Top Issues in Behavioral Health 2025 Newsletter

ANNUAL NEWSLETTER FROM THE BEHAVIORAL HEALTH LAW GROUP

POLSINELLI® | What a law firm *should* be.™

Contents

Behavioral Health Investment 2025 – Legal Risks and Mitigation Strategies 2

AI in Behavioral Health: Regulation or De-Regulation in 2025? 6

Autism Therapy Industry Crystal Ball: Predictions and Trends for 2025 10

Managed Care Trends and Developments in Behavioral Health 14

Telehealth and Behavioral Health: Legislative Outlook and Trends 17

Hospitals Seek a Solution for the Behavioral Health Crisis through Joint Ventures with Experienced Partners 21

Lessons from the Trenches: Four Tips for Accessing Opioid Settlement Funds 27

Behavioral Health Perspectives from the Host of The ***10 Minute*** HealthBizCast 30

About Polsinelli's Behavioral Health Law Group 32

Behavioral Health Investment 2025 – Legal Risks and Mitigation Strategies

Nathaniel "Tani" Weiner
Health Care M&A | Co-Chair Behavioral Health Group
San Francisco

Ryan J. Mize
Attorney
Kansas City

With 2025 now underway, behavioral health industry stakeholders are cautiously optimistic that an improving economic and regulatory environment will result in increased investment activity, and with that, expansion of access to care. As investors and operators consider mergers & acquisitions (M&A) and other investment options, we note some of the key legal risk areas–along with actionable mitigation strategies–based on evolving clinical and business models. Incorporating these strategies during the early stages of your next transaction can help promote compliance with applicable standards, avoid potential pitfalls and support sustainable value creation.

Key Risk Areas

Behavioral health encompasses a broad range of services and treatment modalities that can be used in treatment of one of more diagnoses in areas including mental health, substance abuse, developmental disorders and/or related conditions. Often a treatment provider will treat co-occurring behavioral conditions and even integrate aspects of primary care into its treatment program. The broad range of service lines within behavioral health, along with varying layers of state, federal, and at times local regulation, makes it imperative for providers to carefully calibrate to the legal and reimbursement guidelines that apply to their specific business and care delivery system.

Licensure and Credentialing

Adherence to applicable licensing requirements, at both the facility and professional levels, is a fundamental building block for a compliant treatment program, and a primary potential risk area. The provider's clinical and business model should align with the facility-types, programs, and services licensed in their jurisdictions. Any gaps or mismatches between services provided and services licensed come at the risk of not only adverse action by the licensing agency, but also audit, recoupment and/or overpayment liability under commercial insurance and government-pay reimbursement arrangements. Payor arrangements typically require provider compliance with all legal requirements applicable to patient services reimbursed by the payor, and mis-matches in licensing and credentialing are a frequent area for payor enforcement.

A separate but related risk area is the legal structure of the business, particularly in markets that have a strong corporate practice of medicine (CPOM) doctrine. CPOM prohibitions could require ownership of the clinical operations by a licensed professional, which is typically addressed via a PC-MSO or "friendly PC" model. Failure to implement a compliant friendly PC structure where legally required jeopardizes the provider's legal arrangements with physicians and associated non-competition agreements and can create an additional potential basis for payors to recoup payments made to the provider.

CONTINUED ON PAGE 3

CONTINUED FROM PAGE 2

For providers that hold licensure at the entity level and/or receive third party reimbursement, applicable change of ownership (CHOW) filings and timelines can materially impact transaction timing; as depending on structure and applicable rules, the process can require pre-closing filings and site inspections over a timeline that is subject to agency discretion and bandwidth. These are separate and apart from transactions that are subject to antitrust review at the federal and/or state level, and as discussed elsewhere in this Newsletter, we have continued to see state-level transaction review regimes advance at the state legislative level over the past year.[1] Mapping out and developing a strategy to address applicable CHOW requirements will help keep a transaction process on track for a timely closing and avoid risks of adverse licensure, payor and/or other regulatory actions.

Billing and Reimbursement

A behavioral health provider's contracted commercial and governmental payors have overlapping, but not always identical, requirements. These requirements are often grounded in the licensure, credentialing and CPOM areas discussed above, but can also arise when a target company is not meeting payor requirements for, among other things, collection of patient financial responsibility amounts, provider credentialing, "incident to" billing, "all inclusive" and similar contract provisions, to name just a few. Additional regulatory compliance requirements can apply to programs that receive Medicaid or other government-pay reimbursement, including the Anti-Kickback Statute (AKS) and the physician self-referral law (Stark), among others. Failure to meet these requirements, including inability to provide supportive charting to the standards that payors require, can be a significant potential risk area.

We continue to see payors targeting behavioral health providers for audits and recoupments for alleged non-compliance with requirements. Payor recoupment claims are typically not covered by a provider's insurance policies and may be excluded from or subjected to heightened underwriting review in transaction representation and warranty coverage. Acquirors are advised to conduct a third-party coding review in coordination with transaction counsel–discussed further below–and sellers are advised to consider this a due diligence pre-requisite as part of a sale process.

Patient Housing and Travel Assistance

Providing free or below fair market value housing or travel assistance to patients receiving behavioral health care, including particularly addiction treatment, can expose providers to exposure under the federal Anti-Kickback Statute (AKS), Stark and Eliminating Kickbacks in Recovery Act (EKRA) laws and similar state regulations. These regulations could construe the offering of financial incentives or non-monetary benefits, such as housing or travel assistance, as unlawful inducements to patients in exchange for referrals to treatment services. These risks can also arise in connection with remuneration between a treatment provider and a referral source–and in some cases, workforce members--tied to the volume or value of referrals.

[1] "*Hospitals Seek a Solution for the Behavioral Health Crisis through Joint Ventures with Experienced Partners*." Infra this Newsletter.

CONTINUED ON PAGE 4

CONTINUED FROM PAGE 3

In addition to regulatory risks, providing housing or travel assistance may also conflict with payor requirements, as noted above. We recommend that providers and acquirors ensure that any housing or travel assistance is justified by a legitimate medical purpose and be structured to comply with applicable regulations and any safe harbors.

HIPAA, Privacy, and IT

Privacy laws, including federal level HIPAA and 42 CFR Part 2 which applies to substance abuse treatment providers, along with state level rules, create an additional area for compliance attention. We have seen a concerted uptick in regulatory enforcement of these standards, as well as civil class action lawsuits alleging failure by providers to adhere to them. As a starting point, providers are advised to develop and maintain policies and procedures geared to the requirements applicable to their program, along with rigorous implementation, including systems assessment, staff training and avoiding practices that may inadvertently create privacy liability. Potential risks in failing to sufficiently address these standards include operational disruption, regulatory enforcement, and financial liability for data breaches.

A particular recent hotspot in this area has been the collection and sharing of patient or prospective patient information via web-tracking technologies including via tracking pixels and/or social media platforms. AI and similar emerging technologies will create similar issues relating to the use and accounting for use of consumer and patient information. While these issues are faced by many health care providers, behavioral health providers that conduct outreach and marketing activities over the internet and/or incorporate emerging technologies into their care models will be at heightened risk.

Mitigation Strategies

Financial Due Diligence

Review of a target's financials and quality of earnings to validate Earnings Before Interest, Taxes, Depreciation and Amortization (EBITDA) is often the first type of diligence conducted by a buyer and helps determine the purchase price proposed to the seller. This process should be ongoing throughout the deal to account for and address any revenue, liabilities, or other financial irregularities and concerns and potentially may help flag issues for legal follow up.

Specific focus areas in behavioral health transactions should include payor mix, reimbursement rates and any reimbursement components that may be subject to true-up such as value-based arrangements and/or state-directed payments under Medicaid programs. Where applicable, buyer should assess the extent of a program's reliance on specific payors and/or how existing payor relationships can be leveraged to support expansion of services or into new markets. Coordination between financial, legal and other advisors can help confirm valuation along with the target's revenue cycle and compliance with payor standards and help avoid post-closing surprises.

Legal and Regulatory Due Diligence

Along with standard legal due diligence touch points, thorough review of regulatory compliance matters fundamental to the operation of a treatment program by experienced legal and other advisors is critical. Core areas generally include (i) compliance with licensing and accreditation standards, including any investigations, deficiencies, and associated

CONTINUED ON PAGE 5

CONTINUED FROM PAGE 4

plans of correction; (ii) payor relations, including any associated audits, prepayment reviews, and similar actions, as well as compliance with payor-specific payment policies that are material to the provider's service lines; and (iii) chart and coding review, in coordination with transaction counsel.

Additional legal diligence focus areas could be warranted depending on the transaction's attributes, including purchase price, the target's clinical and business model, and the regulatory landscape in relevant markets. For example, review of the reimbursement and/or regulatory environment in relevant markets should be considered with a keen eye on potential changes in reimbursement levels or methodologies and/or where there has been regulatory enforcement activity involving similarly situated providers.

