Top Issues in Behavioral Health Newsletter 2024

Annual newsletter from the Behavioral Health Law Group

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Behavioral Health M&A 2024 Legal Trends

Nathaniel 'Tani' Weiner
Co-Chair, Behavioral Health Law Group
San Francisco

Paul A. Gomez
Co-Chair, Behavioral Health Law Group
Los Angeles

Ryan J. Mize
Attorney
Kansas City

Introduction

While behavioral health Mergers and Acquisitions (M&A) activity over the past 12 months is down from 2021-22 levels, we are still seeing strong investment interest in the space. Key investment drivers include the still-unmet social need for behavioral health treatment, expanded third-party reimbursement and evolving business models that create opportunity for established providers and new entrants alike. At the same time, capital constraints, higher interest rates, inflation, ongoing staffing challenges and lingering economic uncertainty have made buyers more selective and placed an (even) greater emphasis on due diligence and vetting applicable regulatory/third party reimbursement issues. Some sellers have elected to defer a sale process, awaiting improved market conditions and/or stronger financial performance to maximize exit value; parties seeking to transact in current market conditions are well advised to prepare for a thorough diligence process to avoid disruption or delay on the path to closing. For transactions that make it to a letter of intent, market conditions along with heightened regulatory scrutiny place a premium on close alignment between business and legal teams on both sides of the table to support a timely and successful transaction process.

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An overview of some of the key legal hot spots we are seeing in behavioral health M&A transactions follows, which we hope will be useful background for market participants.

Let's Start With Structure

Behavioral health encompasses a wide range of treatment modalities, including but not limited to psychiatric hospitals, residential mental health, substance abuse, eating disorder and IDD treatment facilities; outpatient care modalities ranging from partial hospitalization, intensive outpatient, clinic-based and/or medical practice-based; and telehealth/digital treatment. Each of these modalities can hold different licenses issued by different agencies and can co-exist with other modalities in the same treatment program. Implications of this diversity and overlap can drive key organizational and deal structure considerations, some of which are discussed below.

To PC or not to PC

While many levels of behavioral health care fall under a state agency license, certain levels of care may only be rendered by a professional corporation (PC). Often this will be the case for outpatient mental health and/or clinician-provided services within a residential setting in one of the many states that has a corporate practice of medicine prohibition, which can impact legal structure in varying degrees of scope and scale. Where this prohibition exists, and absent an applicable exception, certain clinical services may only be provided through a physician-owned PC.

We are seeing PCs with increased frequency in behavioral M&A transactions, for example, due to the heightened investment interest in outpatient mental health treatment providers where the core service is clinical (including psychiatry, prescribing of medications and certain ancillary services) in nature. On the other hand, residential treatment providers with a more limited clinical service component are at times drawing payor claim and/or credentialing denials due to payors alleging non-compliance with corporate practice of medicine restrictions to deny claims or credentialing. Heightened payor focus on managing and/or minimizing their spending on behavioral health—which has been a reality for behavioral providers for several years—is intersecting with somewhat antiquated corporate practice of medicine rules to create risk of disruption in the key investment thesis areas of reimbursement and revenue cycle. While "friendly PC/MSO" arrangements are common in medical and dental practice-based businesses, the need for such arrangements in behavioral health is sometimes less apparent, and can be more challenging to integrate within, a behavioral health business. The threshold question of when, whether and how to utilize a PC can impact transaction economics (including tax), along with regulatory, revenue cycle and other considerations.

Watch out for Earnouts

While a common means of helping buyers and sellers bridge a valuation gap to reach a mutually agreeable transaction price, earnouts warrant special consideration in healthcare transactions. This is all the more so in light of enhanced governmental scrutiny in the behavioral space, and increased use of earnouts to bridge valuation gaps in light of current market considerations. Transactions where a seller will remain with the target business and will be in a position to generate patient referrals (and simultaneously, improve their personal economics via increasing the earnout value) can raise compliance risks that can in turn depend on the provider type and third-party reimbursement sources, among other factors.

When the target business receives reimbursement from Medicare, Medicaid, or another federal healthcare program, there are compliance and risk considerations under the federal Anti-Kickback Statute (AKS) and analogous state statutes. These statutes prohibit providers in such healthcare programs from offering to exchange or exchanging anything of value to in exchange for patient referrals. A more recent regulation applicable to certain behavioral health providers, and regardless of third-party payor source, is the Eliminating Kickbacks in Recovery Act (EKRA). EKRA prohibits knowing and willful payment in exchange for a patient referral or patronage, related to a recovery home, clinical treatment facility, or laboratory service covered by a health care benefit program (whether government or commercial). EKRA was passed relatively recently to bring federal criminal sanctions to bear on patient brokering and other inappropriate inducements to make referrals or generate business associated with substance abuse treatment, recovery housing and laboratory services. The broad statutory language can make it more challenging to comply with applicable requirements.

Earnouts can be used for sound economic reasons that are not intended to induce or encourage referrals, generation of business or patronage for the business. However, if the parties decide to employ them, care must be taken not to violate either the AKS, EKRA or any applicable state law corollaries. The criteria to be used for earnouts should be carefully vetted by qualified health care transaction counsel to help define and align

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to targets that are consistent with applicable legal requirements and economic expectations, ideally at an early stage of the transaction.

Things that Change or Stay the Same

The licensure approval process is a key gating and timing item with respect to completion of transactions and can mean the difference between closing later this month, later this quarter, or later this year. This is particularly true for providers that operate via a facility-based or agency-issued licenses, as distinct from PCs, where licensure is typically personal to individual clinicians and issued by a medical board or similar body. There is a wide range of state agency formulations for when a licensure change of ownership ("CHOW") approval requirement has been triggered. Careful assessment and selection of transaction structure can help expedite or avoid pre-closing CHOW approval requirements in some cases. For example, some state agency pre-closing CHOW requirements may or may not apply depending on factors that include: (i) whether the transaction is structured as a stock purchase as opposed to an asset purchase (and whether there will be any change in tax identification number); (ii) the licensing and/or legal structure of the parties to the transaction; and (iii) whether and to what extent an interim management services arrangement between buyer and seller may be available. CHOW process requirements (where implicated) can require filing and approval of a new license application and passing an onsite inspection, along with discretionary review and/or certificate of need approval, which can add 90 days to 6 months or more to the pre-closing timing. In other cases, post-closing application and/or post-closing notice-only will suffice.

Heightened service line diversity and complexity of behavioral health providers, along with still-evolving regulatory standards that largely vary by state, make CHOW assessment much less than a one-size-fits all assessment. Engaging in a CHOW assessment at the outset of a transaction process can be a highly valuable component to align with tax and other key structure elements and to serve as a blueprint to timing and execution steps. Similarly, parties will want to assess notice and/or approval requirements with third-party payors, given heightened importance of commercial and government reimbursement for behavioral health providers and to ensure the smoothest possible revenue cycle transition.

"New-ish" for 2024: Additional Approvals and/or Government Scrutiny Impact and Timing

In addition to the structure and approval gating items discussed above, buyers and sellers alike should take notice of new antitrust and similar review and approval requirements at the federal and state level. These requirements are separate from and additional to the license and third-party payor CHOW approvals noted earlier and will increasingly play a role on timing and likelihood of execution for transactions subject to them. As the large majority of behavioral health M&A transactions have historically been below the Hart-Scott-Rodino Act (HSR) reporting threshold,[1] these review and approval requirements merit special attention by behavioral health M&A market participants. We recommend assessment and preparation for applicable filings early in a transaction process, with the help of qualified and experienced health care transaction counsel.

Heightened Federal Antitrust Scrutiny

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 now been developed.[2] The new guidelines reflect the Biden Administration's view that "decades of industry consolidation have often led to excessive market consolidation" across multiple sectors, including health care.[3] The new guidelines focus on additional theories of competitive harm and lower thresholds at which certain transactions will be presumed illegal under antitrust laws.

For example, the new guidelines presume that a deal is anticompetitive if it results in a post-transaction market share greater than 30% together with an increase of 100 or more in the so-called **Herfindahl-Hirschman Index** ("HHI"), a measure of market concentration commonly used by antitrust enforcers and the courts. By lowering the threshold percentage of market share and levels of market share concentration several health care transactions, including potentially behavioral health transactions that would likely have been presumed lawful under the former merger guidelines of 2010 may now be presumed unlawful under the new guidelines.

Additionally, there is an acute focus on "rolls-ups" in the new guidelines. When a transaction is a part of a

1 Effective March 6, 2024, the HSR reporting threshold increases from $111.4 Million to $119.5 Million.

2 **https://www.ftc.gov/reports/merger-guidelines-2023**

3 **https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/**

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series of acquisitions, the revised guidelines indicate that the agencies will examine the current transaction along with all of the prior acquisitions, even if no single transaction would be considered anticompetitive on its own. This will likely increase the risk of antitrust scrutiny for entities such as private equity firms and health systems that engage in multiple acquisitions of various health care providers. Healthcare industry participants should be mindful of plans to acquire multiple practices and clinics (including behavioral health) and that relatively small transactions that would not by themselves be subject to HSR reporting requirements could be subject to scrutiny, including via look-back to prior similar transactions.

