understanding of Congress' intent to provide a streamlined administrative review process for ERISA benefit claims. The Act reflects what may be a growing willingness among legislators and courts to revisit that understanding. On the other hand, the Act would have acknowledged that a court in ERISA benefits litigation is a "reviewing court" even when applying de novo review, suggesting that it was not intended to completely change the administrative review-like structure of ERISA benefits cases.

The Mental Health Matters Act appears to be a casualty of the 2022 mid-term elections, but that it passed the House shows that a growing number of policymakers believe change is in order. While similar legislation is unlikely to be successful in the new Congress, plans and administrators should keep an eye on developments in both Congress and the courts, given the dramatic impact they may have on ERISA benefits litigation.

For more information on this article, please contact Tom Hardy

Politics will influence local abortion prosecutions

Takeaways

- Courts will decide whether pre-*Roe v. Wade* criminal abortion bans are enforceable.
- The success of state prosecutors' decisions to prosecute and secure the conviction of non-providers, like health plans, under direct or derivative theories of criminal liability will likely become clearer in 2023.
- The 2022 midterms have left more questions than answers about which direction politics will push prosecutors.

Over the next 12 months, courts will decide whether state constitutions protect a woman's right to an abortion, and state prosecutors will likely decide just how far to go in enforcing their states' criminal abortion restrictions, including whether to prosecute health plans for covering abortion-related services.

Although any abortion-related decision will likely be appealed, courts will begin ruling on the constitutionality of existing criminal abortion bans this year. These rulings will likely create further tumult for health plans attempting to assess their potential exposure under direct or derivative theories of criminal liability.

Then, layer in the politics of prosecution. While the "red wave" did not sweep across the country in November as predicted, conservative politicians still control 22 states across the country. Conservatives also account for 56 percent of the state attorneys general.

For decades, conservatives have taken anti-abortion policy positions. Without *Roe* to motivate the conservative electorate, the next wave of abortion politics may be abortion-related prosecutions, particularly for state attorneys general with higher political aspirations.

Alabama and Idaho, for example, have statutes that could be construed to specifically criminalize aiding and abetting an abortion. Similarly, Arizona, Delaware, Oklahoma, South Dakota and Texas already have statutes criminalizing procuring or "furnishing the means of procuring" an abortion. Furthermore, every state that criminalizes abortion has general aiding and abetting or conspiracy statutes that could be used to target payors who cover abortion-related services, including abortion-inducing drugs, abortion procedures or travel benefits.

Issues for payors may arise when call centers or members are in states that have criminalized abortion, particularly if payors acquire knowledge about abortion-related services before the member obtains the service. If states attempt to apply their abortion laws extraterritorially, even payors operating in states where abortion is legal could find themselves in the crosshairs.

If abortion-related investigations are already underway in some states, those investigations will mature in 2023, and prosecutors will need to decide whether they want to move forward with cases. Since prosecutors have significant discretion in what charges they bring and what crimes they prosecute, state politics may embolden some while tempering the actions of others facing re-election in the next two years.

In addition, the 2022 midterm elections left us with more questions than answers when it comes to predicting the politics of abortion prosecutions. On the one hand, conservative attorneys general who have defended state abortion restrictions won re-election in states like Texas and Georgia. On the other hand, voters in Montana – historically a red state – rejected a ballot initiative that would have instituted criminal penalties for health care providers (not payors) who perform abortions. Kentucky voters also rejected a proposal to add language to the state constitution expressly stating citizens do not have a right to an abortion.

If politics contribute to state prosecutors' charging calculus, the midterm elections provided an uncertain outlook for the year ahead. The key will be to continue monitoring states with criminal abortion bans to see how their local prosecutors proceed in 2023. If abortion-related prosecutions under the conspiracy or aiding and abetting theories of liability prove to be successful in one state – either through a state prosecutor's decision to charge or secure a conviction – other states will likely follow suit, as will appeals and constitutional challenges.

For more information on this article, please contact Rizwan Qureshi and Justin Angotti

Fraud and government programs

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False Claims Act: Supreme Court to address key issues

Takeaways

- Approximately 90 percent of False Claims Act recoveries come from the health care industry.
- The Supreme Court in *U.S. ex. Rel. Polansky v. Executive Health Resources* will decide whether the government has authority to dismiss an FCA case after declining to intervene.
- *Olhausen v. Arriva Medical LLC* asks the Court to decide whether a party "knowingly" violates the FCA when its "objectively reasonable" statutory or regulatory interpretation proves to be erroneous.

The Supreme Court is considering two False Claims Act (FCA) cases that have the potential to reshape the FCA landscape and impact defense strategy. They are:

- *U.S. ex. Rel. Polansky v. Executive Health Resources*, in which it will decide whether the government retains authority to dismiss an FCA case after declining to intervene; and
- *Olhausen v. Arriva Medical LLC*, in which the petitioner seeks review as to whether an objectively reasonable but ultimately erroneous statutory or regulatory interpretation is sufficient to defeat the requirement for a "knowing" violation.

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The FCA imposes liability on those who defraud the government, specifically those who "knowingly" present a false claim for payment or records and statements material to a false claim. The qui tam provision of the FCA encourages private whistleblowers (relators) to file suit while allowing the government to intervene and take control. The qui tam provision is often debated. Some argue it serves as a check against government corruption, but others believe it allows for meritless litigation, drains judicial resources and imposes undue costs on defendants and the government, which is forced to participate in discovery even when it declines to intervene. Health care companies, as frequent FCA targets, have a particular interest in the outcome of these issues.

Does the government retain dismissal authority after it declines to intervene?

In 2012, Dr. Jesse Polansky, a consultant for Executive Health Resources, a company that assists hospitals in submitting bills to the government for Medicare-covered services, filed an FCA suit alleging the company was over-designating claims as inpatient rather than outpatient in violation of Centers for Medicare and Medicaid Services (CMS) regulations. The government investigated for two years but declined to intervene. Undeterred, Dr. Polansky pursued the case. In 2019, the government moved to dismiss the case, over Dr. Polansky's objection. The district court granted the motion and the Third Circuit affirmed.

The Supreme Court heard arguments as to whether the government retains authority to dismiss an FCA case after declining to intervene and, if so, what standard applies to the dismissal. Dr. Polansky argues that the history, structure and text of the statute (in particular, section 3730(b)(4)) give the government a binary choice to take over the action or decline to do so, and, if the government declines, then the relator has an exclusive right to pursue the action. Dr. Polansky argues the portion of the statute cited by the government for its dismissal authority is inapplicable because it applies only when the government elects to intervene. To the extent the Court finds the government retains authority to dismiss, Dr. Polansky argues that right is not unfettered. Dr. Polansky urges the Court to impose a rational review standard whereby the government must demonstrate that dismissal will achieve a valid government objective because the relator has a property interest in his cause of action such that any right to dismiss arbitrarily violates due process.

The other side maintains that the FCA allows the government to dismiss a qui tam suit at any time. According to the respondent, depriving the government of dismissal authority would render the statute unconstitutional because the Constitution places all executive power in the U.S. president and prosecuting fraud against the government is an executive function. It argues this authority is not subject to any standard of judicial review, because the president has complete prosecutorial discretion. The respondent denies that a relator has any due process rights because they do not have a property interest in their claim unless and until they prevail.

The Court's ruling could impact the incentive for a qui tam relator to pursue his claim after the government declines to intervene, as well as the balance of power between qui tam relators, the government and defendants. A decision is expected later this year.

Does a defendant "knowingly" violate the FCA if its *objectively* reasonable statutory or regulatory interpretation proves to be erroneous?

Troy Olhausen filed an FCA action against Arriva Medical, LLC and its parent companies, suppliers of diabetic testing and medical supplies, alleging that Arriva made false statements and certifications to the CMS to obtain lucrative government contracts. Arriva allegedly certified its compliance with applicable law despite knowing, among other things, that it would use undisclosed and unaccredited suppliers and conceal the suppliers' locations by manipulating billing software so that all claims would appear to be from Florida.

In moving for dismissal, Arriva argued that Mr. Olhausen did not satisfy the FCA's "scienter" requirement because he could not show that every reasonable interpretation of the applicable statutes and regulations prohibited its conduct or that its conduct was contrary to authoritative governmental guidance. The FCA prohibits "knowingly" false or fraudulent claims for payment and defines "knowing" as actual knowledge, deliberate ignorance or reckless disregard of the truth or falsity of information. Mr. Olhausen opposed dismissal arguing that a defendant cannot avoid liability by relying on a "reasonable" interpretation – even post hoc interpretation – when it knows the interpretation runs counter to the law. The district court granted dismissal and the Eleventh Circuit affirmed.

Mr. Olhausen asks the Court to decide whether a defendant "knowingly" violates the FCA when it asserts a "reasonable" interpretation of a statute or regulation that is ultimately erroneous or runs contrary to the defendant's actual knowledge. The petition argues the Court should take the case to resolve a circuit split. According to Mr. Olhausen, the D.C., Seventh and Eighth circuits apply an "objective" test that finds no "scienter" if a defendant's conduct is consistent with a reasonable interpretation of a legal requirement and no authoritative guidance undercuts that interpretation, while the Sixth, Ninth, Tenth and Eleventh circuits apply a "subjective" test to determine whether a defendant knew or should have known that it was violating the FCA regardless of any offer of a "reasonable" statutory interpretation.