Additional Considerations

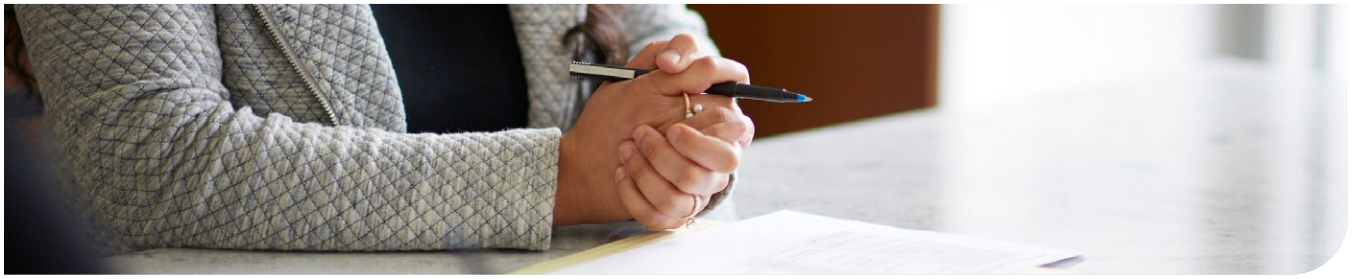
While the diligence process is often driven by legal and financial review, buyers should also account for the importance of workforce transition and integration matters. On the human resources side, assessments of staff turnover, compliance with staffing ratios and applicable certifications or screenings will help a buyer's post-closing operational management. Similarly, candid assessments of how the seller and buyer align culturally, clinically and strategically will set the foundation for a smooth integration process, particularly in cases where sellers will retain a post-closing role with the business.

Additional to the above, an integration plan should be developed to align on management, operational and systems integration, incorporating any areas that may warrant remediation identified in due diligence. A project management process should also be developed that includes defined milestones and designated individuals from both sell and buy-side who will have ownership for various aspects of integration.

While workforce and integration planning matters — along with other key aspects of risk allocation and mitigation—are often memorialized to some extent in definitive transaction agreements, sustained focus on implementation will help avoid misalignment and missed opportunities to realize intended transaction synergies.

Conclusion

The success of a behavioral health investment, particularly M&A transactions, hinges on rigorous due diligence, strategic integration planning, and awareness of potential land mines along the way. A proactive approach to addressing these risks with knowledgeable advisors will support sustainable growth, compliance with applicable standards, and the creation of long-term value and access to care.



AI in Behavioral Health: Regulation or De-Regulation in 2025?

Jean Marie R. Pechette
Shareholder
Chicago

Joelle M. Wilson
Shareholder
Chicago

Artificial intelligence (AI) continues to evolve as a transformative force in health care delivery, and particularly in the field of behavioral health, from clinical decision support to patient engagement tools and personalized treatment plans. However, with innovation comes a complex regulatory landscape. As we continue to venture into a future where AI plays a pivotal role in shaping behavioral health care, the need to balance the potential benefits of AI with continued adherence to legal and regulatory measures will be challenging.

The Biden Administration, with its executive orders and rules aimed at limiting the use of AI and expanding privacy and security measures, ostensibly took a more restrictive approach. It is predicted that the Trump Administration will take a somewhat different, more hands-off regulatory approach. Trump already reversed President Biden's October 2023 AI executive order, tapped David Sacks (former PayPal executive), as his "White House AI & Crypto Czar,"[1] and stated his goal of giving priority to accelerating AI innovation in order to keep the US competitive globally.[2]

Notably, on January 21, 2025 (the day after President Trump's inauguration), President Trump, joined by OpenAI CEO Sam Altman, Oracle Corporation Chairman Larry Ellison, and SoftBank CEO Masayoshi Son (collectively the initial equity funders, along with MGX Fund Management Limited)," announced the U.S. government's support of the "Stargate Project." The Project, which was underway prior to President Trump taking office, is focused on building the infrastructure needed to support AI development and meet the high energy demands of the technology. The Project's first 1 million-square foot data center is being constructed in Abilene, Texas. Currently, the Trump administration has not explicitly pledged federal funding or tax breaks to support the project, but there has been discussion of support via the means of "emergency declarations," which would aim to address regulatory hurdles encountered by the Project. OpenAI, Oracle, Softbank, and MGX will make an initial investment of $100 Billion in the Project, with plans to expand the investment to $500 Billion over the next four years. Other partners include Nvidia, Microsoft and Arm.[3]

---

[1] https://www.reuters.com/world/us/trump-appoints-former-paypal-coo-david-sacks-ai-crypto-czar-2024-12-06/; https://natlawreview.com/article/trump-taps-david-sacks-ai-and-crypto-czar-ai-washington-report

[2] *See, e.g.,* AI Policies Under Trump to Contrast With State Regulatory Trends, January 2, 2025, available here: https://news.bloomberglaw.com/us-law-week/ai-policies-under-trump-to-contrast-with-state-regulatory-trends; AI Companies are Preparing for the Second Trump Administration, January 7, 2025, available here: https://www.npr.org/2025/01/07/nx-s1-5239970/ai-companies-are-preparing-for-the-second-trump-administration; How AI Regulations May Change With the New Trump White House, January 20, 2025, available here: https://www.pymnts.com/news/artificial-intelligence/2025/how-ai-regulations-may-change-with-new-president-donald-trump-white-house/

[3] *See, e.g.,* OpenAI, Announcing the Stargate Project, January 21, 2025, available here: https://openai.com/index/announcing-the-stargate-project/; Project Stargate a 500 Billion AI Venture, available here: https://www.forbes.com/sites/saibala/2025/01/22/project-stargate-a-500-billion-ai-venture-between-oracle-open-ai-nvidia--softbank-that-will-revolutionize-healthcare/; What to Know About 'Stargate,' OpenAI's New Venture Announced by President Trump, available here: https://time.com/7209167/stargate-openai-donald-trump/

CONTINUED ON PAGE 7

CONTINUED FROM PAGE 6

Federal Regulatory Landscape: The Behavioral Health Context

The U.S. does not yet have a binding federal law that regulates the development and use of AI. However, over the past few years we have witnessed preliminary bipartisan efforts to address potential risks in the development and use of AI, including efforts to promote transparency and notice, ensure fairness and nondiscriminatory practices, and protect the privacy and security of health information.[4] While federal regulations for AI in health care remain in their early stages, the unique challenges of behavioral health—such as trust in AI technology, patient privacy, equitable access, need for transparency, and therapeutic efficacy—highlight critical gaps in the regulatory framework.

In behavioral health, these federal priorities could accelerate the adoption of AI tools aimed at improving patient outcomes. For example, AI driven platforms like chatbots for mental health support or predictive analytics for crisis intervention may benefit from fewer regulatory hoops. However, this push for innovation comes with challenges, such as ensuring that these tools are safe, equitable, and effective for diverse patient populations.

Given the potential for increased growth and use of AI across various industries, including health care, federal regulation (or perhaps more likely, de-regulation) of AI technology (to accelerate growth and innovation) is poised to play a significant role as 2025 progresses.

Insights from the Congressional Research Service

While we do not anticipate federal legislation with regard to AI in the immediate future, there is consensus that AI needs to be developed and deployed safely. To that end, on December 30, 2024, the Congressional Research Service (CRS) issued a report on ***Artificial Intelligence in Healthcare***. The report provides members of Congress, their committees, and staff with nonpartisan, objective, and authoritative research, analysis, and policy recommendations and highlights challenges that may arise when AI is used in health care settings. The CRS identified the following areas of concern, including those particularly relevant for behavioral health providers:

- **Transparency and Accountability**
  There is a growing push to ensure AI systems used in clinical settings are explainable and their decision-making processes transparent. While existing Food and Drug Administration (FDA), Software as a Medical Device (SaMD) guidelines call for transparency in AI functionality, AI systems should include explainable features for both providers and patients.
- **Data Privacy and Security**
  Protecting sensitive health data used in AI remains a pressing concern. Developers and providers should expect to address heightened scrutiny around privacy standards.
- **Bias and Equity**
  AI tools may inadvertently perpetuate or amplify biases due to biased data or algorithmic design. Regulators are increasingly

[3] *See our prior analyses addressing the use of AI in the health care industry:* Biden's October 30, 2023, Executive Order on AI: Key Takeaways for Health Care Stakeholders, December 2023, available here: https://www.polsinelli.com/publications/bidens-october-30-2023-executive-order-on-ai-key-takeaways-for-health-care-stakeholders; Proposed Regulatory Oversight on the Emerging Use of Artificial Intelligence in Digital Health, May 10, 2023, available here: https://www.polsinelli.com/publications/proposed-regulatory-oversight-on-the-emerging-use-of-artificial-intelligence-in-digital-health; and Artificial Intelligence's Role in Reshaping Behavioral Health and Navigation of Legal Risks Ahead, pg. 7, March 2024, available here: https://polsinelli.gjassets.com/content/uploads/2024/03/24_Behavioral_Health_Newsletter-v10.pdf

CONTINUED ON PAGE 8

CONTINUED FROM PAGE 7

focused on ensuring AI systems are equitable and clinically validated across diverse demographics.

- **Liability and Accountability**
  There is legal uncertainty surrounding liability when AI tools cause harm or errors. No specific regulatory framework currently addresses AI liability. Such uncertainty may continue to foster reluctance to adopt such technologies, and could slow or not achieve the goal of accelerated innovation.

Overall, the CRS highlights the absence of a unified framework for AI regulation, leading to inconsistent oversight across federal and state agencies, and potential confusion for stakeholders. While the CRS highlights challenges with the use of AI in health care settings and provides Congress with policy recommendations, we anticipate that federal action will continue to primarily come through agency guidance, reports, and requests for information rather than sweeping legislative or regulatory changes.

State-Level Developments: Behavioral Health in Focus

While federal regulation lags, states are taking the lead in AI regulation – though with varying levels of activity and focus. Several states, including California, Colorado, and Illinois, to name a few, are introducing or have passed legislation to regulate the development, deployment, and use of AI tools. These bills often include provisions for transparency, data privacy, algorithmic accountability, and consumer protection.