The new guidelines also reflect a focus on impacts on labor markets. Notwithstanding the ongoing staffing shortages that have plagued the behavioral health care and health care sectors for some time, the FTC and DOJ indicated that they are concerned that some transactions may reduce demand for workers and suppress wages and other compensation. The guidelines state that "[w]here a merger between employers may substantially lessen competition for workers, that reduction in labor market competition may lower wages or slow wage growth, worsen benefits or working conditions, or result in other degradations of workplace quality."[4]

By contrast, this Newsletter has addressed in past publications the effects and possible solutions to remediate behavioral health staffing shortages, and noted that such shortages are often one of the drivers of behavioral health M&A, joint ventures and other transactions.[5]

Many market observers are expecting a more hostile regulatory reception to health care M&A transactions, although it remains to be seen how agency application of the new rules and any related legal challenges may play out.

State Level Antitrust-Related Scrutiny and Rise of "Mini-HSR" Legislation

Over the last few years, several states have enacted legislation and promulgated regulations to subject various health care transaction to review that often were not subject to material review before. If subject to the requirements parties to a given transaction may be compelled to make detailed submissions for prior review, and in some cases, approval, before the given deal can be completed. Some commentators observe that these new series of requirements somewhat resemble submissions that must be made for certain health care (and other) deals under HSR, but often for far smaller dollar values than the HSR reporting threshold. Lower dollar reporting thresholds have in part given rise to the label "mini-HSR" legislation, with Washington State and Massachusetts early adopters of health care market review for certain transactions with thresholds driven by provider size and type and revenue source (as opposed to transaction value) capturing deal values far below HSR requirements. More recent examples of recent mini-HSR legislation include (not exhaustive) notice requirements for certain health care entity transactions that may constitute material change transactions meeting certain dollar, property or other prescribed thresholds (and often covering transactions at values well below HSR requirements). There is significant range in these kinds of mini-HSR requirements, including 30-day advance notice for certain defined transactions in New York,[6] 30-day advance notice for certain defined transactions in Illinois [7] and 90 days advance notice for certain defined health care transactions in California.[8]

Although these new legal requirements appear more aimed toward the broader health care sector, many of the have potential to directly impact the behavioral health sector as well depending on the state law at issue, how the deal is structured, how the behavioral health care providers are structured and size of the transaction (among other things). Like the licensing CHOW rules noted above, the mini-HSR-requirements can apply or not based on the specific provider and transaction structure attributes of a given transaction. We recommend parties to a transaction assess applicability 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.

4 Supra FN 2. *See also, generally* "Newly Finalized FTC/DOJ Merger Guidelines Are Likely to Increase Antitrust Scrutiny of M&A Deals" (summarizing anticipated elevated levels and different types of scrutiny that many health care transactions may face under the new guidelines). **https://www.polsinelli.com/herbert-f-allen/publications/newly-finalized-ftc-doj-merger-guidelines-are-likely-to-increase-antitrust-scrutiny-of-ma-deals** *Herb Allen, Arindam Kar, Mitchell Raup, Matthew Hans.*

5 *See also,* "Top Issues in Behavioral Health 2023 and Top Issues in Behavioral Health 2022." **https://polsinelli.gjassets.com/content/uploads/2023/02/March_23_Behavioral_Health_Newsletter.pdf**

6 NY Pub. Health Law §4550 et. seq.

7 IL Public Act 103-0526.

8 CA Health & Safety Code § 127500, et seq.

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What Should Behavioral Health Providers, Investors and Other Stakeholders Do Now to Help Address These Issues?

As discussed previously, current market conditions warrant special attention to legal structure and regulatory considerations in planning and execution for a successful transaction. Those same considerations, along with a behavioral health M&A market that remains choppy at this time, place a premium on advance preparation for legal workstream items at early stages in a transaction process. Careful attention to structure and approval processes that may be implicated can help keep a transaction moving and avoid surprise and/or delay on the path to closing. Similarly, increased regulatory scrutiny for health care and behavioral health care transactions may create new substantive barriers to investment at a time when behavioral health providers are in need of investment to meet challenges posed by long-term increased demand and more complex business model, operating and reimbursement challenges.

As behavioral health care providers, private equity investors, health systems and other stakeholders consider and plan for investment and transaction activity in the behavioral health space, we recommend the following:

- Get started on legal and regulatory assessment of your deals and the issues discussed above early. The novelty and complexity of these issues and "one size fits few" nature of behavioral health providers means that early assessment may pay dividends in avoiding surprises and helping expedite closing.
- Be mindful that transaction structure can significantly impact necessary transaction approvals and related process, along with substantive regulatory compliance risks. Involve experienced healthcare transaction counsel at early stages in developing the transaction blueprint.
- Plan for and be prepared to conduct thorough legal due diligence, including in the areas of marketing activities/fraud and abuse, reimbursement billing/coding and privacy matters. Review of these issues with appropriate risk allocation in transaction documents can help protect against potential liability and provide the parties with a greater likelihood of finding appropriate, practical solutions and help facilitate a successful closing.
- Strategize early to try to pre-emptively address agency antitrust-related enforcement concerns and to try to head off or limit follow up questions/request and potentially more lengthy review (where applicable). Coordination among buyers and sellers in preparing for such notice and review can help manage and mitigate timing and substantive process considerations.
- Monitor evolving legal and regulatory standards applicable to behavioral health providers, including ongoing changes to federal and state antitrust and mini-HSR requirements as more becomes known on how heightened scrutiny, review processes and/or legal challenges to same take hold.[9]

9 Polsinelli's Behavioral Health Law Group continues to monitor and assess legal and regulatory trends, along with federal and state antitrust review of health care and behavioral health care transactions.

Will Mental Health Parity Get Some Teeth in 2024?

Bragg E. Hemme

Co-Chair, Behavioral Health Law Group
Denver

As part of the Administration's focus on mental health care, the Departments of Labor, Treasury and Health and Human Services published a proposed rule on July 25, 2023, attempting to strengthen the regulations implementing the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act ("MHPAEA"). The proposed rulemaking, if finalized, would provide guidance on provisions of the Consolidated Appropriations Act of 2021 that required all health plans and insurers that impose Non-Quantitative Treatment Limitations ("NQTLs") on mental health and/or substance abuse benefits to conduct and document a comparative analysis of the design, application, and impact of NQTLs to show compliance with MHPAEA.

If the rule is finalized as proposed, it would fill some gaps in understanding the requirements of MHPAEA, generally, and it would identify detailed requirements for health plans and insurers to use in determining whether an NQTL imposes greater limits on access to mental health and substance use disorder benefits as compared to physical health benefits. If material differences are found, it would be a strong indicator that the NQTL violates the MHPAEA, and the plan or insurer would need to take reasonable actions to mitigate those differences or not impose the NQTL.

The proposed rule would also newly require plans and insurers to collect and evaluate network and outcomes data to assess the impact of NQTLs. This would require plans and insurers to collect data regarding, for instance, out-of-network utilization, reimbursement of out-of-network providers, prior authorization requirements, time and distance standards, and denial rates. This data collection would force plans and insurers to actively show parity with respect to access to mental health and substance use disorder treatment services.

The proposed rule would allow for a couple of exceptions, which, if satisfied, would insulate a plan or insurer from liability. Plans and insurers that apply NQTLs that (1) apply generally accepted standards of care and/or (2) apply solely for the purposes of detecting or preventing fraud, waste and abuse (as established through objective, unbiased data) would not violate MHPAEA with respect to the specific excepted NQTL.

These rules would take a significant step toward parity-related transparency and enforceability, but payors have expressed broad dissent over the proposals, calling them vague, overreaching, and costly. Payors argue the proposals could lead to higher costs and less access to mental health care services. We will continue to watch indications as to how the administration will respond to those concerns and/or whether it finalizes the proposed parity rules later this year.

Artificial Intelligence's Role in Reshaping Behavioral Health and Navigation of Legal Risks Ahead

Jean Marie R. Pechette

Shareholder
Chicago

Neal D. Shah

Shareholder
Chicago

Joelle M. Wilson

Shareholder
Chicago

Cat Kozlowski

Counsel
Seattle | Los Angeles

Matthew T. Lin

Associate
Los Angeles

Introduction

As artificial intelligence (AI) continues to redefine the landscape of healthcare delivery, its transformative influence on behavioral health is both profound and promising. The integration of AI technologies in behavioral health care holds the potential to revolutionize diagnostics, treatment approaches, and overall patient outcomes. Virtual mental health assistants, driven by AI, may enhance accessibility by providing continuous support and monitoring. Additionally, predictive analytics could enable early identification of potential issues, facilitating proactive interventions. However, amidst this technological evolution, it is imperative to acknowledge and address the legal and regulatory implications that accompany such advancements. As we venture into a future where AI plays a pivotal role in shaping behavioral health care, balancing the potential benefits of AI with robust legal and regulatory measures will be instrumental in harnessing its transformative power responsibly, ethically and sustainably.