Respondent's opposition the petition was filed on January 20, 2023.

For more information on this article, please contact Karen Braje and Christian Martin

Fraud, waste and abuse in 2023: Spotlight on ancillary services

Takeaways

- Update template contracts, credentialing requirements and payment policies to prevent improper payments.
- Use FOIA requests and provider questionnaires to obtain information about service providers.
- Enhance claims data analytics to spot troubling billing patterns.

Managed care companies continue to face increased risk from providers engaging in fraudulent, abusive and wasteful health care services and billing, and 2023 will be no exception. Our team anticipates at least two areas likely to garner new or increased attention in 2023: (1) COVID-19 laboratory testing; and (2) durable medical equipment (DME).

Abusive payment demands for COVID-19 testing

To encourage the widespread availability and public use of COVID-19 testing during the pandemic and to reduce barriers to testing, the federal government enacted speedy but seemingly conflicting guidance regarding coverage of COVID-19 testing services from non-contracted laboratory providers. The guidance increased patient access to testing services and reduced barriers to obtaining testing by encouraging new entrants into the laboratory testing community.

On the flip side, loose federal regulatory guidance led to a number of providers taking advantage of the public health emergency by engaging in abusive billing practices, performing unnecessary services and/or committing fraud. Notably, a number of providers performed unrequested and unnecessary tests and/or submitted excessive billed charges for tests many multiples above Medicare rates.

While a handful of bellwether cases creeping throughout the U.S. court system are highlighting these issues, the full scope and extent of abusive billing by laboratory providers remains unknown. It will take time for claims data to become clearer and more robust and for additional information to be uncovered surrounding the circumstances of the various laboratory tests that were performed and billed.

In the meantime, our team has identified some best practices for preventing and uncovering these abusive billing practices and how to approach litigation in the event that it is necessary.

Tips for uncovering and/or preventing abusive COVID-19 lab billing

- **Robust data analytics.** Identification of patterns that may establish testing was done as a part of a general surveillance program, such as workplace or school testing, that is not required to be covered under federal regulatory guidance.
- **Targeted medical record requests.** Medical record requests are an important tool for identifying the circumstances in which the testing was performed and who performed the testing. Record review may also assist in identifying trends.
- **Strategic public record requests.** Freedom of Information Act requests to the Centers for Medicare and Medicaid Services (CMS) and state licensing agencies can be a goldmine of information. Many of the actors involved in questionable COVID-19 testing and billing practices likely did not comply with state licensing requirements or Commission on Office Laboratory Accreditation (COLA) regulations if they performed testing at unlicensed locations. Information regarding a laboratory's ownership and affiliation may also reveal fraudulent or abusive practices, such as manipulating the submission of claims for services performed by an in-network entity that were then billed through an out-of-network entity under common ownership to inflate payments.

Tips for developing claims and defenses for COVID-19 lab test litigation

- **Consider the tests billed.** Single out panel tests, which are often the most expensive tests at issue, and pay attention to collection fees, which might not require coverage. Similarly, to the extent that multiple tests (such as antigen and antibody tests) are performed on the same date, it is possible to argue that both are not required to be covered.
- **Examine the circumstances around the tests.** If a common physician requested laboratory tests involving a significant number of patients in a short time period, examine the circumstances of the patient population. Workplace and school monitoring tests are not required to be covered under federal guidance.
- **Consider the theories asserted.** Many providers assert claims under the Families First Corona Virus Response Act (FFCRA) and the Coronavirus, Aid, Relief, and Economic Security Act (CARES Act), but it can be argued that neither imparts a private right of action. Alternative theories may include unjust enrichment and quantum meruit (pay what's due) theories where there is a developed body of case law that no benefit confers to a health insurer in the provision of health care services to members by non-contracted providers.
- **Examine state price-gouging laws.** Such laws cover times during a state of emergency, and they prohibit abusive pricing and billing behavior. Federal guidance on the coverage of COVID-19 lab tests is deferential to state price-gouging laws.

Durable Medical Equipment

A second area where a high risk of abusive and/or fraudulent billing exists is durable medical equipment (DME). This is an area of particular concern due to increased consolidation among DME providers and because these types of medical services and supplies are more difficult to monitor.

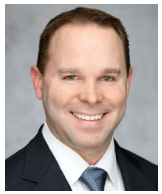
Increased risks around DME

- **Consolidation among DME providers.** This can lead to entities acquiring legacy contracts with generous fee schedules to then pass through a significantly increased volume of supplies or services that were not contemplated under the original contracts. DME providers have been known to structure acquisition agreements in ways to circumvent anti-assignment clauses in contracts.
- **Problematic oversight of DME care management companies.** Payors often have contracts with third-party companies to assist in managing DME. A lack of adequate oversight of those contracts can lead to contractors ordering large amounts of equipment without specific medical provider orders.
- **Failure to align payor coding policies on DME with Medicare policies on DME.** Payors may be susceptible to improper or abusive billing of DME under unlisted Current Procedural Terminology (CPT) / Healthcare Common Procedure Coding System (HCPCS) codes where Medicare has provided updated guidance on correct coding for these services. This can lead to overpayment recoveries against payors by CMS and its auditing partners.
- **Provider billing abuse of CPT/HCPCS unlisted or miscellaneous codes.** These code types are highly susceptible to abusive billing where lower-paying codes might better describe the equipment or services rendered.

Identifying and preventing abusive or fraudulent DME supplies and services

While these types of supplies and services are susceptible to fraud and abuse by health care providers, many options are available to payors to help detect and otherwise prevent making payments for claims involving these problematic behaviors:

- **Update provider contracts to more recent template contracts.** DME contracts are often legacy contracts that may be 10 or more years old. Updating contracts can help discourage providers from engaging in questionable billing practices.
- **Update template contract provisions on notification requirements.** Strengthen provisions on the change of ownership / control of a DME contract. Distressing provider billing practices often occur when a new owner or administrator takes control of the provider or the contract. Having robust notification provisions keeps the payor informed about its contractors.
- **Update credentialing and re-credentialing requirements to ensure more robust disclosures on provider ownership and management, as well as services and equipment provided.** This will help the payor identify whom they are doing business with and prevent "creative" transactions from circumventing contractual anti-assignment provisions.
- **Monitor how providers select DME.** Consider outreach questionnaires to the DME providers or health care providers to determine whether they are getting any questionable financial incentives for selecting a particular piece of equipment or product.
- Ensure the payor's fee schedules, coding policies and payment guidelines are up to date and follow current industry practices for coding, including recent Medicare guidance.
- Update coding payment policies regarding the use of unlisted or miscellaneous codes to ensure clear guidance as to when the codes should be used for payment.



For more information on this article, please contact Bryan Webster

False Claims Act dangers lurk beyond Medicare Advantage Risk Adjustment

Takeaways

- New and evolving FCA cases will arise against plans based upon alleged Anti-Kickback Statute violations.
- Data submissions leading to payment (beyond risk adjustment) and medical loss ratios will create additional FCA risk.
- Program non-compliance such as marketing, enrollment and claims denials can create FCA liability.

The federal False Claims Act (FCA) has long been a threat to Medicare Advantage organizations (MAOs) and Medicaid managed care organizations (Medicaid MCOs) due to the nature of the business. Historically, however, health plans were not primary targets as the government and relators' counsel focused on providers. Medicare Advantage Risk Adjustment (MA RA) shifted that landscape, with Department of Justice (DOJ) and whistleblowers bringing numerous cases against MAOs for the alleged submission of false MA RA data. While those MA RA cases create significant risk, they are just the tip of the iceberg as the government and relators' counsel now have plans directly in their crosshairs.

Other emerging areas of FCA risk include:

- **Federal Anti-Kickback Statute (AKS)**. The AKS comes into play for MAOs, Medicare Part D plans and Medicaid MCOs in many ways. A kickback violation creates FCA liability, and the AKS will almost certainly fuel new and evolving FCA claims against health plans. One area of particular concern is Medicare Advantage (MA) marketing, where improper payments to providers or others involved in the marketing and enrollment process can create FCA liability. As an example, in July 2022, an MCO agreed to pay the government $4.2 million to settle FCA allegations that it implemented a gift card incentive program in violation of the AKS. As MA marketing heats up and the industry becomes more competitive, plans must closely analyze marketing programs to ensure that improper payments are not being made for referrals.

Another area of increasing importance for health plans – and potential AKS liability – is provider relationships such as investments, loans, exclusivity deals, joint ventures and other non-traditional collaborations.

These arrangements present potential AKS risk especially when they involve providers that are in a position to refer members to Medicare or Medicaid health plans, such as primary care physicians. In order to mitigate potential FCA risk, health plan lawyers must consider the facts and circumstances surrounding the relationship, most importantly understanding the parties' intent as to the purpose of the payments, and ensure that they are implemented in a way that is not perceived to be a means to refer members to the Medicare or Medicaid plan.