In the behavioral health space, state laws could create compliance hurdles for providers utilizing AI-driven solutions. For instance, California bill AB 3030 imposes significant disclosure requirements on any health facility, clinic, physician's office or other group practice utilizing generative AI for clinical-based communications. Such mandates could affect providers using AI-enabled diagnostic tools or virtual mental health assistants, as they would need to ensure compliance with disclosure and transparency requirements.

Colorado, on the other hand, recently passed SB24-205, which requires developers and deployers of certain AI tools to use reasonable care to protect consumers from known or foreseeable risks related to algorithmic discrimination. As a result of this law, impacted providers will need to think about the governance and risk management frameworks they have in place for the use of AI tools as a first step in complying with the act.

Another example is Illinois HB 5649, which died in session, but highlights the ever-growing importance states are placing on transparency surrounding the use of AI. This bill would have made it unlawful for a licensed mental health professional to provide mental health services to a patient through the use of AI without first obtaining informed consent.

These developments highlight the broader trend of integrating AI into health care while addressing key concerns like transparency, accountability, and patient safety. Providers operating in multiple states and developers marketing behavioral health AI tools nationwide will need to navigate these varying regulatory requirements as they emerge.

CONTINUED ON PAGE 9

CONTINUED FROM PAGE 8

What is on the Horizon for Behavioral Health AI?

As AI continues to transform the behavioral health landscape, several trends are emerging for providers to watch:

1. **Increased Use of Generative AI in Therapy**
   Generative AI tools are being developed to assist clinicians in creating treatment plans, documentation, and patient communication. Providers should evaluate how these tools align with their practice models and ensure compliance with any applicable regulations, particularly around data privacy and accuracy of generated content.
2. **Scrutiny on Bias and Focus on Equity**
   Policymakers are paying increasing attention to algorithmic bias and its impact on underserved populations. Behavioral health providers adopting AI tools should assess the inclusivity of these technologies.
3. **Integration with Value-Based Care Models**
   As value-based care becomes more prevalent, AI tools that demonstrate improved outcomes and cost-efficiency will be critical. Behavioral health providers must stay informed about emerging AI solutions that align with value-based reimbursement models.

Conclusion

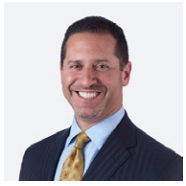
As the promise of a new environment for accelerated use of AI and innovation under the Trump Administration takes shape, behavioral health providers may have a more favorable opportunity to leverage AI to enhance patient care. The intersection of behavioral health and AI holds immense potential to reshape care delivery, but it also demands careful navigation of the emerging regulatory landscape. The federal government's possible de-regulatory push may accelerate innovation and competition among existing and new players in the AI industry, while potentially varying state-level efforts could create a more complex compliance environment. By staying informed, nimble and adaptable, providers can position themselves to succeed in this transformative era.

Autism Therapy Industry Crystal Ball: Predictions and Trends for 2025

Michael T. Flood
Shareholder
St. Louis

Scott Kremeier
Managing Director, Health Care
Piper Sandler
Chicago

Paul A. Gomez
Behavioral Health Co-Chair
Los Angeles



Barry D. Alexander
Office Managing Partner
Raleigh

As we move into 2025, the autism therapy industry will remain an area of focus and activity for each of the major behavioral health industry constituencies. Over the past few years, headlines highlighted an industry with both tremendous growth and challenging headwinds. Industry growth was driven by the increasing demand for autism therapy services including applied behavioral analysis (ABA) fueled by improved diagnosis of autism spectrum disorder, expanded insurance coverage mandates for autism therapy treatment, and an influx of investment activity in the space to support growing autism therapy platforms. While the industry's growth has been significant, challenges with workforce capacity, scalability, compliance and payor relations are at the heart of any conversation around the challenges of investing in or operating an autism therapy provider.

In this article we will examine the current business and dealmaking environment within the autism therapy industry, assess the development and implementation of multi-modal models to provide comprehensive care to autistic individuals, evaluate emerging payor and regulatory scrutiny of ABA therapy, and discuss potential unknowns based on health policy reforms from Washington, D.C.

2024 Market Recap and the Look Ahead.

The autism therapy mergers & acquisitions (M&A) market looks to build on the strong momentum following a rebound year in 2024. The second half of 2024 saw the successful closing of multiple platform level transactions with GTCR's acquisition of Caravel Autism Health, Tenex Capital Management's acquisition of Behavioral Innovations, Goldman Sachs Alternatives' acquisition of Center for Social Dynamics, and the recent sale of Unison Therapy Services to Ascend Capital Partners as well as multiple small tuck-in acquisitions.

The autism industry enters 2025 on a more stable footing from both a labor perspective and positive trends on the reimbursement front for government and commercial payors. These tailwinds should support continued interest by capital providers in the space, with particular emphasis on platforms of scale with the infrastructure in place to support the human capital demands of the business and the technological capabilities to address payor's increasing focus on outcomes data. Additionally, capital partners are highly attuned to those platforms with attractive geographic characteristics, which includes favorable state level reimbursement levels, positive workforce dynamics and provider density within those states.

CONTINUED ON PAGE 11

CONTINUED FROM PAGE 10

Since 2018, the industry has seen a significant amount of capital invested by private equity and other capital providers. Today there are more than fifty private equity backed ABA therapy platforms. Many of these platform investments were made between 2017 – 2019 and have reached or exceeded the typical private equity hold period. Capitalizing on the momentum of several successful exits in 2024, the sector is expecting a number of other ABA platforms to seek a liquidity event in 2025. Coupled with the significant amount of dry powder at private equity firms, 2025 has the potential to be a banner year from an M&A perspective.

Notably, the platforms that have transacted over the past year are comprised of more than one service setting (clinic, home, or school). In addition to infrastructure investments and broader care models, capital partners are focused on providers with a more diversified service model that can deliver the best learning environment for children while also providing flexibility for the workforce. While many platforms in the space started as a single service setting model, the industry has recently trended to a more clinic or center-based model complemented by an ability to deliver services on a smaller scale in the home or in a school setting.

Buyer expectations have also evolved as the industry has matured, with a heavy focus on provider platforms that have invested resources to create a scalable platform supported by technology systems including finance and accounting, recruiting and human resources, and clinical support. To achieve a platform level valuation, service providers must demonstrate a certain level of sophistication to address the growing requirements by payors around utilization and care plans further detailed below. Those companies that have invested in these areas will be positioned well for a potential transaction in 2025.

Comprehensive Care Models With an Eye Towards Value Based Payment.

The autism therapy industry continues to mature at a rapid pace. Over the last decade there have been a series of federal and state legislative and regulatory actions that have combined to ensure ABA therapy coverage by third party payors and state Medicaid programs in all 50 states. As a result, many autism therapy providers who were previously cash pay operations with limited scale either increased their operational footprints as additional resources became available or were potential acquisition opportunities for institutional investors.

Today, many of the businesses acquired or built following insurance coverage expansion are looking to further develop their service offerings or become a hub-and-spoke for coordinating ABA and other medically necessary services such as physical therapy, occupational therapy or speech language pathology services for children with autism. At their most complex, some companies are integrating primary care and dentistry in an attempt to manage all of the health care needs of the child. These models are being undertaken with an eye towards value-based care and an acknowledgement that specific needs of autistic individuals are at the center of their entire health care journey.

Our expectation is these models will continue their growth because they provide a single provider for the multiple services autistic children require and reduce burdens on already overburdened families in coordinating care. These models are also attractive to payors, particularly commercial payors, who

CONTINUED ON PAGE 12

CONTINUED FROM PAGE 11

may have a preference for a smaller group of providers to provide treatment to a complex patient population to reduce the administrative burden, improve utilization management and facilitate improved outcomes through increased levels of care coordination. However, the industry continues to be plagued by a lack of standardized approach to quality measures and other benchmarking data, which has slowed the pace of transition to a value-based payment model.

As more autism therapy providers look to expand their service offerings, careful attention should be paid to corporate structures to ensure compliance with "corporate practice" requirements. Structuring multi-profession and multi-state operations to ensure compliance with professional ownership requirements, and if applicable, multi-jurisdictional operations will be necessary to ensure compliance and preserve enterprise value as operators of these models seek additional scale.

Increasing Utilization Draws Increasing Payor and Regulatory Scrutiny?

The same demographics driving investment interest and growth in the autism therapy industry are also responsible for increasing scrutiny from payors and regulatory bodies. In December 2024, ProPublica published an article investigating United Healthcare's approach to managing ABA therapy for children with United Healthcare Medicaid managed care coverage in several states.[1] The article detailed a plan to limit the admission of new providers to United Healthcare's networks and terminate those that are current "cost outliers." It also highlighted the insurer's focus on reviewing the medical necessity for the intensity of ABA services as well as enhancing clinical guidelines for authorizing treatment.

Although specific to just one payor, the ProPublica article highlights that ABA therapy providers can expect enhanced scrutiny from payors with a specific focus on utilization management and adherence to evidence based standards for determining medical necessity. Payors are also likely to continue their focus on supervision, documentation, credentialing and diagnosis and referral documentation. ABA therapy is reimbursed and paid on a fractional hourly basis rather than an episodic or prospective manner, which makes the clinical documentation and adherence to each specific payor's documentation and supervision requirements crucial to each provider's operational success. Audits and investigations based on documentation deficiencies will continue to present challenges for industry participants who lack robust compliance plans and internal controls to ensure all care is appropriately documented.