AI-Based Tools for Behavioral Health

Developers and behavioral health providers have explored many ways to apply AI in behavioral health settings, and these applications are certain to expand as the capabilities of AI technology and trust in AI-based systems continue to grow. One of the highest profile applications of AI in behavioral health (if not all of healthcare in recent years) is the development of AI-based chatbots providing chat therapy to patients. Some companies have developed apps using AI chatbots to deliver chat therapy to patients with mild-to-moderate signs of depression or anxiety and assistance to providers in delivering Cognitive Behavioral Therapy (CBT). AI tools are also being developed to monitor patient biometric data through smartwatches or other wearable technology for behavioral changes that are potentially symptomatic of depression.

Over the past few years, we've also witnessed a rise in the use of AI in Electronic Health Records (EHR) technology to assist in diagnosis and treatment. These tools aim to leverage large language models (LLMs) to assist providers in handling large amounts of clinical data, with applications ranging from data management assistance for accessing patient information to clinical decision support systems (CDSS) that recommend potential diagnoses and treatment options based on the AI's review of a provider's EHR. Within the behavioral health space, EHR developers have introduced CDSS tools that use AI to, for example, assist in the diagnosis management of treatment for major depressive disorder and identifying institutional patients that have the highest need for interventional care.

While these are a few of the AI technologies being used and explored in the behavioral health space, it is likely that the future of behavioral health will come to rely on, at least in part, AI and machine learning technology.

The Current Regulatory Landscape for AI and Behavioral Health

Given the ever-expanding uses of AI, in both the behavioral health space and in health care more generally, regulation of AI technology is poised to play a major role as 2024 progresses. As of today, the US does not yet have a binding federal law that regulates the development and use of AI. However, over the past year we have witnessed preliminary bipartisan

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efforts to address potential risks in the development and use of AI, including efforts to promote transparency and notice, ensure fairness and non-discriminatory practices, and protect the privacy and security of health information.[1] These efforts include:

- **The White House "Blueprint for an AI Bill of Rights,"** which identifies five guiding principles for AI development: 1) standards for safety and effectiveness; 2) protections against algorithmic discrimination, including nondiscrimination based on protected classes; 3) requirements for data privacy, including rules around disclosure, appropriate consent, security, and standards for surveillance; 4) standards for notice and explanation; and 5) defined rules for human roles, including alternatives to AI processes. Health use cases are prominently featured in the Blueprint. For example, health data is deemed a "sensitive domain" subject to higher regulatory concern. It is likely that the Blueprint will be consulted in developing regulations in the health space.

- **The AI Accountability Policy Request for Comment,** which requested information on regulatory and other measures and policies designed to provide assurance that AI systems are legal, effective, ethical, safe, and otherwise trustworthy. The request for comment is aimed at informing the Department of Commerce's National Telecommunications and Information Administrations development of a formal report on AI accountability policy.

- **The Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence,** an Executive Order (EO) introduced by the Biden Administration to promote AI innovation while protecting against potential harmful consequences. Section 8 of the EO focuses on the risks and developments associated with AI in the health care industry, specifically covering critical areas including AI use in drug development, predictive/diagnostic AI use cases, safety, healthcare delivery and financing, and documentation and reporting requirements.

- **The Office of the National Coordinator for Health Information Technology's (ONC) Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Final Rule** ("HTI-1 Final Rule"), which creates new certification criterion under ONC's Health IT Certification Program that requires health IT developers and their health IT modules to participate in public facing transparency efforts. These new requirements signal a tonal shift that will impact how health care providers interact with health IT modules, including AI systems. ONC's new decision support interventions (DSIs) certification criterion promotes "responsible AI" as health IT developers are required to assess, quantify, and publish consistent, baseline sets of information about their health IT modules/AI algorithms to the public in effort to provide health care providers insight into the tools available to support their patient care decision making.

- **Federal Trade Commission (FTC) Omnibus Resolution,** which authorizes FTC to issue civil investigative demands (CIDs) (a process like a subpoena) in investigations relating to AI to obtain documents, information and testimony that advance FTC consumer protection and competition investigations. Through this resolution, FTC recognizes that although AI, including generative AI, offers many beneficial uses, it can also be used to engage in fraud, deception, infringements on privacy, and other unfair practices, which may violate the FTC Act and other laws. AI can also raise competition issues in a variety of ways, including if one or just a few companies control the essential inputs or technologies that underpin AI.

Interestingly, recent congressional discussions highlight questions over which level of government should regulate AI, with some arguing that it should be left to states and others pushing for a federal law. Lawmakers in some states like California have proposed their own health care AI legislation, which could lead to a clash between State and federal regulations, as has happened with privacy regulation. While the use of AI in health care and behavioral health is well underway, stakeholders are eager to understand how to effectively use AI while adhering to guardrails that may be, soon, mandated by state and federal legislatures.

1 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; and Proposed Regulatory Oversight on the Emerging Use of Artificial Intelligence in Digital Health, May 10, 2023, *available* here.

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Overview of potential key legal risks based on the use of AI in behavioral health treatment and some practical ways to mitigate the risks.

As noted above, the regulatory landscape for behavioral health providers is still highly unsettled and is likely to change in the coming years. Still, providers, vendors, and investors should be aware of certain foreseeable key risk factors, which include, among others, data privacy, algorithm bias, and professional liability.

- **Data Privacy:** Behavioral health providers face significant data privacy risks when implementing AI tools in their practice, particularly concerning compliance with the Health Insurance Portability and Accountability Act (HIPAA) and its implementing regulations, 42 CFR Part 2 (Part 2), and state privacy laws governing sensitive information. Behavioral health providers are by and large covered entities, and as such have an obligation to ensure that any AI tools being used comply with HIPAA. This includes safeguarding protected health information (PHI) and implementing appropriate security measures to prevent unauthorized access or disclosure. As a best practice, providers should seek to obtain informed consent from patients before using AI tools that analyze or process their PHI to ensure that patients understand how their data will be used and shared, as well as any potential risks associated with AI-driven interventions. Additionally, providers should carefully vet third-party vendors offering AI solutions, to ensure they adhere to data privacy and security rules. Providers should understand how the AI tool stores, transfers, retains, and uses patient data, and whether each of these forms of processing is permitted under HIPAA.
  Behavioral health providers that furnish substance use disorder (SUD) treatment should also be aware of patient privacy and confidentiality requirements under Part 2. Part 2 has historically governed the confidentiality of SUD patient records, and until recently, providers subject to Part 2 and HIPAA have had to deal with long standing inconsistencies between the two laws, largely pertaining to patient consent and disclosure requirements. HHS' final rule released on February 9, 2024 streamlines some SUD patient record requirements under the two frameworks.[2] The update permits use and disclosure of Part 2 records based on a single, one-time patient consent for treatment, payment, and health care operations purposes, and expanded permission for the redisclosure of Part 2 records by entities that are subject to HIPAA, which are generally consistent with HIPAA (except for disclosures in law enforcement and the judicial and administrative context). However, the changes also include enhanced requirements for deidentification of Part 2 records, among other requirements aimed at better aligning Part 2 with HIPAA. Further, to the extent that a provider may share or consider sharing PHI to train an AI model, the provider will need to ensure that such sharing of information complies with Part 2 to the extent applicable. Importantly, for PHI to be used in compliance with HIPAA in relation to the creation and development of AI algorithms and machine learning, it must meet the research exception. However, the requirements under Part 2 for the use or disclosure of identifiable information from a behavioral health or substance use disorder patient in research is more restrictive.
  Providers should also stay abreast of state privacy laws that govern the use and disclosure of sensitive health information, which includes behavioral and mental health information. These laws may impose additional requirements or restrictions on data handling practices, such as mandatory breach notification requirements.

- **Algorithmic Bias:** While there is hope that AI tools will increase access to and streamline behavioral health care, the behavioral health industry must remain cautious of risks related to algorithmic bias. "Algorithmic bias" refers to an AI algorithm that are trained on data that includes inequalities in socioeconomic status, race, ethnic background, religion, gender, disability, or sexual orientation, which can then lead to the perpetuation of existing biases and discrimination against certain groups of people. AI models are trained on large amounts of data, detecting and incorporating patterns and connections within that data, which may lead to the AI tools relying on data that includes historic bias. While for the time being, algorithmic bias is largely an ethical issue that AI developers face, providers using AI tools should seek transparency from developers and vendors and ensure that they understand the data in which the tools they rely upon were trained.

2 For more information on the update to Part 2, see our update: HHS Finalized Part 2 Revisions: What Has Changed? *available here*.