- **Medical loss ratio (MLR)**. MAOs and most Medicaid MCOs have an MLR requirement with refunds required if the plan does not meet the MLR. However, if the MLR is incorrectly calculated or money is shifted from one business line to another to manipulate the MLR – either knowingly or recklessly – that can trigger potential FCA liability.

Similar to MA RA, scrutiny of MLRs has increased.

For instance, a project that is currently on the Office of the Inspector General's (OIG) Work Plan is to examine states' oversight of Medicaid MCO MLRs, including analyzing whether states have received all appropriate data and whether Medicaid MCOs are complying with MLR requirements. Similarly, in August 2022, the DOJ announced a $70 million settlement with Gold Coast Health Plan in California. In that case, a whistleblower and DOJ alleged that Gold Coast and two providers improperly included in their MLR dollars for services that were billed as "Additional Services" and which were provided to Adult Expansion Medi-Cal members, but those services were not allowed medical expenses under Gold Coast's contract with the California Medicaid agency. Plans often operate through inter-company agreements to perform services, have risk-based contracts with providers, and are often vertically integrated with health systems, and each of these arrangements creates the opportunity to shift dollars for MLR purposes.

- **Other data submissions leading to payments**. The MA RA situation has shown us that data submissions leading to payment can create false claims risk. However, as we all know, MAOs and Medicaid MCOs submit numerous data streams to the government that lead to payment, including bid data, MLR data, encounter data, enrollment data, HEDIS and other quality metric data, STARS, risk corridors and many others. In addition to the fact that this data leads to payments, generally MAOs and Medicaid MCOs must attest to the accuracy of the data. If the plans knowingly submit inaccurate data, then, just like MA RA, that will lead to potential FCA violations.

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- **Program activities**. Program activities, such as MA marketing and utilization management practices by MAOs and Medicaid MCOs, can be re-characterized as FCA violations. For instance, in November 2022, the Senate Finance Committee issued a report lambasting MA marketing practices and recommending increased oversight. MA marketing has been criticized in national media such as The New York Times. This increase in scrutiny will likely cause relators' counsel to allege that marketing violations resulted in improper enrollments. Similarly, the OIG recently released its Report 09-18-00260, in which it concluded that MAOs were excessively denying authorization for services that met Medicare requirements. That report triggered the American Hospital Association to write DOJ and encourage it to use its FCA authority to punish health plans that purportedly improperly denied care and payment for services, and furthermore create a Medicare Advantage Fraud Task Force to investigate MAOs' alleged excessive denials. OIG also has three active work plan items focused on service denials by Medicaid MCOs, including analyzing rates of plan denials, rates of Medicaid MCO denials being overturned and compliance with mental health parity requirements.

So what should a health plan do to mitigate this risk? First, it should proactively educate key business stakeholders on emerging areas of FCA risk. This can be done in many ways, including through periodic legal or compliance training, roundtable discussions or privileged emails. Second, health plan lawyers need to stay abreast of emerging business practices and work with compliance to identify potential risk early. Finally, remember that while eliminating all FCA risk may be impossible, the risk can be minimized. So if a business practice creates potential false claims risk, the organization must identify ways to mitigate it while still accomplishing its business objectives.

For more information on this article, please contact Steve Hamilton

Mergers and transactions

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Antitrust enforcement under Biden: Mixed results for enforcers, lessons for MCOs

Takeaways

- FTC and DOJ have backed up aggressive antitrust enforcement talk with action.
- Although results have been mixed, expect the antitrust enforcement agencies to challenge mergers that may not have been challenged in the past.
- Managed care organizations are critical players – whether as witnesses and providers of information or as merging entities – in this active antitrust enforcement environment.

In 2022, the Biden administration and its antitrust enforcement agencies – the Federal Trade Commission (FTC) and the Department of Justice's (DOJ) Antitrust Division – have backed up their considerable talk about vigorously enforcing the antitrust laws, particularly in the health care sector. We expect this trend to continue in 2023.

Payor mergers

On February 24, 2022, the United States, through the DOJ Antitrust Division, and two states sued in federal court in the District of Columbia to block the acquisition of Change Healthcare (Change) by UnitedHealth Group (United).

United is one of the 10 largest U.S. companies by revenue and owns the largest health insurer in the United States. United's subsidiaries include one of the largest pharmacy benefit managers in the country, OptumRX; a large provider network, Optum Health; and a health care technology business, OptumInsight. Relevant to the government's theory, OptumInsight offers a claims-editing product and operates an electronic data interchange (EDI) clearinghouse, both of which largely are used in-house by United, though the claims-editing product is sold and used by several competitors.

Change was an independent health care technology company based in Nashville. According to the DOJ, Change provided "health care analytics, software, services, and data to providers, insurers and other" firms in the health care space. Change's offerings included the leading first-pass claims-editing solution, ClaimsXten, which the DOJ says has allowed insurers to realize $12 billion in annual savings. Change also operated the largest EDI clearinghouse, which the DOJ described as the "pipes" that connect providers to insurers for electronic claims processing purposes. Its clearinghouse connected 5,500 hospitals and 900,000 physicians with 2,400 government and commercial insurers. Change held data on the claims that flowed through its system going back to 2012 and for 211 million unique patients.

The case went to trial in August 2022. The DOJ relied on two core theories: one based on more traditional antitrust principles and the other more nuanced. First, the DOJ attempted to prove that the merger would give United a monopoly share of the market for first-pass claims editing. The principal difficulty with this argument for the DOJ was that United reached an agreement with TPG, a private equity firm, to divest ClaimsXten contingent on the closure of the merger, which remedied any potential anticompetitive effects of the merger. The second, less straightforward theory was that the acquisition of Change would give United an unfair competitive advantage in the market for the sale of commercial insurance to national accounts and large groups. The DOJ contended that even though Change had a vertical relationship to the participants in the sale of health insurance, Change played such a key role in the flow of data in that market that if it were acquired by United, United could stifle competition in those commercial health insurance markets. According to DOJ, United could accomplish this using its "vast trove of competitively sensitive data" to gain insights into its competitors' innovations, reduce innovative products Change would have developed and made available, and generally raise costs for competitors.

On September 19, 2022, the U.S. District Court for the District of Columbia rejected the DOJ's theories across the board. The court concluded that the agreed-upon divestiture of ClaimsXten effectively resolved the DOJ's horizontal claim. On the vertical theory, the court found that the government failed to introduce sufficient facts to carry its burden to prove that United's Optum entities would gain access to the claims data of United's health insurer rivals, that such data would then be shared with United's health insurer subsidiary, and that sharing of such information would have a chilling effect on rivals that would reduce innovation and harm competition. Simply put, the court found the DOJ's vertical theory to be too speculative and not sufficiently supported by facts. The DOJ filed a notice of appeal to the D. C. Circuit on November 21, 2022. United and Change closed their deal on October 3, 2022.

Hospital mergers

The FTC has been historically active in opposing hospital mergers that it concludes would harm competition. After suffering its first defeat in 20 years in a hospital merger case in 2020 – Jefferson Health's acquisition of Einstein Healthcare, which cleared after a December 2020 order denying the FTC's motion to enjoin the deal – the FTC had renewed success in 2022.

In March of 2022, the FTC obtained a preliminary injunction to block Hackensack Meridian Health's proposed acquisition of Englewood Healthcare Foundation. According to the FTC, the merged health care system would control three out of the six inpatient general acute care hospitals in Bergen County, NJ. The FTC argued that the proposed acquisition would eliminate close competition between Hackensack Meridian Health and Englewood in Bergen County and leave insurers with few alternatives for inpatient general acute care services. The parties abandoned the merger after the preliminary injunction was entered.

In June of 2022, RWJBarnabas Health and Saint Peter's Healthcare System abandoned a proposed merger after the FTC filed a complaint alleging the merger would give the combined entity a 50 percent share of the general acute care services market in Middlesex County, NJ. That same month, the FTC filed an administrative complaint and motion for preliminary injunction in federal court in an effort to block HCA's proposed acquisition of Steward Health Care System in Utah. As in the RWJBarnabas case, the parties dropped their plans to merge shortly after the FTC filed its complaint.

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Looking ahead

All indications are that the antitrust agencies will continue to take an aggressive approach to enforcement in 2023. In fact, on December 9, 2022, the DOJ Antitrust Division and the Department of Health and Human Services's Office of Inspector General announced a partnership – memorialized in a memorandum of understanding (MOU) – aimed to "promote competitive health care markets." The MOU contemplates that these agencies will share information and coordinate enforcement activity, among other things. Similarly, on November 22, 2022, Deputy Assistant Attorney General Michael Kades delivered a keynote address at the American Bar Association's Antitrust Fall Forum, in which he discussed how the Executive Order on Competition embraces a "whole-of-government" competition policy. The Executive Order explains that a number of executive departments and agencies exist to protect conditions of fair competition and identifies over a dozen departments and agencies with responsibility to promote competition.

As we look to 2023, managed care organizations should be mindful of the three key lessons of 2022.

(1) the antitrust agencies will continue their aggressive merger enforcement efforts to the point of pursuing novel or less traditional theories of competitive harm.
(2) expect broader interagency efforts when it comes to antitrust enforcement.
(3) whether in hospital mergers, or mergers involving payors, evidence developed from managed care entities will be critical.