As utilization has increased, the federal government has also taken note. The U.S. Department of Health and Human Service Office of the Inspector General (HHS-OIG) recently released an audit in December 2024 evaluating ABA service delivery in Indiana Medicaid. The audit evaluated claims for a two-year period from January 2019 to December 2020 and found "potentially improper" ABA therapy payments of approximately $76.7 million and recommended Indiana refund $39.4 million to

[1] *Waldman, Annie,* UnitedHealth is Strategically Limiting Access to Critical Treatment for Kids with Autism, ProPublica *(Dec. 13, 2024), available at:* https://www.propublica.org/article/unitedhealthcare-insurance-autism-denials-applied-behavior-analysis-medicaid

CONTINUED ON PAGE 13

CONTINUED FROM PAGE 12

the federal government.[2] HHS-OIG's findings primarily centered around documentation deficiencies which either did not support the billed code, failed to disclose the full extent of services provided, indicated claims were submitted for non-therapy time or activities that were not therapeutic in nature.

Both the ProPublica article regarding United Healthcare and the Indiana Medicaid HHS-OIG report highlight the growing scrutiny of the autism therapy industry being driven by the intensity and cost of the services. We expect there to be additional friction between providers and payors around the amount of ABA therapy ordered for each individual child as their course of therapy progresses (i.e., 40 vs. 30 vs. 25 hours per week). In January 2025, Indiana Medicaid recommend a proposal to a state legislative budget committee where it would potentially limit ABA coverage for children in its Medicaid program to 30 hours per week and create lifetime limits on coverage.[3] Although, it is unclear whether that action was related to the HHS-OIG report, the collective signals from both public and private payors demonstrate that autism therapy must remain vigilant in only providing services when medically necessary and that it continues to deploy robust compliance plans and processes centered around clinical documentation and demonstrating all relevant coverage requirements are satisfied with a specific eye towards whether the intensity of the service should decline as the child progresses through their course of care.

New Developments from Washington and Beyond.

The regulatory environment for autism therapy continues to shift and evolve. The Autism Collaboration, Accountability, Research, Education and Support Act (Autism CARES Act), was reauthorized in 2024 and provides the main source of federal funding for autism research, services, training and monitoring. It will deliver over $2 billion in dedicated federal funding to autism therapy research and workforce development. As the page turns to the new Trump Administration, Congress intends to deliver an extension of the tax package passed in President Trump's first term in 2017. One major question for the autism therapy industry is whether Congress will choose to offset those potential tax cuts by reducing Medicaid funding or significantly redesigning how the federal government funds the Medicaid program. President Trump's first term saw a discussion on potentially replacing the federal match funding mechanism with a block grant funding mechanism. Because autism therapy is heavily dependent on Medicaid funding, any changes at the federal level are likely to have direct impacts on how autism therapy providers will meet demand for their services moving forward.

Concluding Thoughts

The pent-up demand for autism therapy services will continue to drive conversation about the future of the sector from all participating constituencies. While conditions for dealmaking appear to be improving, enhanced scrutiny from payors and regulators will continue to require that operators and current investors remain vigilant in ensuring compliant operations for 2025 and beyond.

---

[2] United States Department of Health and Human Services Office of Inspector General, Indiana Made at Least $56 Million in Improper Fee-for-Service Medicaid Payments for Applied Behavioral Analysis Provided to Children with Autism *(Dec. 2024), available at:* https://oig.hhs.gov/documents/audit/10123/A-09-22-02002.pdf

[3] Larson, Chris, Indiana Medicaid Proposes 30-Hour Weekly, Lifetime Cap for ABA, Behavioral Health Business *(January 17, 2025), available at:* https://bhbusiness.com/2025/01/17/indiana-medicaid-proposes-30-hour-weekly-lifetime-cap-for-aba/

Managed Care Trends and Developments in Behavioral Health

C. Ryan Morgan
Shareholder
Denver

The landscape of behavioral health care continues to undergo significant transformations, driven, in part, by evolving managed care trends. As we move further into 2025, stakeholders in the health care sector are witnessing pivotal changes that are aimed at enhancing access, improve quality, and ensure cost-effectiveness in behavioral health services. This article explores four current trends shaping the future of managed care in behavioral health: the expansion of behavioral health in Medicare Advantage, the narrowing of provider networks by payors, increased payment audits, and the shift towards value-based reimbursement models.

Medicare Advantage Expands Coverage and Access

In the last two years, the Centers for Medicare & Medicaid Services (CMS) has taken steps to improve behavioral health coverage and access. The 2024 Medicare Advantage final rule[1] expanded the list of provider-types subject to objective network access and adequacy standards to include clinical psychologists and licensed clinical social workers.

The 2025 Medicare Advantage final rule[2] formally expanded coverage to permit reimbursement for marriage and family therapists and mental health counselors. It again expanded the list of provider-types subject to objective network access and adequacy standards, this time adding a new provider type, "Outpatient Behavioral Health." This new provider type includes marriage and family therapists, mental health counselors, opioid treatment programs, community mental health centers, and, when furnishing counseling or therapy services, nurse practitioners, clinical nurse specialists, addiction medicine physicians, outpatient mental health facilities, and substance use treatment facilities.[3] Also in the 2025 final rule, CMS implemented a 10% credit to its measurement of certain network adequacy standards when the plan includes telehealth providers in the network.

Looking forward, the 2026 Medicare Advantage proposed rule introduces a requirement that in-network cost sharing for behavioral health services must not exceed the cost sharing under traditional Medicare. This includes mental health specialty services, psychiatric services, partial hospitalization, intensive outpatient services, inpatient hospital psychiatric services, outpatient substance use disorder services, and opioid treatment program services.

These changes are intended to enhance access to behavioral health services for enrollees by ensuring these provider-types and specialties are included in the plan's provider network. Consequently, they also all serve to better position behavioral health providers seeking contracts with Medicare Advantage plans.

Payors Move to Narrow Provider Networks

In a time of increasing coverage for behavioral health

[1] 88 Fed. Reg. 22120 (*Apr. 12, 2023*).
[2] 89 Fed. Reg. 30448 (*Apr. 23, 2024*).
[3] 42 C.F.R. § 422.116(b)(2)(xiv).

CONTINUED ON PAGE 15

CONTINUED FROM PAGE 14

and a growing understanding of its importance, it is not surprising that behavioral health care utilization has increased steadily and significantly. The percentage of insured adults who report receiving mental health care services rose from 20% in 2019 to 25% in 2022.[4] Despite increasing clinical demand and expanding insurance coverage for behavioral health, we are seeing increased action by payors to reduce the size of their already narrow behavioral health provider networks. Recently, payors have terminated contracts or moved to reduce the scope of services or the insurance products covered by the contracts, likely in response to this trend.

Our experience with respect to this trend is supported by a recent ProPublica article, which highlighted how United Health Care, through its subsidiary Optum, is limiting access to Applied Behavior Analysis (ABA) therapy for children with autism, focusing on cost-cutting measures targeting Medicaid enrollees.[5] Optum's internal documents revealed plans to reduce the number of ABA providers in its network, prevent new providers from joining the network, and renegotiate reimbursement rates for those who stay.

Efforts to narrow provider networks might not only run afoul of applicable network adequacy and access requirements, but they might also violate the federal Mental Health Parity and Addiction Equity Act, which mandates equal coverage for mental health and physical conditions. Providers should understand their patients' legal and contractual rights to access behavioral health services to ensure they are not casualties of payor efforts to narrow provider networks.

Increased Payment Audits

Another trend impacting behavioral health care is the rise in retrospective payment audits. The increase in audits suggests that payors have expenditures in excess of actuarial projections, forcing them to take more aggressive audit action. Some of the audits involve a concerning lack of rigor and consistency when making determinations of medical necessity, with payors using unfounded criteria and applying it unevenly across similar claims.

We have seen audits where inconsistent medical necessity determinations stem from unqualified personnel making the determinations, ambiguous clinical criteria (e.g., ASAM, InterQual®) and the application of restrictive clinical criteria without acknowledging recognized exceptions.

Other audits focus on the qualifications of the treating practitioner, especially when the treating practitioner is different from the billing practitioner. This audit trend might be driven by national behavioral health staffing shortages[6] and the growing integration of behavioral health into primary care settings, both of which have the potential to introduce provider types that are not found in the traditional model of care, making payors skeptical.

Even routine claims audits are burdensome and aggressive audits are likely to be more so. Providers should be prepared with comprehensive medical record documentation and with confidence that all personnel treating patients are appropriately licensed and credentialed.

[4] https://www.kff.org/mental-health/issue-brief/exploring-the-rise-in-mental-health-care-use-by-demographics-and-insurance-status/
[5] https://www.propublica.org/article/unitedhealthcare-insurance-autism-denials-applied-behavior-analysis-medicaid
[6] https://documents.ncsl.org/wwwncsl/Labor/Workforce-Shortages-State-Resource-Systems.pdf

CONTINUED ON PAGE 16

CONTINUED FROM PAGE 15

Continued Shift to Value-Based Reimbursement

The shift towards value-based reimbursement models continues to gain momentum in behavioral health care. Value-based reimbursement emphasizes outcomes and quality of care over the volume of services provided. By aligning provider incentives with patient outcomes, value-based models aim to improve the quality of care while controlling costs. As behavioral health services become increasingly integrated into primary care, value-based reimbursement models are expected to play a crucial role in shaping the future of managed care for behavioral health providers.