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- **Professional liability:** AI tools create a legal thicket of professional liability considerations for behavioral health providers and vendors. Sophisticated AI-enabled strategies can support clinicians to deliver more accurate diagnoses, promote person-centered treatments, and enable patient self-management. But as with any clinical support tool, licensed clinicians continue to hold ultimate legal responsibility for their medical judgment in providing patient care. If the use of an AI tool results in an adverse patient event (for example, misdiagnosis or poor outcomes), the clinician may be held liable. Malpractice claims inherently turn on whether a clinician's actions were consistent with the standard of care.
  Navigating potential liability for clinicians using AI tools can be difficult to discern given the rapid development of AI technology, the changing use patterns of clinicians, and the lack of clear regulatory guidance. The failure to comply with regulatory standards may make it easier for a plaintiff to successfully allege malpractice, which puts providers in a difficult position in an environment where those standards are still being developed and refined. Moreover, malpractice claims inherently turn on a clinician's failure to perform consistent with the standard of care for his or her profession. This can be difficult to assess at a time when the standard of care maybe changing to accommodate AI – there is little uniformity around clinicians' adoption of tools, evaluation of the quality of such tools, or the supplemental use of AI-enabled tools to support patient education and self-management.
  AI-enabled tools may also have implications for professional liability coverage. As AI tools become more integrated into behavioral health practice, insurers may adopt requirements concerning the permitted use of tools, audit obligations, or the implementation of technical or procedural standards. On the other hand, if AI-enabled tools reduce liability risk (for example, by helping identify high-risk patients or avoiding harmful medication interactions), professional liability insurers may advocate the use of AI-enabled tools. Insurers may also define certain AI use cases (for example, a patient's independent use of self-management tools) as "excluded coverage," or acts not covered by the professional liability policy. Clinicians should consider reviewing the scope of their professional liability coverage before adopting AI-enabled tools.
  These issues do not only concern clinicians. Due to the uncertain legal and regulatory environment, clinicians are likely to shift as much risk as possible to the vendors of AI technology. For example, clinicians will likely require vendors to contractually represent and warrant that the technology complies with all applicable law and will comply with future changes to the law. Clinicians may also insist on indemnification provisions or other requirements that shift liability for the use of these products to the vendor.[3] To the extent patients directly interact with AI-enabled tools (for example, chatbots incorporated into patient education models), the contracts should specify standards and expectations around the content of such interactions. Finally, clinicians may attempt to shift potential liability risk to vendors by pointing to vendor representations around safety, effectiveness, and lack of bias.

Conclusion

The utilization of AI in behavioral health care signifies a groundbreaking leap toward more effective and accessible mental health services. However, as we navigate this transformative landscape it is crucial to anticipate and address the evolving regulatory frameworks and legal risks associated with AI applications. AI regulation is a moving target with significant developments expected in the coming years and anticipating and mitigating legal risks will be instrumental in fostering a trustworthy and secure environment for both practitioners and patients.

3 Additionally, if the AI tool was trained on or was derived from proprietary data and other third-party content, such tool may be vulnerable to claims that it infringes or misappropriates the intellectual property rights of others. The healthcare system providing the AI tool for its clinicians may be exposed not only to infringement claims but may be potentially enjoined from continuing to use the AI tool (which would be costly and disruptive to its operations). The system may consider contractually requiring the vendor to defend it against such claims and indemnify it against any resulting liability. Also, the user should consider requiring that the vendor provide additional remedies such as the vendor providing a non-infringing functionally equivalent replacement, or a refund of fees paid for licensing the allegedly infringing tool. The vendor will want to consider disclaimers and other contractual clauses to limit its liability.

Rise of Value-Based Care: Integration and Coordination

Kathleen Snow Sutton

Shareholder
Denver

Behavioral health is the next frontier in value-based care. The evolution of behavioral health payment toward value-based care is accelerating, fueled by experimental programs and pilot projects designed to identify best practices for clinical and payment models that enhance patient care while controlling costs. Now is the time for providers to participate in and influence the development of whole-person and patient-centered care payment models.

The current trajectory for value-based care in behavioral health involves two different, but complementary paths: integration with physical health and coordination along the behavioral health continuum of care. Each path offers different practical benefits and challenges for providers. This article evaluates the opportunities presented by each path and identifies next steps for providers who want to engage in the development of these care models.

Whole-Person Care: HHS Promotes Behavioral Health Integration

The first path to value-based care is behavioral health integration. Integrating behavioral health care with physical health, particularly through primary care, has clear benefits for patients.[1] There has been some movement in recognizing the value of care coordination and behavioral health integration under current payment systems.[2] However, calls for behavioral health integration are growing more urgent, and providers have more opportunities to participate in and benefit from the development of models that incentivize and reward providers for improved care that results from integration.[3]

In particular, the Department of Health and Human Services ("HHS") identified behavioral health integration as a core tenant of its strategy to address the United States' mental health crisis.[4] HHS is taking steps to encourage and fund projects to promote behavioral health integration, as well as enhancing federal mental health parity requirements to promote financial feasibility for providers to furnish behavioral health services.[5]

On January 18, 2024, CMS announced a new innovation model aimed at providing whole-person care to Medicare and Medicaid beneficiaries with moderate to severe mental health conditions and substance use disorder.[6] The Innovation in Behavioral Health ("IBH") Model focuses on four main pillars:

1. Care Integration,
2. Care Management,
3. Health Equity, and
4. Health Information Technology.[7]

1 See, e.g., Janine Archer, et al., Collaborative care for depression and anxiety problems, Cochrane Database of systematic reviews, (October 17, 2012), available at **https://www.ncbi.nlm.nih.gov/pubmed/23076925**; Balasubramanian, B. et al., Outcomes of Integrated Behavioral Health with Primary Care, J Am Board Fam Med. (2017), available at **https://pubmed.ncbi.nlm.nih.gov/28379819/**. See also Prom, M., et al., Implementation of integrated behavioral health care in a large medical center: Benefits, challenges, and recommendations, J. Behav. Health Serv. Res (July 2021), available at **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8144234/pdf/nihms-1649955.pdf**.

2 See Behavioral Health Integration, MLN Booklet (May 2023), available at **https://www.cms.gov/files/document/mln909432-behavioral-health-integration-services.pdf**.

3 See, e.g., Integrating Behavioral and Physical Health: The Time is Now, American Hospital Association (September 2023), available at **https://www.aha.org/system/files/media/file/2023/09/AHA-BH-Integration-TimeisNow-whitepaper-september-2023.pdf**.

4 Erin Bagalman, et al., HHS Roadmap for Behavioral Health Integration, ASPE (Sept. 14, 2022), available at **https://aspe.hhs.gov/sites/default/files/documents/4e2fff45d3f5706d35326b320ed842b3/roadmap-behavioral-health-integration.pdf**.

5 Id. For more on mental health parity, see within this Newsletter, Bragg Hemme, Will Mental Health Parity Get Some Teeth in 2024?

6 Press Release: Innovation in Behavioral Health (IBH) Model, CMS Newsroom (January. 18, 2024), available at **https://www.cms.gov/newsroom/press-releases/cms-announces-new-model-advance-integration-behavioral-health**

7 Innovation in Behavioral Health (IBH) Model, available at **https://www.cms.gov/priorities/innovation/innovation-models/innovation-behavioral-health-ibh-model**

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CMS will issue awards to eight Medicaid state agencies to develop and implement a model to deliver integrated physical and behavioral health care.[8]

The IBH Model envisions leadership by behavioral health practices who participate in the program. Behavioral health providers screen and assess eligible patients for behavioral, social,[9] and physical health needs and lead interdisciplinary teams to comprehensively address those needs.[10] Providers are paid based on the quality of care provided to patients and improved patient outcomes.[11]

The behavioral health integration model has the benefit of energy, supportive studies, and funding through grants and pilot projects. Providers have an opportunity to benefit from this momentum and the support to design models that work for providers and patients. However, this model requires resilient and trusting relationships between physical and mental health care providers to facilitate this type of whole-person care and to ensure that compensation for these programs is allocated appropriately to support the programs operational and staffing needs and the program's operational goals.

Coordination Across the Behavioral Health Continuum of Care

While behavioral health integration has the attention of industry stakeholders—for good reason—it is not the only path to provide person-centered, high-quality, and efficient care in behavioral health. A second path to value-based care in behavioral health is a focus on improving care along the continuum, from inpatient psychiatric care to outpatient settings.

This second path improves patient outcomes (such as reduced mental health hospitalizations)[12] and may also facilitate a more targeted approach to patient-centered care that yields clearer metrics for improvement and more rapid adoption. Identifying clear quality metrics for behavioral health has been a challenge in the development of value-based models, but coordinating care between levels of care can provide clear standards and metrics for improved patient outcomes. For example, demonstrating that a patient successfully moved to a lower-level setting for treatment and remained stable at that lower level would demonstrate a positive patient outcome as well as cost-savings, which is the type of win-win target that value-based care aims to achieve. Additionally, this framework may be more familiar for third-party payors, since this type of coordination has often been the focus of value-based care efforts for physical health, which may lead to more productive conversations around value-based models.[13] Finally, focusing on enhancing care within the behavioral health continuum of care may allow for a more targeted and aligned approach among participating providers.

In short, behavioral health providers have an opportunity to walk parallel paths toward providing patient-centered care by working together to improve care along the continuum, and capturing the value associated with the benefits of providing supportive, patient-centered care.

What Next?