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Payor acquisitions likely to become more complex in 2023

Takeaways

- Increased regulatory scrutiny, recession fears, inflationary concerns and rapid changes in the health care industry will complicate dealmaking.
- Dealmakers will face increasing challenges that may require creative solutions.
- Despite that, the outlook for health care acquisition activity in 2023 is positive.

Consolidation and acquisitions in the health care industry have steadily increased in recent years, with payors looking to expand their market share and grow their businesses through mergers and acquisitions. However, the process of acquiring other health care companies, whether plans or providers, appears likely to become more complex as we move into 2023.

One major factor that is likely to contribute to this complexity is the increased scrutiny by state and federal regulators into health care consolidation. For example, California Senate Bill 184, adopted in the 2022 legislative session, will require prior notification of health care transactions, including transactions involving both providers and health plans. Connecticut, Illinois, Maryland, New York and Pennsylvania have adopted or strengthened similar laws in recent years. These laws are generally intended to increase transparency and oversight of health care consolidations to ensure that consolidation does not lead to reduced competition and higher prices for consumers. These state laws also may have the effect of slowing the pace of transactions. Additionally, the Federal Trade Commission has issued statements about the potential antitrust implications of consolidation in health care, indicating that it will be closely monitoring any deals that might reduce competition in the industry.

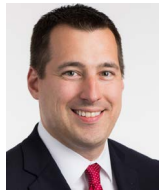
Other challenges payors may face in acquiring other health care companies include a decrease in available capital, labor challenges and an ongoing overall increase in operating costs in the current economic environment. As a result of these financial constraints, business leaders may be more cautious when considering acquisitions by requiring more due diligence and potentially tightening the terms of any escrows, holdbacks or earnouts.

Health care organizations are also facing rapid changes in how health care services are delivered, with analytics and technology improvements continuing to be a significant focus. The adoption of AI tools, the transition to value-based payments, the use of remote services and the growing preference among patients for a retail experience are all impacting health care. These changes may make it more challenging for payors to align their incentives and compensation with health care providers and intensify an existing struggle to retain practitioners if compensation or equity drops due to declines in revenue or increased costs.

Despite these regulatory and financial challenges, health care acquisitions are expected to remain robust in 2023, with strategic investors, private equity firms and non-traditional investors all looking to invest. Managed care companies seeking to control costs, increase efficiency and improve their bottom line through strategic acquisitions must contend with robust competition for attractive targets. Many investors are still seeking returns through consolidation and roll-ups in the health care industry.

In light of regulatory challenges, the economic environment and declining public company valuations, companies seeking to expand are likely to continue to focus on strategies that were successful in the second part of 2022, including smaller acquisitions, as well as exploration of opportunities through partnerships and joint ventures. Acquirers with well-defined strategic objectives and effective deal processes that can efficiently move through the transaction process may be able to capitalize on attractive valuations and opportunities resulting from the economic environment.

While the health care industry has seen a trend of consolidation in recent years, the process of acquiring other health care companies is likely to become more complex in 2023. Health care companies looking to expand through acquisitions will need to navigate increased regulatory scrutiny, financial constraints and rapid changes in the way health care services are delivered, as well as competition from other investors. This combination of factors will require payors to be more strategic and diligent in their approach to acquisitions, as well as being able to adapt to the evolving health care landscape.



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Mitigating risk

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Insurance recovery: Strategies to navigate a challenging insurance market

Takeaways

- The hard insurance market for MCOs will continue in 2023.
- Shop insurance programs, assess coverage options and seek policyholder preferred language.
- Explore alternatives, like captives, to enhance risk mitigation.
- Be proactive in claims handling and push back on carrier efforts to reduce coverage obligations.

The management liability insurance market for managed care organizations (MCOs) – i.e., errors and omissions (E&O), directors and officers (D&O), and cyber insurance – is expected to remain a "hard market" in 2023. Systemic concerns exist around exposure to antitrust claims, class actions and other emerging claims. In addition, the carriers no doubt seek to improve loss ratios in light of the *In Re Blue Cross Blue Shield Antitrust Litigation* (MDL 2406) (*BCBS MDL*). While this market may begin to stabilize, MCOs will likely continue to face significant premium rate increases, albeit leveling off in trend.

What steps should you and your MCO take?

- **Start placement efforts early**. Go to the market and actively shop your insurance programs in order to maximize interested carriers and coverage options. Push carriers on proposed pricing and language before "picking a horse."
- **Assess options**. Carriers may no longer unilaterally impose reductions in limits and increases in retentions for MCOs in 2023 as was the case in recent years, but MCOs should still assess retention levels, co-insurance and sub-limits, as well as seek pricing on various options. Some carriers are requiring both E&O and D&O placement in their quotes. Be aware those carriers' policies will likely include "tie in of limits" provisions, such that the limit of only one coverage line applies to a "Claim" implicating E&O and D&O coverage (even though premiums were paid for both).
- **Scrutinize proposed policy language and exclusions**. Seek preferred language and enhancements. In recent years, "Association"/"Enterprise Liability" exclusions for Blue Plans have become commonplace as a result of *BCBS MDL*. Likewise, carriers have imposed "Opioid" exclusions. MCOs may be unable to avoid these exclusions, but should still push for preferred policy language to "pressure test" the carriers' flexibility on policy language.
- **Enhance risk mitigation efforts**, such as increased focus on and investment in network security and information privacy protection systems. As carriers require more robust cyber applications and underwriting processes, including expanded use of underwriting calls with information security professionals, MCOs may reduce their exposure to risk and loss, but also assist their cyber placements through such information and network security efforts.
- **Explore alternatives**, such as use of a "captive insurer" – an insurance company set up and owned by the MCO itself – for issuance of excess or other coverage to your MCO. In light of high premium pricing and narrowing of coverage, some MCOs are expanding use of captive insurers in their insurance programs, while other MCOs are looking to set up captive insurers for the first time.
- **Be proactive in claims handling matters** to maximize insurance recovery. Carriers often assert hourly rate caps and litigation guidelines, not found in the policy language. Carriers also unilaterally impose improper reductions in defense fee payments through granular audits of defense invoices. In addition, carriers are becoming more aggressive in asserting "cooperation" obligations and consent to settle defenses to avoid coverage. Insurance recovery expertise must be brought to bear in order to properly manage carriers on these issues. There is ample support in the insurance case law and policyholder's playbook for MCOs to combat these tactics.

In terms of claims trends against MCOs, False Claims Act (FCA) and Mental Health Parity Act claims are on the rise.

Regulatory investigations have become more frequent and expensive.

We expect more large and complex provider disputes, many of which are difficult to defend based on sheer volume alone of the "health benefits claims" involved. MCOs should report "Claims" under all potentially implicated coverages as a matter of course. Complaints need to be examined for allegations that present a potential for coverage and a possible defense fee payment obligation. Coverage should be evaluated at the outset and not as an afterthought.

A key insurance coverage case to watch in 2023 for MCO policyholders is *Astellas US Holdings, Inc. v. Starr Indemnity & Liability, Co.* In *Astellas*, the federal court in the Northern District of Illinois held that a $50 million component of *Astellas*'s settlement payment to the U.S. Department of Justice for settlement of its FCA investigation/claims was "covered Loss" under the company's D&O policy. *Astellas* is currently on appeal in the Seventh Circuit. The case was briefed and argued in 2022. The parties await a decision, which is expected in 2023.

The district court held that the $50 million payment was not "uninsurable as a matter of law," nor uninsurable "restitution or disgorgement of profits." The district court found that the label of the payment as restitution to the United States in the settlement agreement did not preclude coverage because some forms of restitution are compensatory and the FCA provides for civil money penalties or compensatory damages, not restitution in the form of disgorgement.

The *Astellas* case is very important to MCO policyholders dealing with FCA claims or investigations. But, more broadly, the court rejected numerous carrier arguments often asserted against MCOs in many other contexts. The court also applied various insurance principles favorably for the policyholder, which will be useful in MCO coverage battles with carriers.

In conclusion, these strategies require effort and expertise. But, that investment of time and resources can provide handsome returns over time. Indeed, these recommended steps can mean millions in insurance recoveries for your MCO. Despite the historically hard market and carrier challenges in recent years, our insurance recovery team has recovered hundreds of millions of dollars for our MCO clients in the last three years alone.

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Adapting to the new age of whistleblowing in a managed care context

Takeaways

- Whistleblowing complaints increased during the COVID-19 pandemic.
- There are increased protections for and categories of whistleblowers in many states.
- Managed care companies can help protect themselves through effective investigations.

Managed care companies have long been aware that statutes such as the False Claims Act (FCA) allow private citizens to file lawsuits on behalf of the federal government against organizations that have defrauded it, potentially resulting in significant recoveries for such individuals should the claims be successful. Yet, how high can these recoveries be? In September 2022, a relator in an FCA case against Biogen Inc. received a $250 million whistleblower award in a settlement, which is reported to be the highest award ever given to a whistleblower. The relator was a former employee who alleged he was demoted for trying to prevent the company form paying kickbacks to health care providers to influence them to prescribe its multiple sclerosis drugs.