Conclusion

The current trends in managed care for behavioral health reflect a complex interplay of efforts to expand access, control costs, and improve care quality. While the expansion of Medicare Advantage coverage represents a positive step towards comprehensive mental health care, the narrowing of provider networks and increased payment audits pose challenges that must be addressed to ensure equitable access to services. The continued shift towards value-based reimbursement models offers a promising path forward, aligning incentives with patient outcomes and fostering a more sustainable health care system. As these trends evolve, providers must remain vigilant by understanding and exercising their respective legal rights.

Telehealth and Behavioral Health: Legislative Outlook and Trends

Joelle M. Wilson
Shareholder
Chicago

Michael T. Flood
Shareholder
St. Louis

Laura D. Pone
Shareholder
Chicago

As we move further into 2025, several unresolved reimbursement, regulatory and policy questions continue to loom over the use of telehealth in behavioral healthcare delivery. Despite a new Congress and Presidential Administration, providers, payors and investors are continuing their years-long efforts to receive regulatory clarity post-pandemic. While historically there has been significant bipartisan support in Congress to extend, and in certain cases make permanent, telehealth flexibilities, the path forward remains unclear.

Medicare Telehealth Reimbursement: Meaningful Reimbursement Changes or More of the Same?

Expanding the Medicare telehealth benefit remains top of mind for policymakers, healthcare providers, and patients alike as we enter 2025. The second half of 2024 demonstrated once again the strong bipartisan support in Congress to extend telehealth flexibilities created in response to the COVID-19 Public Health Emergency (PHE).

The PHE brought unprecedented changes to Medicare reimbursement requirements for telehealth services through the use of administrative waiver authority. These waivers included changes and flexibilities to originating site and geographic restrictions, the expansion of audio-only services, and increasing the types of providers eligible to receive payment for telehealth services, among others. Originally set to expire on December 31, 2024, these measures were temporarily extended through March 31, 2025 as a result of the temporary **continuing resolution** passed by Congress to avert a government shutdown. Importantly, the extended telehealth flexibilities include delaying the in-person requirements for mental health services, allowing physicians and practitioners to continue to provide telehealth services, absent an in-person examination, for purposes of diagnosis, evaluation, or treatment of a mental health disorder.

The short-term nature of this extension creates another "telehealth cliff" and underscores the necessity for decisive action by President Trump and Congress, as well as industry stakeholders, to determine the future of telehealth policies. While specific policy positions on telehealth from the Trump Administration have yet to be detailed, several factors provide insight into possible directions:

- The costs of widespread legislative expansion of Medicare telehealth coverage will need to be offset by Congress with corresponding spending reductions. Because a permanent expansion of telehealth coverage (either on a service line

CONTINUED ON PAGE 18

CONTINUED FROM PAGE 17

or geographic basis) would create significant new Medicare program expenditures, Congress may instead choose incremental approaches (for instance a limited extension of the existing telehealth flexibilities) to lessen the projected costs that would be offset.

- There is broad bipartisan support for telehealth expansion in Congress and recognition of its ability to drive outcomes consistent with value-based payment systems, and increase patient access to care in underserved areas and with underserved populations. Such support is evidenced by HR 7623, the **Telehealth Modernization Act of 2024**, which unanimously passed out of the House Energy and Commerce Committee as part of a full committee markup in September 2024.
- Since the enactment of the Comprehensive Addiction and Recovery Act in 2016 and Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) Act in 2018, behavioral health has been a policy emphasis of both Republican and Democratic Presidential Administrations. Because telehealth has proven effective as a delivery mechanism for behavioral health services, Congress or the Administration may be more likely to prioritize behavioral health telehealth policy priorities over other policies.
- Ensuring financial stability and program integrity for Medicare will remain an overarching goal of Congress and the Administration. Any potential expansion of the telehealth benefit may be met by additional monitoring of telehealth to guard against fraud and abuse while ensuring continued access to care.

Recent Drug Enforcement Administration (DEA) Actions

In a separate but related policy area, the U.S. DEA announced a third temporary extension of the telemedicine controlled substance prescribing flexibilities through December 31, 2025. These measures, originally tied to the PHE, ensure patients can continue accessing critical treatments via telemedicine. Specifically, the flexibilities continue to allow practitioners to prescribe Schedule II-V controlled substances via telemedicine without an in-person evaluation. Practitioners can also prescribe schedule III-V narcotic-controlled medications approved by the Food and Drug Administration (FDA) for maintenance and withdrawal management treatment of opioid use disorder (OUD) via audio-only telemedicine. It is important to note that this extension is not indefinite. Stakeholders widely anticipate that the DEA will release a permanent rule in 2025, clarifying policies around the prescribing of controlled substances via telemedicine. The forthcoming rule is expected to strike a balance between ensuring access to care and addressing concerns about controlled substance misuse.

Buprenorphine Final Rule Effective February 17, 2025

On January 17, 2025, the DEA finalized its rules regarding telemedicine prescribing of Schedule III-V controlled substances used to treat OUD – most notably, buprenorphine. While buprenorphine prescriptions are currently allowed under the DEA telemedicine prescribing flexibilities expiring at the end of 2025, this final rule provides necessary clarity for practitioners providing OUD treatment.

CONTINUED ON PAGE 19

CONTINUED FROM PAGE 18

Under the new rule, practitioners may prescribe up to a six-month supply of buprenorphine via telemedicine without an in-person visit. Generally, practitioners engaged in the practice of telemedicine must use an interactive telecommunications system that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication. However, recognizing patient access barriers, the final rule clarifies that audio-only telecommunication may be used in certain circumstances, such as when a patient is at home, unable to use video technology, or unwilling to consent to a video visit.[1]

The final rule includes several safeguards aimed at preventing potential misuse or diversion. First, prior to issuing an initial prescription of buprenorphine via telemedicine, practitioners must check the state prescription drug monitoring program (PDMP) database for the state where the patient is located. In addition, prior to dispensing the drug, pharmacists must verify the patient's identity with a state government-issued ID, a federal government-issued ID, or other acceptable documentation (U.S. passport, military card, paycheck, bank statement, voter registration card, etc.).

The rule also establishes criteria for practitioners who seek to continue treatment after the initial six-month period. Practitioners may issue subsequent prescriptions if they conduct an in-person medical examination of the patient, or if they meet one of the telehealth exceptions outlined in the Ryan Haight Act.

DEA Telemedicine Registration Proposed Rule

The DEA also issued a long-awaited proposed telemedicine special registration rule that outlines the process for practitioners to register with the DEA for telemedicine-based prescribing of controlled substances. This registration would create a long-awaited pathway for practitioners to prescribe certain controlled substances to patients without having to conduct an in-person evaluation after flexibilities expire on December 31, 2025.

The proposed rule creates three new categories of special registrations for telemedicine.

1. **Telemedicine Prescribing Registration**
   The Telemedicine Prescribing Registration would allow the registrant to prescribe Schedule III-V controlled substance to patients via telemedicine. The proposed rule notes that the registration would be available to physicians and advanced practice providers who demonstrate a "legitimate need" for such a registration, for example, those whose patients face significant burdens traveling for in-person visits. Practitioners with this category of registration would not be authorized to prescribe Schedule II controlled substances via telemedicine.
2. **Advanced Telemedicine Prescribing Registration**
   The Advanced Telemedicine Prescribing Registration would allow specialized practitioners to prescribe Schedule II-V controlled substances via telemedicine. Specialized practitioners include: psychiatrists, hospice physicians, palliative care physicians, physicians at long term care facilities, pediatricians, and neurologists, as well as advanced practice providers or physicians from other specialties who are board certified in the

[1] DEA and HHS references the CMS definition of "interactive telecommunications system," as described in 42 CFR 410.78(a)(3), for purposes of the final rule.

CONTINUED ON PAGE 20

CONTINUED FROM PAGE 19

treatment of psychiatric or psychological disorders, hospice care, palliative care, pediatric care, or neurological disorders unrelated to the treatment and management of pain. This registration type also requires a "legitimate need" demonstration and the DEA has noted that it seeks to limit the prescribing of Schedule II substances via telemedicine to only the most "compelling" use cases.

3. **Telemedicine Platform Registration** This registration authorizes covered online telemedicine platforms, in their capacity as platform practitioners, to dispense Schedule II-V controlled substances. The DEA outlined several factors it would use to determine "legitimate need" for a platform, including factors like compliance with state and federal regulations, oversight provided to practitioner prescribing practices and demonstrating measures taken to focus on patient safety.

In addition to obtaining a special registration, practitioners, including platform providers, would be required to maintain a DEA issued Telemedicine Registration for every state in which they provide patient care, unless an exemption applies.

Looking Forward to 2025

The recent Congressional and DEA actions present several opportunities and questions for telehealth providers engaged in the provision of behavioral health services. Perhaps most clear is the view that the temporary flexibilities created by CMS and the DEA during the PHE were incredibly popular and enjoy broad bipartisan support. The more nuanced question policymakers and regulators will need to balance is how to preserve the gains in patient access to behavioral health services while ensuring reasonable regulatory controls exist around program integrity, the prescription and utilization of controlled substances, and multistate practice.