While there are many potential paths to value-based care in behavioral health, integration with physical health as well as focusing on enhancing the behavioral health continuum of care are two opportunities that provide clear benefits to patients, as well as opportunities and a framework for compensation. Providers who are interested in pursuing value-based care opportunities should consider taking the following steps:

8 Id.

9 See within this Newsletter, Lori Oliver, The Joint Commission's National Patient Safety Goal: Advancing Health Equity.

10 Id.

11 Id.

12 Positive Effect of Collaborative Chronic Care Model on VA Mental Health, U.S. Dep't of Veterans Affs. (April 22, 2020), available at **https://www.hsrd.research.va.gov/impacts/chronic-care-model-mh.cfm#:~:text=Findings%20showed%20that%20mental%20health,health%20clinics%20in%20those%20facilities**.

13 See, e.g. Value-Based Care: What It Is, and Why It's Needed, Commonwealth Fund (February 7, 2023), available at **https://www.commonwealthfund.org/publications/explainer/2023/feb/value-based-care-what-it-is-why-its-needed#:~:text=Also%20known%20as%20value%2Dbased,%2C%20quality%2C%20and%20equity%20metrics**.

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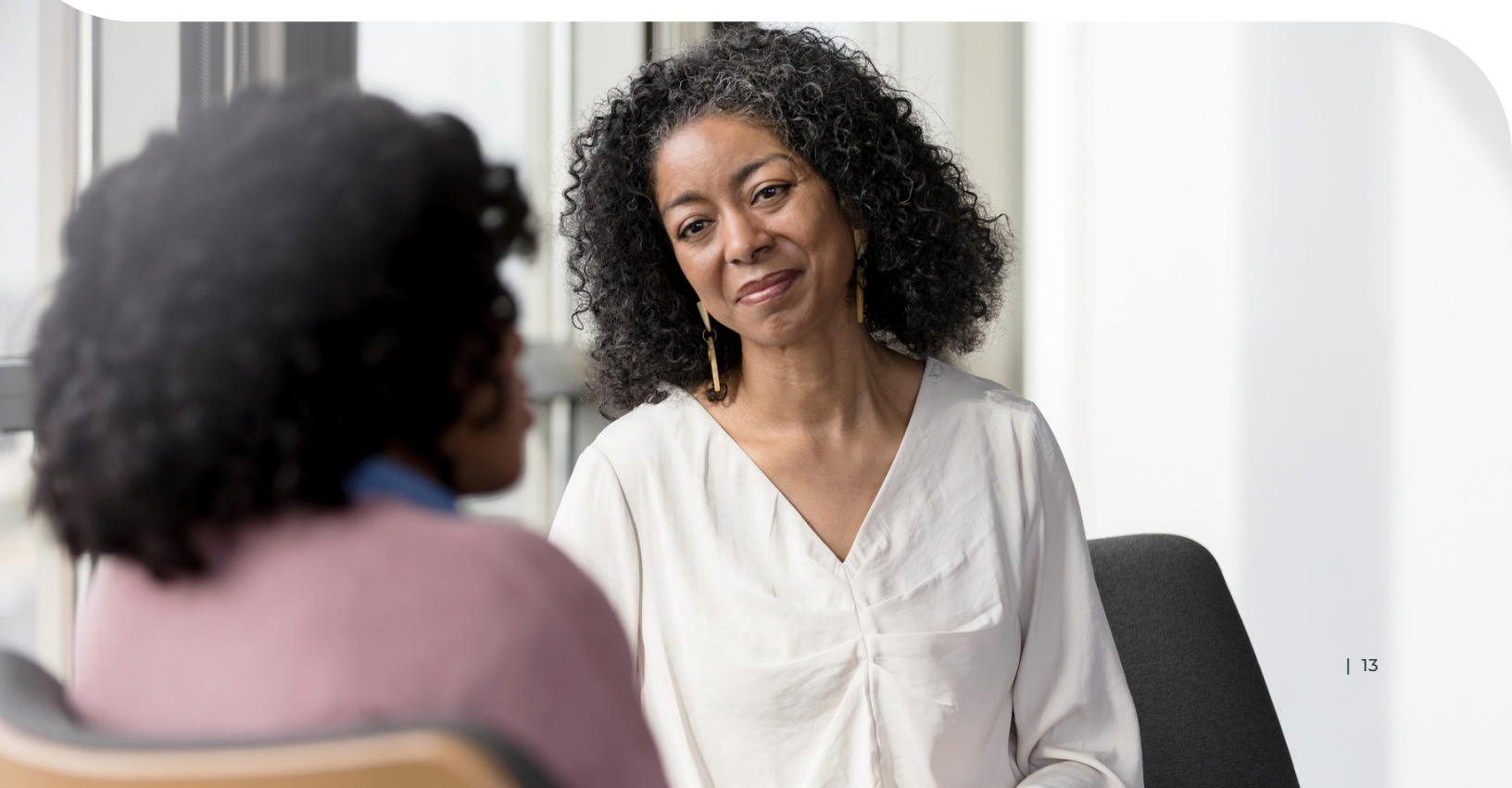
1. **Medicaid State Agency Engagement** – Providers have an opportunity to encourage states to participate in the IBH Model (applications will be due in Spring 2024) and to engage in the state's program design and implementation. Additionally, many state Medicaid agencies have other grants and programs to support and provide coverage for integrated behavioral health care for Medicaid beneficiaries.[14]

2. **Identify and Design Partnerships** – Coordinating care between physical and behavioral health or along the continuum of care requires strong partnerships among providers. Participation in, or creation of, a clinically integrated network provides a framework for coordination of care and negotiation of agreements to support new care models, but requires consideration of how the parties share information, commit to quality standards, and support each other.

3. **Collect and Use Data** – Providers who capture and understand the care they provide to patients will be in a stronger position to negotiate value-based agreements. For example, providers can use information from measurement-based care to demonstrate the effectiveness of treatment. Providers can use that information to design metrics to support quality-related bonus payments or other value-based compensation models.

For years, the behavioral health industry has discussed the benefits of integrating physical and behavioral health care, as well as care coordination and value-based care, but implementation has been sluggish. Providers who are ready to walk the walk have a significant opportunity to control the narrative and build models that benefit patients and providers, while capturing the value of providing thoughtful and comprehensive person-centered care. Working together through a clinically integrated network or other provider partnerships can help providers reach the critical mass necessary to break free from the inertia and implement care models that reward providers who provide excellent, whole-person, and valuable care to their patients.

14 See, Madeline Guth, et al., How do States Deliver, Administer, and Integrate Behavioral Health Care? Findings from a Survey of State Medicaid Programs, (May 25, 2023) available at Kaiser Family Foundation **https://www.kff.org/mental-health/issue-brief/how-do-states-deliver-administer-and-integrate-behavioral-health-care-findings-from-a-survey-of-state-medicaid-programs/**; HCPF Awards $29 Million in Behavioral Health Care Integration Grants, Colo. Dep't Health Care Policy & Financing (September. 5, 2023), available at **https://hcpf.colorado.gov/hcpf-awards-behavioral-health-care-integration-grants**.



The Joint Commission's National Patient Safety Goal: Advancing Health Equity

Lori A. Oliver

Shareholder
Seattle

Improving equity in health care continues to be a top national priority. In addition to federal initiatives [1] that require ongoing attention to improving health equity by reducing health disparities, The Joint Commission ("TJC") recently adopted new requirements intended to improve health equity. TJC first announced standards to reduce health disparities (effective January 1, 2023) as part of the leadership accreditation standards.[2] TJC placed the standards in the leadership chapter "because success demands leadership" and "achieving healthcare equity will require commitment, vision, creativity and sustained effort at all levels, including the C-Suite and the Board."[3] Shortly thereafter, TJC announced that the content of the leadership standard (LD.04.03.08) would be elevated to a new National Patient Safety Goal ("NPSG").[4] The elevation of health equity as a NPSG should come as no surprise.[5] In the U.S., outcomes data related to health equity continues to challenge and highlight the need for change in the delivery of health care.[6] In the new standard, TJC is directing organizations to improve health equity as a NPSG.

To fully appreciate TJC directive, the following definitions are important to understand:[7]

- Health equity means that "everyone has a fair and just opportunity to attain the highest level of health."[8]
- Health disparities are "preventable differences in the burden of disease, injury, violence, or opportunities to achieve optimal health that are experienced by populations that have been disadvantaged by their social or economic status, geographic location, and environment."[9]

1 CMS and other federal agencies are creating frameworks and regulatory expectations related to improving health equity. **https://www.cms.gov/priorities/health-equity/minority-health/equity-programs/framework**. *See also* the CDC's approach and efforts to harmonize terminology across federal agencies and others. **https://www.cdc.gov/healthequity/index.html#:~:text=Health%20equity%20is%20the%20state,their%20highest%20level%20of%20health**. Unique to behavioral health, CMS recently announced a new innovation model that requires behavioral health practice participants to conduct screenings for health-related social needs and to refer patients to appropriate community-based services. **https://www.cms.gov/priorities/innovation/innovation-models/innovation-behavioral-health-ibh-model**. *See also* Kathleen Snow Sutton, Rise of Value-Based Care: Integration and Coordination within this Newsletter.

2 R3 Report Issue 36: New Requirements to Reduce Health Care Disparities, June 20, 2022, The Joint Commission. **https://www.jointcommission.org/-/media/tjc/documents/standards/r3-reports/r3_disparities_july2022-6-20-2022.pdf**

3 *Id*. TJC recognized that many organizations' efforts at health equity were project driven and even when successful, lacked an institutional leadership focus.