Aside from the FCA, it is important to be aware that whistleblowing complaints increased during the COVID-19 pandemic and that beyond the FCA, employees have a growing arsenal of potential remedies available to them in the wake of increased legislative initiatives protecting whistleblowers. According to the SEC's November 15, 2022 annual report, the SEC received 12,322 whistleblower tips in fiscal year 2022, which was the record for the most tips it has received. In August 2022, in the wake of these increased tips, the SEC adopted two amendments related to dollar recoveries for whistleblowers, which effectively more highly incentivize individuals to bring tips forward.

Also, in New York State, for example, amendments to existing legislation protecting individuals from retaliation for engaging in protected complaints – Labor Law 740 – took effect in 2022. The amendments expanded the definition of "employee" to include current and former employees, as well as independent contractors. They also expanded the scope of protected activity to prohibit retaliation against an individual who not only who discloses or threatens to disclose an unlawful activity but also reasonably believes the unlawful activity poses a substantial and specific danger to the public health or safety. New York is just one of many states amending or creating new laws designed to protect whistleblowers in expanded contexts.

The Association of Certified Fraud Examiners' biennial study, *Occupational Fraud 2022: A Report to the Nations*, found that tips continue to be the most common method of detection and that they mostly come from employees. The study also found that tips most frequently come through email and web-based or online reporting systems, with email being the most common method and reporting via telephone hotlines decreasing as a means of reporting fraud.

Training programs targeted at identifying protected complaints can help ensure that managed care companies are aware of and protect themselves against risk. When employees report complaints through emails rather than official reporting tools, it can be harder to detect whether they are whistleblowers. Employees sending emails do not necessarily use buzzwords such as "fraud" or "whistleblower" in their communications but may more subtly raise complaints that nevertheless serve to put companies on notice that they are raising a protected complaint.

Often, complaints go directly to an individual employee's manager rather than through compliance outlets. Employees often feel more comfortable sending their concerns in this way, such that it is important to ensure that managers are trained to recognize complaints and know where to direct them. Employees often ask for confidentiality when raising complaints in this way, but concerns must always be escalated so that the company can conduct effective investigations. There is no such thing as an "off the record" complaint when protected conduct occurs.

A robust investigative program can also help protect managed care companies when and if litigation arises from or on behalf of whistleblowers. Training individuals on how to conduct thorough and effective investigations should be done as often as possible. Not only does this help managed care companies determine whether fraud has occurred and, if it has, give them the opportunity to remedy the situation but it also provides companies with effective defenses in any ensuing litigation. How investigations are conducted should be consistent among investigators and training materials created and used can be offered as evidence in any ensuing legal proceedings.

In some instances, employees who end up suffering unrelated adverse actions (including termination) scour the details of any investigations that were conducted to help argue that the reasons for the adverse actions were pretextual. In a recent case from the Third Circuit – *Crosbie v. Highmark, Inc.*, 47 F.4th 140 (3rd Cir. 2002) – a terminated compliance officer, Alastair Crosbie, brought suit under the FCA, arguing that his termination was in retaliation for raising concerns that doctors had prior convictions for selling opioid prescriptions without required Medicaid licenses. The main issue on appeal was whether Crosbie could establish pretext, which he argued was established, inter alia, via the allegedly "flawed" quality of human resources' investigation into the events leading to his termination and his manager's involvement. The Third Circuit disagreed, finding the investigation "was far from a façade" where, inter alia, human resources interviewed a number of individuals and was unaware of Crosbie's prior complaint.

Upticks in whistleblower complaints, the potentially more difficult ways of identifying these complaints and expanded legislation protecting whistleblowers all make it increasingly more important for managed care companies to expand manager training to ensure managers know how to recognize protected complaints. Companies also should ensure comprehensive programs are in place that are designed to instruct and guide those charged with conducting investigations on best practices when performing those investigations so that they can best protect themselves against these complaints.

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Discovery readiness: Preparing for investigations and litigation

Takeaways

- Discovery is evolving with the rise of new data sources and proliferation of data.
- Companies that fail to properly prepare for discovery demands face substantial additional liabilities, burdens and costs.
- By taking proactive steps now, companies can significantly reduce e-discovery and data protection risk exposure.

By adopting best practices in 2023, you can significantly reduce discovery and privacy risks and costs arising from data proliferation and new data sources. In today's hybrid work environments, all data from non-traditional data sources – such as texts from employee cellphones, data maintained by third-party providers and information from Teams, Slack and Zoom – can be subject to litigation discovery, whether the information is on company, employee or third party devices. Preserving and producing data from those sources can be difficult and expensive, but the consequences of failing to do so when required are much worse. Accordingly, it is critical to take proactive steps now, including updating your information governance practices, remediating obsolete data and preparing to use the latest technology tools to manage information and discovery demands.

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New data and new data sources

Managed care data and its governance has changed significantly in recent decades and continues to evolve at a rapid pace due to four contributing factors.

1. The rise in electronic claim processing has dramatically increased the amount of data held by managed care companies, and, this data often includes protected health information of members.
2. The uptick of new technologies has changed the way that we communicate and what kinds of records we have, while also resulting in the proliferation of new data. For example, only a few years ago there was limited use of collaboration tools like Teams and Slack or communication tools like Zoom and WhatsApp, but now those tools are significant sources of documents that are becoming increasingly important in discovery.
3. The COVID-19 pandemic led most companies to move to remote work and, for many companies, that will not be completely reversed – remote or hybrid work is here to stay. As a result, there is more data on personal devices like home computers and smartphones, not all within the direct control of the company (e.g., texts sent from cellphones).
4. Data increasingly is stored "in the cloud," whether on company networks using Microsoft 365 or Google Enterprise, or in the control of outsourcing providers.

All four of these factors complicate data preservation and production that may be required for litigation or investigations.

Becoming "discovery ready"

Here are the five key elements to "discovery readiness":

1. **Know where your data is**. Keeping an updated data map or inventory can give you a great head start, while also assisting with privacy compliance.
2. **Maintain updated information governance policies**. This includes: (1) an updated retention policy and schedule; (2) an updated electronic communications policy; (3) an updated disaster recovery policy; (4) an updated legal hold policy (including standard procedures and forms); and (5) updated bring your own device (BYOD) and work from home policies. Such policies should not only ensure that data is kept as long as needed (and no longer) for business, compliance and legal holds, but also should specify what data is or is not within the company's control.
3. **Implement training, enforcement and tracking** that maximize compliance with policies. This should include legal hold tracking that allows the company to quickly identify records and custodians that are or are not subject to legal holds.
4. **Remediate (i.e., delete or otherwise properly dispose of) obsolete documents and data** no longer needed for business, legal compliance or legal holds. This includes old hard copy archives, old emails, "orphaned" data from departed employees or business operations, legacy data, backup data, SharePoint data and data from other data sources, including the new data sources identified above. Discovery costs and risks (as well as privacy risks) are directly correlated with the volume of data an organization maintains. Retaining only what is necessary is the biggest key to slashing associated costs.
5. **Be prepared to act quickly and efficiently** through existing relationships with experienced e-discovery counsel who are fully conversant with the latest legal technology, including early case assessment (ECA) and technology assisted review (TAR) tools. This approach should result in efficient, consistent and defensible processes rather than abdicating control of e-discovery to counsel or service providers that may follow differing procedures, fail to follow "best practices," fail to minimize costs or otherwise have varying levels of experience and competence with regard to handling e-discovery.

How does your company currently rate with regard to the above elements? The bad news is that very few managed care companies currently can give themselves high marks on all of the elements identified above. The good news is that companies that are ready to address any "less than optimal" policies or practices can make rapid progress with only a relatively modest investment of time and money if they retain experienced counsel to help guide them.

Conclusion

Taking the proactive steps identified above, to address information governance and e-discovery readiness, should be a high priority for most managed care companies in this rapidly evolving information age. This is an area where attention to improvement, before any calamity occurs, can provide returns on investment many times over by significantly reducing future liability risks and costs.

For more information on this article, please contact David Cohen and Alexandra Lucas

Out-of-network and emergency services issues

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ERISA trends: Out-of-network payments and COVID-19 testing reimbursement

Takeaways

- In 2023, many pricing disputes will center on how to confine discovery in the pricing context and how to define or evaluate the usual and customary rate.
- COVID-19 reimbursement cases continue to evolve and point to general principles for defending provider disputes in 2023.
- Plans and insurers should implement best practices. These best practices include drafting the most defensible plan provisions before litigation, properly opposing new theories and resisting broad discovery during litigation.

Recent cases indicate several characteristics about how out-of-network pricing disputes will proceed in 2023. First, insurers and plans should be mindful of appropriately opposing discovery in actions contesting whether insurers or plans satisfied obligations to pay the usual and customary rate (UCR) or another pricing rate. In litigation involving out-of-network reimbursement, insurers/plans and providers often clash over the issue of how deeply providers can investigate reimbursement methodologies and documents potentially relevant to them, particularly in light of legal privileges or the requirements of the Employee Retirement Income Security Act of 1974 (ERISA).