This consideration is apparent in the DEA's recent special registration proposed rule which would require new telehealth registrants to demonstrate there is a "legitimate need" for a practitioner or a platform to obtain a telehealth registration. Such proposed controls come on the heels of a high-profile Controlled Substance Act (CSA) settlement against mental telehealth platform **Cerebral** for overprescribing Adderall and other ADHD medications based on Cerebral's alleged "failure to protect patients from the harms caused by the unnecessary or overprescribing of potentially-addictive ADHD medications." Similarly, the CEO of **Done Global Inc.** and its Clinical President were indicted for violations of the Controlled Substances Act for causing doctors and pharmacists to overprescribe or dispense ADHD medication through a subscription-based service. Although these cases appear to be outliers, telehealth behavioral health platforms engaged in the prescription and delivery of controlled substances must remain mindful that their clinical policies are compliant with the Controlled Substances Act and other federal and state health care laws and that their compliance programs have adequate policies and procedures in place to detect and respond to potential compliance matters.

At present, it remains unclear whether the DEA's new special registration proposed rule will be significantly amended or withdrawn by the Trump Administration. Telehealth stakeholders in the behavioral health space have the opportunity to submit

CONTINUED ON PAGE 21

CONTINUED FROM PAGE 20

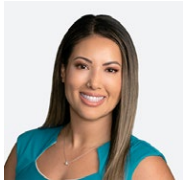
comments and influence the policies ultimately adopted by the DEA if the proposed rule is not withdrawn. Most importantly, the industry requires clarity and stability on key reimbursement and regulatory matters in 2025 to ensure its long-term sustainability and to fully unlock its potential to enhance patient access to clinically necessary behavioral health services.

Hospitals Seek a Solution for the Behavioral Health Crisis through Joint Ventures with Experienced Partners

Michael Tierney
Managing Director
Fifth Third Securities
Chicago

William Teague
Managing Director
VMG Health
Nashville

Paul A. Gomez
Behavioral Health Co-Chair
Los Angeles



Jasmine C. González
Counsel
Denver

Background/ Introduction

Behavioral health utilization is rising for licensed health care facilities offering mental health and substance use disorder treatment; according to SAMHSA, designated bed utilization reached 122% in 2023.[1] This increased demand is shouldered not only by private practice and community-based behavioral health providers but also by hospitals. In effect, our hospital system has been handed the non-delegable duty, by way of the Emergency Medical Treatment and Active Labor Act, of stabilizing and treating individuals experiencing behavioral health crises who present to emergency rooms nationwide. Additionally, emergency departments cannot discharge many patients without an inpatient bed, creating more need for investment. The heightened demand, coupled with the financial and operational pitfalls of providing behavioral health services, has an increasing number of hospitals exploring joint venture opportunities with third parties.

Mutual Benefits of Behavioral Health Joint Ventures

Behavioral health is regularly viewed as one of the highest concerns when assessing issues confronting hospitals; in fact, hospital CEOs ranked behavioral health third in a 2023 survey of the top problems these leaders face, with workforce and financial challenges rounding out the top (dis)honors.[2]

Pervasive exhaustion, dwindling resources, low wages, and taxing working conditions have led to an acute shortage of behavioral health providers and staff. Notably, 150 million Americans live in federally designated mental health professional shortage areas.[3] Large

[1] Substance Abuse and Mental Health Services Administration, Nat'l Substance Use and Mental Health Services Survey 2023: Data on Substance Use and Mental Health Treatment Facilities, *available at:* https://www.samhsa.gov/data/sites/default/files/reports/rpt53012/2023-nsumhss-annual-report.pdf (last accessed Jan. 15, 2025).
[2] American College of Healthcare Executives, Survey: Top Issues Confronting Hospitals, *available at:* https://www.ache.org/learning-center/research/about-the-field/top-issues-confronting-hospitals (last accessed Jan. 15, 2025).
[3] Health Resources & Services Administration, HPSA Find Tool, *available at:* https://data.hrsa.gov/tools/shortage-area/hpsa-find (last accessed Jan. 15, 2025).

CONTINUED ON PAGE 22

CONTINUED FROM PAGE 21

for-profit operators often have substantial resources dedicated to provider recruitment and usually maintain an extensive network of behavioral health providers. These resources frequently serve as a significant motivation for hospitals, health systems, and health care providers to align with for-profit behavioral health providers in some fashion.

In other cases, a hospital's behavioral health unit may suffer from outdated and inefficient facilities, lack of quality management and may be operating at a loss. Behavioral-focused profit operators with considerable experience and expertise in operating cutting-edge, high-quality behavioral health facilities can offer their knowledge to help a hospital or health system underperforming across multiple metrics. The for-profit partner may also be able to take on more of the managerial burden of operating the department, freeing up much-needed capital, administrative time, and other resources to focus on core competencies.

Additionally, many non-profit health systems have aging behavioral health facilities that need replacement or upgrading. Behavioral-focused partners, who develop templated facilities in a cost-effective manner, can offer a hospital the ability to provide patients with modern, more therapeutically appropriate facilities. With many hospital and health system budgets confronting shrinking margins, a joint venture with a partner can offer a much-needed infusion of capital.

Joint venture arrangements also offer hospitals and health systems the ability to increase the wellness of their communities through increased interest and efforts toward the integration between behavioral health and physical health. Further, joint venture relationships allow key stakeholders from both sides to highlight the need for behavioral health reforms that would benefit providers and patients alike. These relationships offer more than financial and operational gains – joint ventures enable providers to work together to improve their communities' health, wellness, and welfare.

Current State and Certain Legal Challenges Facing Hospital/ Behavioral Health Joint Ventures

2024 saw record highs and lows for hospital and third-party joint venture partners. From industry leaders seeing record-breaking increases in the number of their privately-operated beds to public condemnations of the inpatient industry, there are several reasons to pay attention to the current state of hospital/behavioral health joint ventures.

Despite the acknowledged need for additional beds and services, communities do not always welcome partnerships. Many states put restrictions on operators that make profitable operations nearly impossible. As noted below, hospitals and health systems are exploring ways to partner with for-profit operators beyond the traditional joint venture arrangements. This pivot towards new models is primarily impacted by the complex regulatory, reimbursement, and operational environment encompassing the behavioral health industry.

At the federal level, the DOJ and FTC have withdrawn long-standing health care merger guidance that they viewed as outdated and overly permissive. New merger and consolidation guidelines have been developed that may affect sizeable behavioral health transactions.[4] The new

[4] https://www.ftc.gov/reports/merger-guidelines-2023

CONTINUED ON PAGE 23

CONTINUED FROM PAGE 22

guidelines focus on additional theories of competitive harm and lower thresholds at which certain transactions will be presumed illegal under antitrust laws, with a notable focus on transactions and models that are often of interest to and utilized by private equity investors. As discussed immediately below, these requirements, including those at the state level, can apply to transactions beyond traditional mergers and acquisitions, including joint ventures and certain types of affiliations (not exhaustive).

Over the last few years, several states have enacted legislation and issued regulations to subject various health care transactions to review that were often not subject to material review. Some commentators have noted that these new series of requirements resemble certain aspects of submissions that must be made for some health care (and other) deals under the Hart-Scott Rodino Act (HSR) but often involve transactions that have far smaller dollar values (and usually, far smaller size of parties to the transaction) than the applicable HSR reporting thresholds. The foregoing has, in part, given rise to the now commonly used label "mini-HSR" legislation, with Washington State and Massachusetts early adopters of health care market review for certain transactions with thresholds capturing deal values far below HSR requirements. More recent examples of mini-HSR laws include a range of applicable advance notice, review and/or approval requirements (as appropriate), including a 30-day advance notice for certain defined transactions in New York8, 30-day advance notice for certain defined transactions in Illinois[5], and 90 days advance notice for certain defined health care transactions in California[6]. Advance preparation and review can be significant. We recommend that parties to a transaction assess the application of these requirements early. Where applicable, the mini-HSR requirements can add months or even close to a year to the time frame needed to close a deal.

Similarly, parties must be attuned to whether the contemplated joint venture triggers state licensing requirements and/or requires a certificate of need. Scale is often critical in ensuring successful operations and any CON restrictions that hinder achieving the necessary scale could derail a project. 2024 saw several new joint venture psychiatric hospitals being built; awareness of your state's licensing laws is key to ensuring projects progress smoothly. If you are contemplating a joint venture in a state with a certificate of need program, special attention should be paid to contingency provisions in your joint venture transaction documents. Finally, many states have recently or are in the process of relaxing their certificate of need regulations – specifically for inpatient behavioral health services. This creates opportunities for partnerships as new facilities may now be feasible that were not previously due to regulatory hurdles.

While positive strides have been made towards increasing the compensation for behavioral health services from governmental and commercial payors, prospective joint venture partners must be mindful of the potential impact of the evolving behavioral health reimbursement laws. Despite the movement towards increased compensation, inpatient and outpatient behavioral health services are among the lowest reimbursed

[6] NY Pub. Health Law §4550 et. seq.
[5] IL Public Act 103-0526.
[6] CA Health & Safety Code § 127500, et seq.

CONTINUED ON PAGE 24

CONTINUED FROM PAGE 23

services, with reimbursements of approximately 30% less than the cost of providing the services.[7] Similarly, Medicare's annual increase to inpatient psychiatric prospective payment rates has not kept pace with inflation; inflation grew by 12.4% between 2021 and 2023, while Medicare rates increased by 5.2% over the same period.[8]

Changes in joint venture investment and governance have also given rise to the desire of hospitals and for-profit operators to explore non-traditional arrangements. Experienced operators are willing to split governance 50/50, regardless of ownership. For -profits will still have reserve powers, but both parties share in clinical, quality, and staffing decisions. Having oversight into those key areas helps alleviate acute-care providers' concerns about maintaining quality.