4 R3 Report Issue 38: National Patient Safety Goal to Improve Health Equity, December 20, 2022, The Joint Commission. **https://www.jointcommission.org/-/media/tjc/documents/standards/r3-reports/r3_npsg-16.pdf**. As background, the National Patient Safety Goal ("NPSG") program was established in 2002 and helps organizations address specific areas of concern regarding patient safety.

5 *See supra* Note 1.

6 Racial Equity and Health Policy. **https://www.kff.org/racial-equity-and-health-policy/**. The Kaiser Family Foundation tracks and publishes data on disparities on health data based on race and ethnicity and other key metrics related to health equity. The research consistently demonstrates that people of color experience poorer health outcomes than others. *Id*.

7 There continues to be slight variations in definitions, depending on the source and ongoing evolution concerning what terminology best achieves the goals identified. For example, the Centers for Medicare and Medicaid ("CMS") recently endorsed the term "drivers of health" ("DOH") as preferred terminology over "social determinants of health" noting that the term minimizes confusion, misinterpretation and negative connotations. 87 FR 69404 at 70054-55. *See also* Melinda K. Abrams, Rachel Nuzum, Debbie I. Chang and Rocco Perla, Let's Get It Right: Consistent Measurement of Drivers of Health, The CommonWealth Fund. **https://www.commonwealthfund.org/blog/2023/lets-get-it-right-consistent-measurement-drivers-health**.

8 The Center for Disease Control and Prevention offers several definitions as part of its public health mission. **https://www.cdc.gov/healthequity/index.html#:~:text=Health%20equity%20is%20the%20state,their%20highest%20level%20of%20health**.

9 *Id*.

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- Health related social needs ("HRSN") are an "individual's unmet, adverse social conditions . . . that contribute to poor health and are a result of underlying social determinants of health (conditions in which people are born, grow, work and age)".[10]

The new NPSG [11] (Goal 16) applies to behavioral health and human resources organizations providing the following services: addiction services, eating disorders treatment, intellectual disabilities/developmental delays, mental health services, and primary physical health care services.[12]

There are six elements of performance ("EP") identified to further the goal of improving health equity:

1. The first EP requires organizations to designate an individual to lead organizational activities to improve health equity for the population served by the organization.[13] The designated individual may have this accountability as the individual's primary role or it may be part of other job duties.[14] Importantly, each separately licensed facility will need an identified individual who is responsible to lead health equity.[15]

2. The second EP requires the organization to assess the individual's HRSN and provide information about community resources and support services.[16] To meet this PE, an organization should engage in a three part analysis to determine which HRSNs to include in an assessment, which individuals to include (all or a representative sample of individuals served) and what information about community resources and support services is available to target the HRSN.[17] TJC stresses that there is flexibility for an organization in selection of HRSNs.[18]

3. The third PE requires an organization to identify health care disparities in the population it serves by stratifying quality and safety data using the sociodemographic characteristics of the individual's served.[19] An organization has flexibility to either rely on known health disparities identified in the scientific literature[20] or may rely on the results of organization's disaggregation of its own data. It is important to understand the barriers in order to design appropriate interventions as discussed below.

4. The fourth PE requires the organization to develop a written action plan that describes how it will improve health equity by addressing at least one of the health care disparities identified in the organization's population.[21] The action plan should identify the organization's improvement goal, the strategies and resources needed to achieve the goal, and the process that will be used to monitor and report progress. [22]

5. The fifth PE requires the organization to act if it does not achieve or sustain the goal(s) in its action plan to improve health equity.[23] This creates a continuous

10 Elizabeth Hinton, A Look at Recent Medicaid Guidance to Address Social Determinants of Health and Health-Related Social Needs. (February 22, 2023) *available at* Kaiser Family Foundation. **https://www.kff.org/policy-watch/a-look-at-recent-medicaid-guidance-to-address-social-determinants-of-health-and-health-related-social-needs/**. The TJC, in its HRSN screening guidance, provides examples of the primary HRSN domains to include as food insecurity, housing instability, transportation challenges, education and literacy and difficulty paying for prescriptions or medical bills. TJC focuses on HRSN, rather that social determinants of health "to emphasize that HRSNs are a proximate cause of poor health outcomes for individual patients. . . ." R3 Report Issue 38: National Patient Safety Goal to Improve Health Equity, December 20, 2022, The Joint Commission. **https://www.jointcommission.org/-/media/tjc/documents/standards/r3-reports/r3_npsg-16.pdf**. *See also* NPSG.16.01.01.

11 R3 Report Issue 38: National Patient Safety Goal to Improve Health Equity, December 20, 2022, The Joint Commission *available at* **https://www.jointcommission.org/-/media/tjc/documents/standards/r3-reports/r3_npsg-16.pdf**. *See also* NPSG.16.01.01.

12 *Id.*

13 *Id.* Performance Element 1

14 *Id.*

15 *Id.*

16 *Id.* Performance Element 2.

17 At an individual level, HRSNs may include access to transportation, difficulty paying for prescriptions, education and literacy, food insecurity, or housing insecurity. *Id.*

18 *Id.* Flexibility may be helpful for organizations just beginning this work. However, there are others who advocate for greater tracking consistency, particular among public payers of health care. *See Infra* Note 7.

19 Examples include age, gender, preferred language or race and ethnicity. *Id.*

20 Examples include treatment for substance abuse disorder, use of restraints, or suicide rates. Id. Performance Element 3.

21 *Id.*

22 *Id.*

23 *Id.* Performance Element 5.

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process improvement expectation and requires the identification of follow-up actions as needed.[24]

6. The sixth and final PE requires a process to inform key stakeholders at least annually of the organization's progress to increase health equity.[25] Key stakeholders include organizational leaders, licensed practitioners, staff and governing bodies.[26]

As your organization executes on these PE (effective July 1, 2023) it may be helpful to consider the original guidance offered when TJC first announced the leadership standard prior to elevating the standards to a NPSG because TJC does not view the content of the NPSG as changing significantly from the leadership guidance. Rather, TJC continues to rely upon the existing body of research reflect in the leadership review, public field review and expert engagement.[27] TJC's earlier view that success demands leadership is undoubtedly unchanged. While there are many non-financial resources available to organizations seeking to improve health equity, TJC offers an approach that allows every organization to start the journey. TJC's approach relies on integration of health equity into an organization's quality improvement activities just like any other safety and quality priorities.

The opportunities for meaningful progress are significant and your organization's efforts to understand the root causes of inequity and address those root causes with targeted interventions is critical. Using established quality improvement processes is crucial to advancing health equity and creates an important education and training opportunity within your workforce to elevate an understanding of health equity across an organization. Further, health inequities drive low value care (i.e., poor outcomes and variations in the cost of care). [28] While value-based care initiatives that are aligned with the "Triple Aim" of improving the care experience of the individual, the health of populations and reducing per capita costs of care are conceptually aligned with the goal of reducing health inequities, in practice value-based care has not always demonstrated improvement.[29] The new NPSG creates an opportunity to do better with a more targeted focus on reducing inequity, a goal which continues to have the potential to reduce variations in costs and health outcomes.[30] There are clear opportunities for investors, providers and payers to engage more deeply in the interplay between inequity, cost and outcomes to build targeted interventions that do not further exacerbate inequity. Partnership with community organizations engaged in work to reduce health disparities through addressing HRSN will be critical.

24 *Id.*

25 *Id.* Performance Element 6.

26 While not specifically mentioned in the NPSG, the governing body was a focus of the former leadership standards and should be included in this reporting as a matter of quality oversight accountabilities.

27 *Id.* In fact, both the leadership standard and the NPSG have identical published research underpinning both, starting with the Institute of Medicine's twenty-year-old "Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care."

28 Pinnock C, Rothen J, Carlough T, Shah NR. Improving value for underserved populations with a community-based intervention: a retrospective cohort study. Arch Public Health. 2023 May 29;81(1):96. doi: 10.1186/s13690-023-01117-z. PMID: 37248512; PMCID: PMC10225756.

29 Amanda Shi, MPH, MPA, Tiara Ranson, MPHc, Julie Chinitz, JD, Karina Patel, MPH, and Danisha-Jefferson Abye, MPH, Sustaining a Community-Designed Model of Care: Exhisitng Payment Lnadscare and Opportunities to Address Structural Drivers of Inequity (February 2024) *available at* **https://tubmanhealth.org/payment-models-report/** The authors noted that "while promising in theory, value-based purchasing and care in practice has not lived up to its equity aspirations in transforming healthcare and instead contributed to the further medical marginalization of populations most impacted by existing health disparities."

30 *See Supra Note 28* (estimating that social determinants of health are "increasingly seen as an underlying driver of up to 30-80% of variation in health outcomes and costs").