First, in the coming year, plans should be mindful of preserving the defensive privileges surrounding pricing methodology. Some courts will allow invasive discovery into company policies and procedures for reimbursing out-of-network claims, internal communications between in-house counsel and corporate business teams on these issues and other communications mentioning pricing methodology and data. In this context, plans should be particularly aware of recent cases involving the "fiduciary exception" to the attorney-client privilege. Some of these cases somewhat surprisingly place the burden of proof on the plan/administrator to show that it was not acting in its fiduciary capacity at the time of a given communication, rather than requiring providers to show the exception applies. See, for example, *L.D. v. United Behav. Health*, No. 20-cv-02254-YGR (JCS), 2022 U.S. Dist. LEXIS 139618, at *54 (N.D. Cal. Aug. 5, 2022).

Second, insurers and plans should anticipate that the outcome of many cases in 2023 will be decided on how much evidence providers gain through discovery and how clear (or unclear) plan language on pricing is. Insurers and plans should also be mindful that, in certain jurisdictions, courts may require ERISA fiduciaries to disclose certain information about pricing methodology merely as a part of denials. And some courts may hold ERISA fiduciaries to a higher level of proof than others in showing that they properly calculated reimbursement. Compare *In re WellPoint, Inc. Out-Of-Network "UCR" Rates Litig.*, 903 F. Supp. 2d 880, 921 (C.D. Cal. 2012) (in which UCR methodology was not required to be disclosed by an ERISA fiduciary) (collecting cases) with *Zack v. McLaren Health Advantage, Inc.*, 340 F. Supp. 3d 648, 662 (E.D. Mich. 2018) (in which "ERISA requires disclosure of pricing methodology [concerning the reasonable and customary amount] … as part of benefit and appeals denials").

Third, plans and insurers can expect more litigation in 2023, focusing on how UCR should be defined. For example, the Texas Supreme Court recently issued a decision in a pair of cases that will change the landscape in Texas and the Fifth Circuit concerning out-of-network reimbursement: *Texas Medicine Resources, L.L.P. v. Molina Healthcare of Texas, Inc.*, No. 21-0291, 2023 Tex. LEXIS 24 (Tex. Jan. 13, 2023) and *United Healthcare Ins. Co. v. ACS Primary Care Physicians Sw., P.A.*, No. 22-0138, 2023 Tex. LEXIS 24 (Tex. Jan. 13, 2023). In these cases, the Court held that there is no private right of action under Texas emergency care UCR statutes for claims arising prior to January 1, 2020. Plans and insurers can anticipate that parties will cite the Court's recent opinion as precedent in other cases involving out-of-network reimbursement where the parties will argue about the exact scope of the rulings. More broadly, the decision may cast ripples beyond Texas and the Fifth Circuit because cases in other states will question how to determine whether a private cause of action should be implied from a statute and may likewise interpret similar statutory language on out-of-network reimbursement.

Cases involving COVID-19 testing reimbursement foreshadow how providers' claims are expected to evolve

Several provider disputes involving COVID-19 reimbursement have been percolating through the courts. Typically, providers of COVID-19 tests or diagnostic services and medical laboratories assert claims against health plans regarding the plans' failure to properly reimburse COVID-19 testing services. Specifically, the most common allegations include purported breaches of the Families First Coronavirus Response Act (FFCRA) and the Coronavirus Aid, Relief and Economic Security Act (CARES Act). Providers have typically cited provisions of the CARES Act, stating that a plan or insurer "shall reimburse" an out-of-network provider of COVID-19 diagnostic testing for such testing in an amount that equals the "cash price" for such service as listed by the provider on its public website or "may negotiate" a rate with the provider for less than the cash price. These provisions in the CARES Act amend portions of the FFCRA that concern coverage requirements for such diagnostic testing.

As an initial line of defense, the battles in these cases focus on whether providers can bring a private cause of action in the first instance under the CARES Act or FFCRA. Most courts have found that providers do not have a private cause of action under either statute. See, for example, *Murphy Med. Assocs., LLC v. Cigna Health & Life Ins. Co.*, 2022 WL 743088, at *6 (D. Conn. Mar. 11, 2022) ("[N]either § 6001 of the FFCRA nor § 3202 of the CARES Act contains a private right of action."); *Am. Video Duplicating, Inc. v. City Nat'l Bank*, 2020 WL 6882735, at *4 (C.D. Cal. Nov. 20, 2020) ("[E]very court to address whether the CARES Act created an implied private right of action has held that it does not.").

But one outlier court has held that providers do have such standing, and thus, plans should be attentive to any courts that may join this minority view.

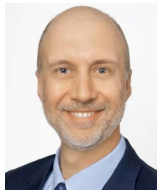
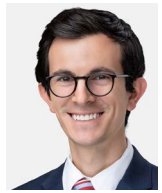
See *Diagnostic Affiliates of Ne. Hou, LLC v. United Healthcare Servs., Inc.*, No. 2:21-CV-00131, 2022 WL 214101, at *4–9 (S.D. Tex. Jan. 18, 2022). That said, thus far, courts that have assessed Diagnostic Affiliates have not found its reasoning to be persuasive or in line with Supreme Court precedent. See, for example, *Saloojas, Inc. v. Cigna Healthcare of Cal., Inc.*, 2022 U.S. Dist. LEXIS 183608, at *12-13 (N.D. Cal. Oct. 6, 2022).

Even so, some courts are allowing providers' claims concerning COVID-19 testing to proceed by reasoning that if a provider has standing to sue under ERISA by virtue of a plan beneficiary's assignment of benefits, then a plan may have breached an ERISA plan's terms in its failure to reimburse certain COVID-19 testing claims. In those cases where providers survived initial motions to dismiss, the litigation is moving into later stages, and thus, we can expect to see more litigation focusing on how much providers should be paid for such claims. Providers are arguing that they should be reimbursed based on the "cash price" they publicly posted based on the statutory language in the CARES Act. If courts like Diagnostic Affiliates agree that providers are, in fact, entitled to some reimbursement, we can expect litigation over this language concerning the "cash price" given providers may have artificially inflated prices they publicly posted.

These cases remain important to watch in 2023 as providers continue to challenge reimbursements by alleging purported violations of the FFCRA and CARES Act. See *Aventus Health, LLC, et al. v. United Healthcare, Inc.*, et al., U.S.D.C. M.D. FL, Doc. No. 6:22-2408-RBD-EJK, (filed Dec. 27, 2022) (a putative class action in which a group of out-of-network laboratories challenge reimbursement rates for COVID-19 testing, seeking to enforce a private right of action under the FFCRA and CARES Act).

Best practices and conclusions

Insurers and plans should implement best practices that account for the developments discussed in this article. They should expect fiercer discovery battles on out-of-network pricing in the near future and take steps to preserve defensive privileges. They should ensure that the language used in plans they administer clearly defines the rate for out-of-network reimbursement and contains more uniform pricing language across plans, where possible. Insurers and plans should keep abreast of how the Texas Supreme Court will define UCR and how its decisions will shape litigation in Texas, the Fifth Circuit and beyond. They should also anticipate new theories, like those arising in the COVID-19 testing cases, and devote attention to accounting for all of these trends expected in the year ahead.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Implications of pending Supreme Court and appellate cases

Takeaways

- The Supreme Court is likely to decide whether individuals can bring suit to enforce rights under Medicaid, and potentially under other federal statutes.
- The Supreme Court is also likely to decide the government's authority to dismiss FCA cases.
- The Tenth Circuit will likely address the level of detail that must be in a denial letter, as well as whether inconsistent denial letters are evidence that a denial is arbitrary and capricious.

Several significant decisions that could impact managed care are slated to come out of courts in the coming year, including opinions that could influence (1) the ability to sue for Medicaid benefits; (2) the viability of federal False Claims Act (FCA) cases; (3) Employee Retirement Income Security Act (ERISA) requirements for communicating adverse benefit determinations; and (4) the constitutionality of portions of the Patient Protection and Affordable Care Act (ACA). Here are a few of the cases we are watching on behalf of our managed care clients.

Right to sue for Medicaid benefits

In *Health & Hospital Corporation of Marion County, Indiana v. Talevski*, the U.S. Supreme Court is considering whether to reexamine its precedent that individuals can bring a federal Section 1983 suit (alleging a state or local official has violated their civil rights) to enforce rights under legislation such as Medicare. The Court is also considering whether the Nursing Home Reform Act provides a private right of action or leaves the enforcement of rights under that Act exclusively to the Centers for Medicare and Medicaid Services (CMS).

This case, while focused on the enforcement of rights under Medicaid, may have implications for rights under other federal programs and the administration of health care overall. Specifically, the case could potentially overturn long-standing precedent allowing individuals to enforce rights under all statutes created by Congress under the Spending Clause that touch on health care, not just Medicaid. Additionally, the enforcement of rights under Medicaid, Medicare, and other health care programs could be left exclusively under the purview of CMS and the Department of Health and Human Services (or other applicable agencies) to administer via administrative and agency remedies. Accordingly, a ruling in this case is one to watch. The U.S. Supreme Court heard oral argument in November 2022, and its ruling is expected by the end of the term in June 2023.