Finally, hospital and for-profit operators have struggled with negotiating business terms and navigating timing challenges. Many non-profit health systems are also wary of partnerships with for -profit operators, especially if they feel their brand/reputation could be impacted. In addition, we have observed for -profit operators requiring the hospital partner to own more of the equity in the JV, requiring additional capital upfront. Finally, the time required to execute a venture and open a new facility can take 3 to 4 years, creating challenges to meet community needs in a timely manner.

The Evolution of Hospital/Behavioral Health Joint Ventures/ Affiliations

There are different types of joint ventures, but traditionally, hospital/ behavioral health joint ventures have manifested as the creation of a new, jointly-owned entity through which the behavioral health operator conducts the administration, management, and operation of the hospital's behavioral health unit. Whether due to governance concerns, election year reticence, or other external factors, 2024 saw several non-traditional, quasi-joint venture arrangements emerge.

As a first step towards exploring a more unified joint venture relationship, many hospitals and health systems have sought professional services agreements with for-profit behavioral health operators. A professional services agreement is among the least-integrated forms of relationship between a hospital and a third-party behavioral health operator. A professional services agreement allows the hospital or health system to "outsource" the performance of professional behavioral health services to a third party. Depending on the financial performance of the hospital's behavioral health service line, the payor mix, and the third party's labor costs, compensation under a professional services agreement can take multiple forms: the third party contractor can bill, collect, and retain its professional fees as sole compensation for the services, the hospital could bill, collect, and retain the professional fees and pay an hourly/per-shift/salary pass-through rate to the contractor, or the hospital may offer a subsidy/collections guarantee if the service line is particularly underperforming. Compared to a traditional joint venture, a professional services agreement is often easier to establish. However, the lack of integration

[7] American Hospital Ass'n, America's Hospitals and Health Systems Continue to Face Escalating Operational Costs and Economic Pressures as They Care for Patients and Communities *(May 2024), available at:* https://www.aha.org/costsofcaring (last accessed Jan. 15, 2025).
[8] Id.

CONTINUED ON PAGE 25

CONTINUED FROM PAGE 24

frequently hinders the contractor's ability to affect the behavioral health unit's performance meaningfully.

Alternatively, hospitals may be inclined to seek out a management services agreement with a behavioral health operator. A management services agreement (MSA) may be entered into in tandem with a professional services agreement for increased integration. Under an MSA, the behavioral health operator provides administrative and managerial services to the hospital's behavioral health unit; the scope of services can range from specific administrative functions to the full suite of administrative/managerial requirements of a unit. In some cases, a behavioral health operator and the hospital may form a joint venture to manage a new behavioral health facility or behavioral health services within the hospital. A management agreement can still allow the Hospital to "own" operations and volumes, helping preserve Medicaid days, DSH payments, and other programs that benefit the entire hospital. It's not perfect, though; while these arrangements can help alleviate managerial gaps, challenges remain. Management companies are still paid regardless of performance; recruiting and revenue cycle challenges often persist. Another key advantage is the ability for a joint venture management services organization (MSO) to be formed for smaller units/facilities. Often, a freestanding psychiatric hospital needs at least 90 beds to achieve the desired economics. A profitable enterprise might not be attainable for smaller units due to economies of scale. The MSO model enables partnership with an experienced operator, which can help make the unit more efficient, even if the service line is not profitable. However, the MSO model is highly dependent on the negotiated terms of the MSA, so they can be more complicated to administer, negotiate, and manage.

Compensation for management services agreements can take the form of a flat fee, a percentage of revenue, or a revenue minus expenses sweep model. Similar to the pitfalls of professional services agreements, a management services agreement is often constrained by minimal integration into the hospital's operations, but may produce some greater degree of alignment between a behavioral health operator that is skilled in managing high-quality, efficient, and streamlined behavioral health services in multiple settings with the hospital when the parties have chosen to provide such management services through a joint venture management services company, as noted above.

Best Practices/ Take Aways

Whether hospitals and behavioral health operators elect to pursue a traditional joint venture relationship or an alternate model, there are several key considerations to remain cognizant of. As the complexity and degree of integration of the joint venture relationship increase, the transaction timeline from letter of intent to closing becomes drawn out. Coupling the standard negotiation process with newly enacted state and federal corporate transparency and transaction notification laws increases the chance of significant delays.

A successful joint venture also relies on the parties being compatible and sharing a common business culture. Mission alignment, executive buy-in, and meaningful stakeholder engagement can often get parties through challenges better than the best-written contract provisions and processes.

CONTINUED ON PAGE 26

CONTINUED FROM PAGE 25

Completing a complex joint venture is a long process, and having C-Suite and Board support early, along with an organizational change leader driving the process, will help ensure success.

Remaining abreast of the issues described in this article, in addition to the hospital and behavioral health industries as a whole, will put organizations in the best position to begin exploring hospital joint ventures. Engaging legal counsel and financial advisors with extensive experience navigating behavioral health transactions is key to keeping joint venture transactions on track.

As hospitals and behavioral health care providers consider and plan for joint venture relationships, we recommend the following:

- Assess the legal and regulatory issues early. Getting ahead of these issues is key to ensuring your closing is not subject to surprise delays.
- Be thoughtful about the joint venture structure and each model's various pros and cons.
- Prepare for legal due diligence and have regular conversations about risk thresholds and allocation between the parties.
- Start strategizing early for the potential pre-transaction notice and antitrust-related concerns that may arise. Determine your desired closing date accordingly.
- Monitor developments in legal and regulatory matters affecting the behavioral health space.

Lessons from the Trenches: Four Tips for Accessing Opioid Settlement Funds

Zachary Rothenberg
Principal
Los Angeles

Many in the behavioral health and Substance Use Disorder (SUD) treatment industry in particular are generally aware that recent settlements of multi-state opioid litigation have led to the nationwide distribution of billions of dollars in settlement funds. But not everyone is sufficiently informed about the details of those funding sources, and how to gain access to them. Perhaps not surprisingly, there are few easy answers, as the funding is not always readily accessible to "rank and file" treatment providers, non-profits, and other organizations.

This article offers some background on the opioid settlement funds, and four lessons for locating and gaining access to those funds.

Background on the Opioid Settlements

What is often referred to as "the opioid settlement" is actually a series of settlements of numerous lawsuits from around the country that were originally filed by a variety of states, municipalities, non-profit organizations, and other community stakeholders. The suits were generally brought against three categories of defendants: (i) opioid manufacturers, (ii) opioid distributors, and (iii) retail pharmacies. Largely for efficiency purposes, many of the individual opioid lawsuits, and the settlements that resulted, were combined together based primarily on the identity of the defendant, such that one frequently hears reference, for example, to the "distributors settlement" or the "retailers settlement."

As part of each settlement, states and other plaintiffs were given the option either to "opt in" to the large-scale agreements, to receive settlement funds in exchange for giving up their own individual claims against the various defendants, or to decline participation and proceed litigating their own unique claims. Most plaintiffs, in most settlements, did opt-in. A helpful table reflecting state-by-state and settlement-by-settlement decisions on whether to opt-in or opt-out, can be found here: **https://nationalopioidsettlement.com/state-participation-status/**.

Once it was determined which claims were being settled and who would be participating in each settlement, the funds were allocated to the participating states in amounts based on a variety of factors, ranging from overall state population to the number of opioid overdose deaths, to the total amount of opioids prescribed in each state. Thus, for example, media outlets have reported that California has received, or is scheduled to receive, nearly $4B in settlement funds (from the various settlement combined), while Wyoming has received/will receive only $77M. Interestingly, some of the states that opted-out of the global settlements and instead litigated on their own, fared better than they likely would have if they opted in. For example, West Virgina, which opted-out of most settlements, has secured roughly the same amount of opioid relief funding as Massachusetts, which opted-in, even though West Virgina has only about one-fourth the population size of its New England neighbor.

In a notable departure from the tobacco settlements of the 1990s, which in hindsight were thought to have failed in

CONTINUED ON PAGE 28

CONTINUED FROM PAGE 27

providing no clear parameters for how the settlement funds would be spent, the opioid settlements expressly mandated parameters for how and by whom the settlement funds could be used. While there was some variation from settlement to settlement, the agreements generally determined that seventy percent of a state's allotted funds would be used for future opioid remediation, fifteen percent would be used on past remediation, and fifteen percent could be used at the state's discretion. Moreover, the settlements identified a schedule of nine "Core Abatement Strategies" for use of the funds, including for example "Naloxone or other FDA-approved drugs to "reverse opioid overdoses," "expanding treatment" for Neonatal Abstinence Syndrome (NAS)," and "treatment for incarcerated population." The settlements likewise identified "Approved Uses" for the settlement funds, with detailed uses grouped into categories such as "treatment," "connections to care," and "prevention."

Finally, it was left to each state to determine exactly how the money would flow from the state level to its cities, counties, and other municipal subdivisions. Some states entered into contracts with their subdivisions, while others enacted statutes that directed the flow of funds. Likewise, each state was free to construct its own oversight mechanisms, to ensure that funds were being allocated in a manner consistent with the substantive guidelines in the settlement agreements.

What follows are four "lessons from the trenches," shared by providers and other stakeholders who have already ventured into the byzantine world of opioid settlement funding.