2024: Tele-Behavioral Health's Promise is Constrained by Ongoing Regulatory and Payment Uncertainty

Joelle M. Wilson

Shareholder
Chicago

Jasmine C. González

Counsel
Denver | Seattle

Telehealth has become an integral feature for the delivery of behavioral health services in a post-pandemic world. While telehealth utilization rates are down across all specialties compared to COVID-level highs, behavioral health services continue to lead all specialties with the highest rate of utilization (37%) through Q3 2023.[1]

Despite the sustained need for behavioral health services, we are continuing to experience a shortage of professionals. Approximately 47 percent of the U.S. population live in a behavioral health workforce shortage area.[2] Rural communities and economically distressed communities experience higher instances of such shortages, positioning telehealth as a necessary tool to address these disparities in access to care.[3]

To address both the ongoing need for behavioral health services and the workforce shortage, there has been a push towards implementing payment parity for telehealth services across the country. Payment parity requires that providers are reimbursed the same amount for telehealth visits as in-person visits. During the COVID-19 pandemic, several states passed temporary payment parity legislation; now, many states are implementing payment parity permanently. As of October 2023, 21 states have implemented policies requiring payment parity, eight states have partial parity and 21 states have no payment parity.[4]

Regulatory Update

The Center for Medicare and Medicaid Services (CMS) recently issued a final rule for calendar year 2024 under the Medicare Physician Fee Schedule (the "Final Rule") that updates key payment policies and Medicare payment rates for services furnished by physicians and non-physician practitioners to Medicare beneficiaries.

The Final Rule implements the telehealth flexibilities passed by the Consolidated Appropriations Act, 2023, which extends through December 31, 2024, many of the telehealth waivers and flexibilities that were put in place because the COVID-19 public health emergency (PHE). Namely, the current flexibilities include among others:

- Waiving geographic limitations and originating site requirements, which allows beneficiaries to receive telehealth services from their home;
- Expanding the types of providers that may furnish telehealth services to include mental health counselors and marriage and family therapists;
- Delaying the requirement for an in-person visit with the physician or practitioner within 6 months prior to initiating mental health telehealth services, and, again, at subsequent intervals as the Secretary determines appropriate;
- Allowing practitioners to render telehealth services from their homes without reporting their home address on their Medicare enrollment while continuing to bill from their currently enrolled location. (This waiver will continue through December 31, 2024.); and
- Extending coverage for audio-only telehealth services in certain limited circumstances. (However, CMS notes in the Final Rule that most telehealth visits require the use of audio and video technology.)[5]

1 Telehealth Utilization Higher Than Pre-Pandemic Levels, but Down from Pandemic Highs (November 21, 2023) *available at* **https://epicresearch.org/articles/telehealth-utilization-higher-than-pre-pandemic-levels-but-down-from-pandemic-highs**

2 William A. Haseltine, PhD., Solving the Mental Health Provider Shortage (September 22, 2023) *available at* **https://www.psychologytoday.com/us/blog/best-practices-in-health/202309/solving-the-mental-health-provider-shortage**

3 *Id.* For additional detail, please also refer to Polsinelli's Top Issues in Behavioral Health 2023 Newsletter, "Despite Additional Funding, Staffing Shortages Will Continue to Reduce Access to Behavioral Health, *available at* **https://polsinelli.gjassets.com/content/uploads/2023/02/March_23_Behavioral_Health_Newsletter.pdf**.

4 American Medical Association, State Telehealth Policy Trends 2023 Year in Review, *available at* **https://www.ama-assn.org/system/files/ama-state-telehealth-policy-trends-2023.pdf**.

5 88 Fed. Reg. 78818, et seq.

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Tele-Prescribing

In late 2023, the Drug Enforcement Agency (DEA) announced that it will allow practitioners to prescribe controlled substances via telemedicine through December 31, 2024, because an extension of pandemic-era telemedicine prescribing flexibilities. As we move through 2024, many question remain. Will DEA flexibilities become permanent? Will DEA implement a special registration process for telemedicine prescribers? What impacts will forthcoming regulations have on behavioral health providers, including addiction treatment and psychiatric care access?

The DEA's initial proposed rules, issued in February 2023, reinstated strict limitations on virtual prescribing of controlled substances and signaled a significant roll back of the in-person medical evaluation flexibilities extended during the PHE. In response to the proposed rules, the DEA received widespread criticism from industry stakeholders, receiving over 38,000 comments, the most the agency has received in response to any proposed rule.

In recent years DEA has also been under congressional pressure to implement a special registration process for tele-prescribing. In a **bipartisan letter** sent to the DEA in September 2023, several senators expressed concerns over both the potential impact of the DEA's proposed rules and the fact that the DEA has yet to develop a special registration process for tele-prescribing despite multiple legislative actions permitting, and in fact requiring, it to do so. The letter emphasized the potential for a special registration process to balance the need for provider clinical judgement and flexibility in prescribing appropriateness via telemedicine encounters.

Without a permanent policy change, telehealth providers, especially mental health providers, will likely have to re-examine their current models to meet patient need and access to care issues stemming from the inability to prescribe controlled substances virtually. Companies that rely on telehealth to increase access to buprenorphine for OUD treatment and MAT are likely to face particular impact without permanent legislative change.

Conclusion

The future of telehealth promises significant advancements in the delivery of behavioral health services, with legislative trends reflecting a growing recognition of its importance. However, behavioral health providers and investment in behavioral health would be fortified by making certain telehealth flexibilities and related payment issues more permanent and reliable. Some key trends that we will be tracking in 2024 include -

- *Payment Parity:* Legislative efforts aimed at achieving payment parity between telehealth and in-person visits are gaining traction. These initiatives seek to ensure that providers are reimbursed fairly for telehealth services, incentivizing the adoption of virtual care options for behavioral health treatment.
- *Cross State Licensure:* As telehealth transcends geographical barriers, there is a push for legislative changes to facilitate cross-state licensure for all providers, including behavioral health providers. This would enable practitioners to deliver care to patients across state lines, increasing access to services and addressing provider shortages in underserved areas, without having to navigate the administrative burden and expense associated with independent state medical board licensure requirements and processes.
- *Regulatory Support for Digital Therapeutics:* The rise of digital therapeutics, including mobile apps and online platforms, is reshaping the landscape of behavioral health care. These innovative solutions offer evidence-based interventions for various mental health conditions, complementing traditional therapy and expanding treatment options for patients. Regulatory bodies are increasingly recognizing the value of digital therapeutics and telehealth in improving access to behavioral health care. Efforts to streamline regulatory processes and ensure quality standards for these technologies are underway, fostering innovation while safeguarding patient safety.
- *Integration with Traditional Care:* Telehealth is becoming increasingly integrated into traditional behavioral health care delivery models. Providers are leveraging technology to offer hybrid models of care, combining virtual visits with in-person appointments to meet the diverse needs of patients and enhance care coordination. Telehealth empowers patients to take a more active role in managing their behavioral health, offering greater convenience and flexibility in accessing care. Legislative initiatives focus on promoting patient-centered approaches, including policies that support patient choice and autonomy in selecting telehealth services.

Continued advancements on the fronts noted immediately above have the potential to revolutionize the delivery of mental health care, making it more accessible, affordable, and personalized for individuals across diverse populations.

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A Market in Transition: Autism Therapy Provider M&A

Michael T. Flood

Shareholder
St. Louis

Paul A. Gomez

Co-Chair, Behavioral Health Law Group
Los Angeles

The autism therapy provider market has faced challenges in recent years relating to economic factors and staffing difficulties contributing to a general slow-down in dealmaking. However, it may be starting to emerge from that more difficult period. Moving into 2024, we first take a brief look back at the recent past of M&A activity for autism therapy providers and then engage in a brief exploration of the factors that may be leading toward more M&A and investment activity ahead.

Challenges in Investing in the Autism Therapy Industry: A Brief Look Back

Applied Behavioral Analysis ("ABA") is the leading treatment for the one in thirty-six children who are diagnosed with autism based on the most recent 2020 data.[1] Unfortunately, the waiting lists for treatment can be months long in some areas of the country. Higher rates of autism diagnosis and corresponding demand attracted significant institutional investment to autism therapy providers and ABA clinics in prior years.[2] However, in 2023, the autism therapy industry faced a number of headwinds, which slowed market activity from its peaks prior to 2020. Common challenges cited by industry executives include low reimbursement rates and labor force issues which stretched margins and stressed a delivery system already in high demand.[3]

Although these challenges are also navigated by other health care providers, in ABA they are exacerbated by the labor-intensive and continuous nature of ABA treatment. Typically, Board Certified Behavioral Analysts ("BCBAs") will develop individual treatment plans and supervise their implementation by frontline therapists who are commonly referred to as Registered Behavioral Technicians ("RBTs"). An RBT will commonly work face-to-face with a child for up to 25 to 40 hours per week (depending on medical need) either at a care center, in the child's home, in school or in the community.

Demand for ABA services is seemingly infinite but, funding is not. There several efforts are underway between payors and providers to create value-based payment mechanisms focused on outcomes, but the dominant form of ABA reimbursement continues to be the time-based CPT codes between 97151 to 97158.[4]

These challenges provided context for the bankruptcy of the Centers for Autism and Related Disorders ("CARD") – one of the largest ABA providers in the country. CARD was a portfolio company of Blackstone and at its peak operated in 24 states and had 221 locations. CARD began showing signs of distress in 2022 when it made the decision to shut down its operations in 10 states.[5] In July 2023, CARD was sold out of bankruptcy back to a group led by its founder, citing challenges servicing its debt taken on to pursue its aggressive growth plan. CARD's bankruptcy underscored the operational difficulties facing many autism therapy providers and serves as a word of potential caution for private equity investors pursuing a strategy of highly leveraged growth with an end goal of securing more favorable reimbursement.