Government control over FCA cases

In December 2022, the Supreme Court heard another case with potentially large ramifications for the health care industry. In *U.S., ex rel. Polansky v. Executive Health Resources, Inc.*, the Court is considering whether the government has the authority to dismiss a qui tam FCA suit after initially declining to intervene and, if so, the applicable standard to apply to dismissal. In this case, which concerns alleged fraudulent billing of Medicare claims, the Justice Department originally declined to proceed with a qui tam suit but later moved to dismiss the action. The government's motion was granted by the district court and affirmed by the Third Circuit. In doing so, the Third Circuit concluded that the government must intervene before moving to dismiss, which it can seek leave to do at any point upon showing good cause and that FRCP 41(a)'s standards for voluntary dismissals govern the motion to dismiss.

A circuit split has emerged over when the government can move for dismissal of qui tam cases, and the applicable standard for those motions, with some circuits (like the D.C. Circuit) holding that the government has "unfettered discretion" to move for dismissal at any point of the litigation, regardless of whether it has chosen to intervene, and other circuits (like the Seventh and Third Circuits) limiting the government's authority to seek dismissal to only when it intervenes in an action and has applied FRCP 41(a)'s standards for a motion to dismiss. Finally, the Ninth Circuit has adopted a rationality standard under which the government must identify a valid government purpose, and a rational relationship between dismissal and accomplishment of that purpose, to obtain dismissal of a qui tam action. The Supreme Court is likely to resolve this split.

With health care being a frequently targeted area for qui tam lawsuits, *Polansky* may have significant implications for managed care companies. If the Supreme Court's ruling imposes a requirement to intervene in order to move to dismiss a qui tam action and a time by which that intervention must occur, the government may be encouraged to intervene earlier and dismiss actions that do not further the FCA's goal of redressing fraud before managed care companies are required to expend significant litigation resources. Further, the adoption of a more heightened standard like the Ninth Circuit's for government motions could also impact the government's ability to dismiss qui tam cases. Ultimately, *Polansky* presents an opportunity for the Justices to weigh in on the rules by which future qui tam actions may proceed. As with *Talevski*, a decision in this case is expected by the end of the Court's term.

ERISA requirements for communicating adverse benefit determinations

In another case of significance, the Tenth Circuit is expected to rule on the level of detail that an ERISA denial letter must contain, as well as whether courts may consider inconsistent denial letters in determining whether an insurer's decision to deny a claim for benefits is arbitrary and capricious under ERISA. A ruling in this case could have significant implications for claims administrators adjudicating coverage determinations under ERISA.

Specifically, in *K. et al. v. United Behavioral Health et al.*, the Tenth Circuit case will clarify the standards for an ERISA benefits claim by determining, among other issues, whether courts may consider inconsistent rationales that a plan provides in denial letters and addressing the level of detail that must be included in such denial letters. Indeed, a ruling in claimants' favor may increase pressure on the internal processes and

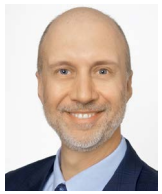
recordkeeping of claims administrators because it would enhance a court's ability to consider inconsistencies in an insurer's denial letters when considering whether a denial is arbitrary and capricious under ERISA, even when the ultimate benefits determination is supported by the record.

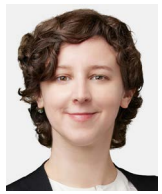
Constitutionality of the ACA's preventive care mandate

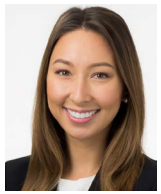
Under the ACA, managed care organizations have been required to cover a number of preventive services without a cost share. To be required, the services have needed to be recommended by one of three groups of medical experts, with one of the groups being the U.S. Preventive Services Task Force (USPSTF).

However, in a case of first impression, the U.S. District Court for the Northern District of Texas recently ruled part of the ACA's preventive services mandate unconstitutional. In *Braidwood Mgmt. Inc. v. Becerra*, eight plaintiffs challenged the preventive services mandate – specifically the requirement to cover PrEP, a medicine taken to prevent HIV contraction – under various constitutional theories. The district court concluded that (1) USPSTF's experts' appointments violated the appointments requirements in the U.S. Constitution; and (2) the requirement to cover PrEP violated the Religious Freedom Restoration Act.

The decision only affects services recommended by USPSTF, and no final remedy has been decided. Under the current schedule, that final remedy will be determined in 2023, and it could include a nationwide injunction. The final district court decision is likely to cause significant adjustments in the marketplace (including the possibility that some insurers will offer lower-premium options that do not cover certain preventive services) and will also likely result in an appeal to the Fifth Circuit.







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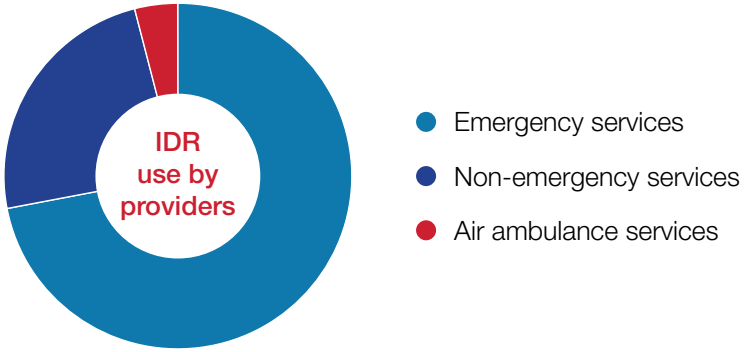
No Surprises Act: What's next for independent dispute resolution in 2023

Takeaways

- High utilization of independent dispute resolution is likely to continue into 2023 as providers hone their IDR processes.
- Due to payors' attempts to renegotiate above-market rates, more providers might go out of network.
- Although there is variation by region and provider types, results to-date have trended near the payor-determined "qualifying payment amount" (QPA).
- Providers could have a higher success rate in the wake of the most-recent *Texas Medical Association* opinion, which vacated regulatory provisions that emphasize QPA in IDR.
- Effective counterarguments and nimble strategy are important, particularly in light of the *Texas Medical Association* opinion.

Independent dispute resolution (IDR) – the federally-administered method of resolving surprise billing disputes under the No Surprises Act (NSA) – has exploded since it went live in March 2022, and this trend likely will continue. Out-of-network providers can use IDR to dispute payments for three types of services: emergency services, professional services at participating facilities and air ambulance services. IDR started slowly but quickly snowballed into a highly utilized federal procedure – and a giant headache for payors. At the beginning of May 2022, roughly 700 IDRs had been initiated by providers seeking additional reimbursement. That number rose to above 7,000 by the end of May; and six months later, providers had initiated over 120,000 IDRs.

The Centers for Medicare and Medicaid Services (CMS) recently issued high-level data regarding IDR statistics from April 15, 2022 to September 30, 2022, confirming the steep and unexpected rise in IDR use by providers. During this period, 72 percent of disputes involved emergency services, 24 percent involved non-emergency services (primarily radiology, anesthesiology, and pathology services) and air ambulance services made up the remaining 4 percent. Texas providers led in IDR initiations by a large margin, with Florida, Georgia, Tennessee and North Carolina providers rounding out the top five in IDR initiations.



The Reed Smith Managed Care team has additional industry-level insights and expects the exponential growth of IDR to continue in 2023. Based on our representations in this space, and confirmed by CMS's initial reporting, the current IDR volume is primarily driven by for-profit providers who are also frequent-flyer litigants. We have seen increased volume from these providers as they hone their processes into assembly-line-style IDR initiations. In addition, less dominant providers are building the infrastructure to systematically pursue IDR, which will add to 2023 disputes. Finally, some payors are renegotiating contracts with providers who leveraged surprise billing to negotiate rates far above reasonable market value. If negotiations fail and the providers go out of network, the loss of revenue stream will likely cause these providers to pursue IDR in 2023 as well.

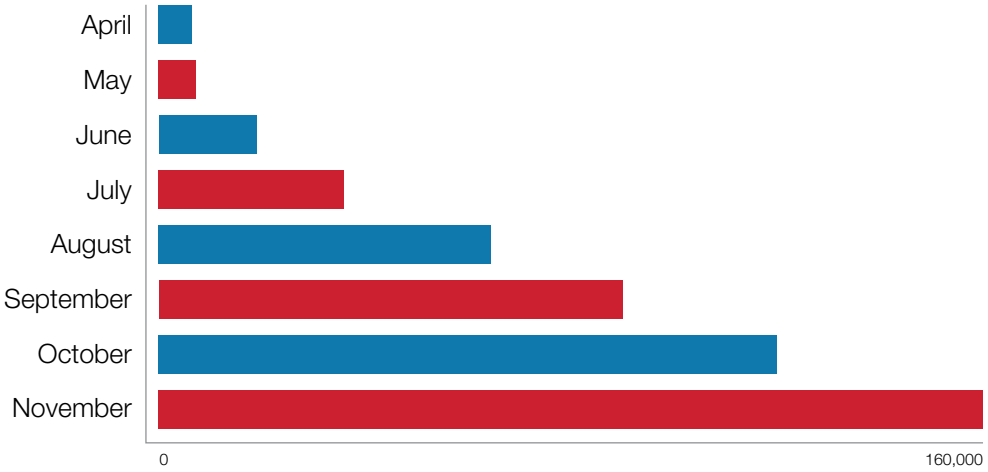
In terms of results to-date, although it varies based on region and service type, payors have generally been winning. IDR is a baseball-style process where each party makes a blind offer and the assigned IDR entity decides the winner. IDR entities, typically medical review companies, are certified by regulators to decide these disputes. These entities have found many of the disputes ineligible for IDR; according to CMS's report, over two-thirds of IDR disputes closed during the reporting period were determined ineligible for reasons such as the application of state surprise billing laws or incorrect batching of multiple patients' services. When disputes proceed to the offer stage, although CMS did not report on these outcomes, we have observed that winning offers tend to be clustered around the qualifying payment amount (QPA), which is the payor's median contracted rate for the Current Procedural Terminology (CPT) or Diagnosis Related Group (DRG) code. Providers often overreach by making offers far exceeding QPA. Given the importance that was until recently placed on QPA in the implementing regulations, IDR entities seemed to consider an offer closer to QPA more reasonable.