Lessons from the Trenches

Become Familiar with the "Core Abatement Strategies," "Approved Uses," and Any State-Specific Priorities and Goals.

The North Star of all opioid settlement funding decisions should be what is frequently referred to as "Exhibit E." This is the document incorporated into each of the primary opioid settlement agreements that identifies the agreed-upon priorities for use of the settlement funds. A copy of Exhibit E to one of the manufacturer settlements can be found here: **https://nationalopioidsettlement.com/wp-content/uploads/2023/02/TEVA-Exhibit-E.pdf**.

Given the oversight mechanisms in place in many states, it is incumbent upon states and municipalities to make funding decisions based upon the "Core Strategies" and "Approved Uses" that are described in detail in Exhibit E. As such, providers would be savvy to ensure their proposals and requests for funding echo the strategies and uses in Exhibit E. The more aligned a proposal is to the strategies and uses in Exhibit E, the more likely state and local decisions makers will be to distribute funding. One additional note: approximately twenty states have supplemented Exhibit E with additional state-specific strategies and approved uses. So, for those states, some additional investigation into any such additional state-specific requirements would be warranted.

Identify Where the Funds are Held and Forge Relationships with Gatekeepers.

While the Core Abatement Strategies and Approved Uses are intended to provide consistent guidance from state to state, the procedures and mechanisms for distributing settlement funds is not a monolith. For better or worse, each state has generally been left to its own devices to determine

CONTINUED ON PAGE 29

CONTINUED FROM PAGE 28

exactly how opioid settlement funding will flow from the states to the cities, counties and other subdivisions. While a deep understanding of the precise mechanics may be unnecessary for most providers, what is imperative is that providers know where the funds are ultimately held, and how to access them.

All states will likely hold some amount of the settlement funds at the state level, to be distributed by state-level healthcare and social service agencies. So, this is an obvious place for all providers to begin, scouring state agency websites for opioid settlement pages, RFP portals, and the like.

But at the local level, processes are likely to differ greatly from state to state, and within each state from city to city and county to county. Moreover, at the local level, the processes for distributing funds are likely to be less formal than their state-level counterparts; rather than systematic online RFP processes, many localities rely on old-fashioned outreach from providers and other stakeholders in the community.

It thus behooves providers to invest time and energy not only in discovering where the funds are held, but, particularly at the local level, forging relationships with key gate-keepers in the funding process.

Remember this is Marathon, not a Sprint.

One significant aspect of the opioid settlement funding is that the agreements generally provide for funding over a period of years – in some instances as many as eighteen years. Moreover, as tranches of money are paid to the states and then pushed down the local levels, each recipient has a mandate to use the funding within a specific amount of time, typically five years. The interplay between these two factors will be significant in when and how settlement funds will flow.

This process is going to be an evolution. Particularly at the local level, where counties and municipalities likely have less experience in funding opioid relief programs, or in distributing funds of this magnitude at all, processes may initially be disorganized and scattershot. But over time, these subdivisions are likely to gain experience and savvy, both from improving their own internal processes and from learning from their counterparts in other cities, counties, and states. As one example, a seemingly disproportionate amount of early opioid settlement funding has been distributed at the local level to law enforcement, in many cases presumably because it was "the path of least resistance." This pattern has received substantial criticism from the recovery community, and it is likely that law enforcement will become less of an emphasis for opioid relief funding going forward. Similarly, where some of the less experienced subdivisions may initially show some reluctance to loosen the purse strings and distribute the funds, the five-year mandate will eventually kick in and force the funding to flow more freely.

All of this is to say: be patient, we're only in the first inning.

Be Creative!

Many stakeholders have expressed a desire for the opioid settlement funds to be used to breathe life into new ideas, particularly for the benefit of historically under-resourced communities – as opposed to simply subsidizing the growth of existing programs. The chatter has been loudest around

1. Programs that work with the uninsured and underinsured, the incarcerated, and pregnant women and young children

CONTINUED ON PAGE 30

CONTINUED FROM PAGE 29

2. Projects focusing on extending the care continuum, such as coaching, care management and job training
3. Outreach and education programming

Regardless, it is generally understood that state and local decision-makers are looking to use the funding to incubate new ideas that would not otherwise get off the ground, and to support patient populations and service lines that have not historically been profitable enough to sustain.

Conclusion

The bottom line here is that, with settlements of this magnitude and complexity, knowledge is power. Opportunity abounds, but only if providers know where to find the funding, and how to access it. The foregoing lessons are just the beginning; early investment in access to information and building key relationships will prove critical in the years to come.

Behavioral Health Perspectives from the Host of The *10 Minute* HealthBizCast

Bobby Guy
Shareholder
Nashville

The 10 Minute HealthBizCast is now in its eighth season and hosted by Polsinelli shareholder Bobby Guy. The podcast features interviews with executives and thought leaders in the health care and life sciences industries and focuses on the future of U.S. health care. Season 8's focus is on "rapid, incremental change."

One of our favorite topics to cover on *The 10 Minute HealthBizCast* is behavioral health care. We often refer to it as "the new acute care." And yes, that could mean a lot of things. What do we mean by it?

The Great Society programs of the mid-1960's saw the creation of Medicare and Medicaid to pay for health care for many Americans, resulting in a massive increase in access to health care, and massive growth in health care resources to deliver that care. We think that the U.S. is on the cusp of a similar change when it comes to psychiatric and behavioral health care. As a country, we've recognized the modern epidemics of loneliness and addiction, we talk of parity, we've seen rapid change in de-stigmatizing behavioral health care, we've got efficacious pharmaceutical solutions, and we've recognized that well-care requires treating people's mental challenges as well as their physical bodies. We've got more payor sources for behavioral health care, and yet the U.S. still has a major shortage of behavioral health providers – and this is creating an access problem that is on the verge of exploding. This sounds remarkably like the acute care needs of the nation just before The Great Society programs. We expect to see massive growth in the number and types of behavioral health providers in the U.S. over this decade.

What do our Album 8 guests have to say about behavioral health care?

On Track 5, we talked to Dr. Alex Jahangir, an expert on public health, about his thoughts on how to improve trust in the health care system, how the opioid epidemic has changed health care, and how we can use

CONTINUED ON PAGE 31

CONTINUED FROM PAGE 30

public health to change the loneliness epidemic in the U.S.

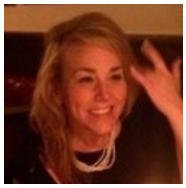
Then, on Track 6, we talked to Carrie O'Connell, a behavioral health care nurse by training who now works at software provider WellSky, about the hierarchies in health care and the difficulty of attracting nurses to the behavioral health settings. Carrie's insights about the differences between physical and psychological care in practice, and the divide between the two, were surprising and motivating at the same time.

On Track 10, we talked to Rikki Harris, CEO of VoicesTN, about their model of providing a statewide network of behavioral health resources, helping people find change and connections that give them alternatives so they can break from their prior settings and habits. Rikki also talked about the reduced stigma around behavioral health care, and the new problem of how to take people from the socially acceptable phrase "I'm not okay," to the next stage of "I'm not okay, and here's what I'm doing about it."

We're excited to continue exploring these themes, and new ones that are sure to arise, as we finish Album 8 and then launch Album 9 in the spring.

The *10 Minute* HealthBizCast Guests:

Dr. Alex Jahangir
Public Health Expert



Carrie O'Connell
Behavioral Health Care Nurse at WellSky

Rikki Harris
CEO of TNVoices

The ***10 Minute*** **HealthBizCast** is available on all streaming platforms.

To sign up for the mailing list and to receive information about when we're launching new albums, **click here**.

About Polsinelli's Behavioral Health Law Group

Behavioral health providers have unique business model, care delivery and regulatory issues that require focused legal expertise informed by real-world experience in the behavioral health space. Polsinelli's Behavioral Health Group, one of the largest in the country, is a cross-functional team with significant experience completing major transactions and resolving complex regulatory matters involving behavioral health providers.

Upcoming Events

BHB VALUE
March 20-21, 2025
New Orleans

Autism Investor Summit
April 7-9, 2025
Beverly Hills

Polsinelli Privacy Retreat
May 15, 2025
Chicago

BHB Addiction Treatment Forum
July 17, 2025
Chicago

BHB INVEST
October 22-24, 2025
Nashville

Contact Sinead McGuire, **smcguire@polsinelli.com**, for more information about any upcoming Polsinelli Behavioral Health Law Group events.

POLSINELLI. | What a law firm *should* be.™

Editorial Board

Barry D. Alexander
Office Managing Partner
barry.alexander@polsinelli.com

Michael T. Flood
Shareholder
mflood@polsinelli.com

Paul A. Gomez
Behavioral Health Co-Chair
pgomez@polsinelli.com

Jasmine C. González
Counsel
jgonzalez@polsinelli.com

Bobby Guy
Shareholder
bguy@polsinelli.com

Ryan J. Mize
Attorney
rmize@polsinelli.com

C. Ryan Morgan
Shareholder
rmorgan@polsinelli.com

Jean Marie R. Pechette
Shareholder
jpechette@polsinelli.com

Laura D. Pone
Shareholder
lpone@polsinelli.com

Zachary Rothenberg
Principal
zrothenberg@polsinelli.com

Nathaniel "Tani" Weiner
Health Care M&A | Co-Chair
Behavioral Health Group
nweiner@polsinelli.com

Joelle M. Wilson
Shareholder
jmwilson@polsinelli.com