However, this trend may change following the February 6, 2023 ruling in *Texas Medical Association v. U.S. Department of Health and Human Services*, Case No. 6:22-cv-372-JDK (E.D. Tex.). The same court previously vacated provisions in the Interim Final Rules (which required selection of the offer closest to QPA) on the basis that the implementing agencies had exceeded their authority and issued rules inconsistent with Congressional intent. In response to this earlier ruling, the agencies issued a standard in the Final Rules that required consideration of QPA, but also permitted consideration of other factors. But on February 6, the court vacated this modified standard as well, reasoning that the statutory text of the NSA requires IDR entities to equally consider all pertinent factors in selecting an offer. The agencies have 60 days to appeal the ruling.

Providers will likely cite this ruling in urging IDR entities to select offers far above QPA. Dispute initiations have also ticked up since the decision was published, potentially signalling an even greater influx of IDRs. But the decision may not have significant impact, given that there are still strong arguments in favor of QPA as reasonable reimbursement. For instance, QPA arguably reflects a competitive rate determined in arms-length negotiations. QPA also already accounts for factors like service complexity and patient acuity since it is based on procedural and/or diagnosis-based coding. These arguments can be made based on the statutory text and independent of the regulations.

Regardless, provider tactics are likely to evolve in 2023. Because each party's offer submission is confidential, IDR entities' written decisions are the best indicator of what providers have argued and what the IDR entities found persuasive. Payors should examine these decisions closely for new trends in provider arguments and adjust their IDR strategy as needed, even if the strategy is specific to a particular provider or IDR entity.

IDRs Initiated, April - November 2022



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Public health

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Preparing for the end of the COVID-19 public health emergency

Takeaways

- The end to the COVID-19 public health emergency on May 11, 2023, and recent federal legislation will also end temporary changes that increased Medicaid enrollment, set coverage and pricing requirements for COVID-19 diagnostic testing, and expanded telehealth access.
- Medicaid MCOs should plan outreach and assistance to both state agencies and members to minimize expected disenrollment for eligible members.
- All plans should prepare for how they intend to cover COVID-19 testing and telehealth and other remote services once the PHE ends.

January 31, 2023, marked three years since the U.S. Department of Health and Human Services (HHS) first declared a public health emergency (PHE) due to COVID-19. The federal government passed a cascade of new laws, regulations and guidance that affected many different aspects of American life, from rent and student loan payment moratoriums to increased family food benefits to expanded access to health care, COVID-19 testing and related items and services and telehealth. While a few of these benefits will continue, most will expire once the PHE ends. The PHE will end on May 11, 2023, and managed care companies should be prepared for the fallout.

Here, we provide a brief overview of the state of the PHE, followed by a discussion of expected changes in Medicaid enrollment, COVID-19 testing and related items and services and telehealth services.

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The state of the PHE

HHS first declared a PHE due to COVID-19 on January 31, 2020, and it has renewed the PHE every 90 days throughout the Trump and Biden administrations to date.

On January 30, 2023, the Biden administration informed Congress that it will end the PHE on May 11.

Expected drop in Medicaid enrollment

The Families First Coronavirus Response Act (FFCRA), one of two signature pieces of federal COVID-19 legislation, increased funding to states for Medicaid so long as the state met certain requirements. One of those requirements is that the state maintain enrollment for those who were eligible for Medicaid as of January 1, 2020, for the duration of the PHE. Ordinarily, individuals must renew their Medicaid coverage annually and show that they meet income and other eligibility requirements. However, under the FFCRA, states receiving extra federal funds through the FFCRA cannot disenroll Medicaid recipients during the PHE so long as the recipient was eligible as of January 1, 2020, is still a state resident, and has not voluntarily left the program. HHS estimates that this "continuous enrollment condition" led Medicaid enrollments to increase by more than 19 million individuals, or nearly 29 percent, during the pandemic.

Through its most recent spending package, Congress has accelerated the end of these provisions. Under the legislation, states may begin processing Medicaid redeterminations of eligibility as soon as April 1. In addition, the enhanced federal funding called for by the FFCRA will phase down between April and the end of 2023. As a consequence of these changes, HHS estimates that up to 15 million people will be disenrolled in the Medicaid program, including nearly 7 million who remain eligible but nevertheless will be disenrolled due to bureaucratic hurdles.

While Medicaid managed care organizations (MCOs) should prepare for a decline in enrollment, MCOs can assist state Medicaid agencies in communicating to enrollees about the end of the continuous enrollment condition to improve coverage and member retention. Outreach and assistance to both state agencies and members is essential to minimizing disenrollment for eligible members.

COVID-19 testing and related items and services

The FFCRA and Coronavirus Aid, Relief, and Economic Security (CARES) Act, the second signature federal COVID-19 legislation, dramatically expanded access to COVID-19 testing and related items and services. Under the FFCRA and CARES Act, for the duration of the PHE, plans and issuers must cover: (1) diagnostic COVID-19 tests approved by the Food and Drug Administration (including under emergency use authorization) or otherwise authorized by a state or HHS; and (2) "items or services furnished to an individual during" an office, clinic, or ER visit that results in an order for a COVID-19 diagnostic test, "but only to the extent the items and services relate to the furnishing or administration of the [test] or to the evaluation of the individual for purposes of determining the need of the individual for such [test]."

Plans must cover such tests and related items and services without imposing cost sharing, prior authorization, or medical management requirements. Federal guidance also clarified that plans should generally find COVID-19 diagnostic testing is medically necessary – even if the individual is asymptomatic and has no known or suspected exposure to COVID-19 – so long as an authorized health care provider ordered the test. And in subsequent guidance, HHS and other agencies made clear that plans must cover authorized over-the-counter COVID-19 tests, even if the individual obtained the test without the involvement of a health care provider.

In addition to these coverage requirements, the CARES Act imposed pricing requirements for COVID-19 diagnostic testing. Specifically, if there was a negotiated rate between the plan and provider when the PHE was first announced in January 2020, that rate applies throughout the PHE. However, if the plan did not have a negotiated rate with the testing provider, then the plan must reimburse the "cash price" listed by the provider or negotiate a rate with the provider for less than the cash price. The "cash price" is the charge that applies to an individual who pays in cash (or cash equivalent) for a COVID-19 diagnostic test, and providers must publicize the cash price of testing on their website.

As noted elsewhere in the Managed Care Outlook, while these requirements greatly expanded access to COVID-19 diagnostic testing and related items and services, they were also ripe for abuse. But once the PHE ends, plans may limit coverage of COVID-19 testing to in-network providers, require a prescription or physician's order for such testing, impose cost sharing for the test and associated visit if they are not deemed preventive services, and potentially even limit the number of covered tests, so long as the conduct is consistent with the member's plan language – and the Affordable Care Act's requirement to cover laboratory services as an essential health benefit where applicable. Moreover, at the conclusion of the PHE, there will be no requirement for plans to reimburse the cost of at-home tests.

Importantly, even after the PHE ends, plans are still required to cover COVID-19 vaccines and boosters without imposing cost sharing when provided by an in-network provider. And while the federal government has largely subsidized the cost of COVID-19 vaccines, tests and treatments, once the government's supply is depleted, plans will be required to take on more of the cost.

Telehealth services

The FFCRA and CARES Act and subsequent federal guidance vastly expanded telehealth services for Medicare recipients. Medicare beneficiaries were permitted to obtain a variety of different types of services, including audiology, speech pathology, mental and behavioral health care, and other services via telehealth. Moreover, the Centers for Medicare and Medicaid Services (CMS) expanded its list of approved locations for telehealth services, suspended its requirement that only "established" patients receive telehealth services, permitted reimbursement for physical health encounters conducted remotely, and waived requirements specifying the types of practitioners that could bill Medicare for telehealth services. Though not compelled to do so under the law, many commercial plans followed suit by expanding access to telehealth services for their members. For Medicaid, state programs largely dictated how and under what circumstances telehealth services would be covered.

For Medicare beneficiaries, access to mental and behavioral telehealth services will remain permanent, and Congress's most recent spending legislation extended Medicare telehealth waivers through 2024. CMS is also encouraging states to permanently cover at least some telehealth services going forward. Plans should be prepared for how to approach such services, including who can provide and bill for telehealth and other remote services, once the PHE ends.

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