In the wake of CARD, there continues to be significant interest by institutional investors in autism therapy providers. High quality assets are still in demand, as demonstrated by two transactions in Q4 2023. One example was KKR portfolio company BlueSprig's purchase of Trumpet Behavioral Health in October 2023. Although terms of the transaction were not disclosed the purchase brought an additional 37 locations in seven states under BlueSprig's national platform and was an exit transaction for Windrose Health Investors which had purchased Trumpet in 2017. Similarly, Cortica, an "all-in-one" provider of ABA and other therapy services to autistic

1 Maenner & Warren et. al, Prevalence and Characteristics of Autism Spectrum disorder Among Children Aged 8 Years – Autism and Developmental Disabilities Monitoring Network, 11 Sites, United States, 2020, 72 Surveillance Summaries 1-14 (2023) *available at* **https://www.cdc.gov/mmwr/volumes/72/ss/ss7202a1.htm?s_cid=ss7202a1_w**

2 Erika Fry, Private Equity is the Biggest Player in the Autism Therapy Industry. Some Therapists Say the 'money grab' is Hurting the Quality of Care. (July 29, 2022) *available at* **https://fortune.com/2022/07/29/autism-therapy-care-centers-private-equity-hopebridge/**

3 Linton Ritchie, Jr. Autism Centers Say They Are In A Staffing Crisis. (September 2, 2022) *available at* **https://www.mprnews.org/story/2022/09/02/autism-centers-say-they-are-in-a-staffing-crisis**

4 American Medical Association, Current Procedural Terminology (2023) (describing adaptive behavioral services).

5 Laura Lovett, Large Autism Provider CARD Shuts Down Operations in 10 States, Behavioral Health Business (Nov. 11, 2022) *available at* **https://bhbusiness.com/2022/11/11/large-autism-provider-card-shuts-down-operations-in-10-states/**

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and neurodivergent children received an additional $40 million investment led by CVS Health Ventures in October 2023, which is intended to fund increases in Cortica's office count and additional technology development.[6]

Potentially Changing Tides in 2024

Moving forward into 2024 we see several trends developing which may influence the industry and dealmaking within the industry more broadly. These include the following:

- *Diversity in Business Models and Services Lines*. The autism therapy industry continues to have a diverse array of treatment models, which vary based on setting, clinical philosophy, needs of the child, geography and funding sources. One factor in investment decisions and business strategies will be how the clinical philosophy of a particular provider aligns with a potential target. While some market participants pursue multidisciplinary models, which include speech language pathology, occupational therapy, and other ancillary services (even including dentistry), others focus on an ABA only service model. Similar distinctions exist among providers based on the setting of care as ABA services are often provided in school, in centers, in the home or via telehealth. As operators scale and become increasingly skilled at providing care through certain modalities, distinctions will continue to emerge among providers and there will be no standard "blueprint" for delivering autism therapy services. One such example will be in value-based care, and how groups like Cortica will develop strategies to share financial risk and provide holistic treatment to their clients.[7]

- *De Novo versus Acquisitive Growth*. Seller expectations for high valuations driven by the pre-2020 deal boom and higher interest rates have led some groups to give more consideration to de novo versus acquisitive growth. Although strategic transactions may make sense in certain circumstances, some CEOs and executives have publicly commented organic growth should be expected as the norm for their practices moving forward. Notwithstanding, the misalignment present in the market in 2023 among buyers and sellers in terms of what buyers were willing to pay under certain conditions and the expectations of sellers based on past years may be evening out as we move forward in 2024.[8] Better diversified autism providers, sustained demand for services and the large number of autism platform deals which occurred in 2018 and 2019 which may be looking for an exit transaction could lead to some degree of uptick in autism sector transactions further into 2024 and beyond. Despite these market conditions interest rates and increasing government scrutiny will continue to play a large role in shaping dealmaking moving forward.[9]

- *Increasing Regulatory Scrutiny*. The growth of the autism therapy sector, increasing role of institutional investment, and the increasing amount of commercial and government payor funds to autism therapy providers, has led to additional regulatory scrutiny of the sector at both the federal and state level. This includes the issuance of investigatory requests and some enforcement actions with public settlements. In 2023, two public settlements were reached with autism therapy providers in Indiana and Massachusetts. First, the U.S. Attorney's Office for the Southern District of Indiana reached a $2,000,000 civil settlement relating to the TRICARE program with Applied Behavior Center for Autism, which was based on the alleged submission of upcoded claims and billing for furnishing multiple services concurrently

6 Chris Larsen, CVS Ventures Leads $40M Series D Extension for All-in-One Autism Therapy Provider Cortica, Behavioral Health Business (October 3, 2023) *available at* **https://bhbusiness.com/2023/10/03/cvs-health-venture-leads-40m-series-d-extension-for-all-in-one-autism-therapy-provider-cortica/**

7 Morgan Gonzales, 'It's A Question of Diversification': ABA Providers May Need to Become More Risk-Averse, Behavioral Health Business (October 11, 2023) *available at* **https://bhbusiness.com/2023/10/11/its-a-question-of-diversification-aba-providers-may-need-to-become-more-risk-averse/?euid=cc6a82f91c&utm_source=bhb-newsletter&utm_medium=email&utm_campaign=9bbf6268ac&mc_cid=9bbf6268ac&mc_eid=cc6a82f91**

8 Chris Larsen, 'It's Not A Disaster': Autism Investment Space Remains Compelling Through Headwinds (April 20, 2023) *available at* **https://bhbusiness.com/2023/04/20/its-not-a-disaster-autism-investment-space-remains-compelling-through-headwinds/**; Morgan Gonzales, Biden Initiatives Dampen Behavioral Health Deals, But ABA Therapy Remains a Hot Target, Behavioral Health Business (February 13, 2024) *available at* **https://bhbusiness.com/2024/02/13/biden-initiatives-dampen-behavioral-health-deals-but-aba-therapy-remains-hot-target/**; Pitchbook Health Care Services Report (February 8, 2024) *available at* **https://pitchbook.com/news/reports/q4-2023-healthcare-services-report**

9 *Id.*

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to the same client.[10] Similarly, the Massachusetts Attorney General settled with two autism therapy providers relating to allegations of making false claims to MassHealth managed care entities.[11] For the reasons stated above we expect that this type of scrutiny and these kinds of enforcement actions will become more common in 2024 and beyond. However, as this area continues to become a larger and more mature sector, autism therapy industry participants can both improve their operations and reduce risk of liability by taking proactive steps and investing in robust compliance plans, policies and protocols, implementing those plans, and engaging in continued monitoring of their revenue cycle management processes, among other things.

Conclusion

The autism therapy provider sector has faced some challenges in more recent years but may be in the midst of a transitional phase now. If that transitional phase is successful it could combine with potentially better economic conditions on the horizon, better aligned perspectives and expectations among potential sellers and buyers/investors and some pent-up appetite for sale of autism platform investments to provide a more favorable deal making environment. The need for greater access to quality autism provider services is clear and is not projected to change in the foreseeable future. Greater investment into this sector going forward, through merger and acquisition activity or otherwise would likely help increase patient access and benefit the larger community.

10 United States Attorney's Office for the Southern District of Indiana, U.S. Attorney's Office Recovers $2 Million from Autism Therapy Provider for Alleged False Healthcare Claims in District's Largest TRICARE Settlement (February 10, 2023) *available at* **https://www.justice.gov/usao-sdin/pr/us-attorneys-office-recovers-2-million-autism-therapy-provider-alleged-false**

11 Massachusetts Office of the Attorney General, AG Campbell Announces More than $2.5 Million in Fraud Settlements with Two Autism Services Providers (October 17, 2023), *available at* **https://www.mass.gov/news/ag-campbell-announces-more-than-25-million-in-fraud-settlements-with-two-autism-services-providers**

ABOUT POLSINELLI'S BEHAVIORAL HEALTH LAW GROUP

Behavioral health providers have unique regulatory, clinical and business issues that require both federal and state legal experience and real-world knowledge of the behavioral health industry and health care law generally. Polsinelli's Behavioral Health Law Group, one of the largest in the country, is devoted to representing investors and operators in the behavioral health space including:

- Private equity and venture capital funds
- Acute care psychiatric hospitals and units
- Substance abuse and eating disorder treatment providers
- Residential, outpatient and adolescent treatment facilities
- Community mental health centers
- Digital and telehealth treatment providers
- Autism treatment providers

Polsinelli's experienced behavioral health law group includes lawyers with deep experience representing leading behavioral health providers in all facets of their legal affairs. Our extensive industry experience spans corporate and M&A, regulatory, privacy, payer relations, real estate and other legal disciplines that allow us to fully partner with investors and providers to help them effectively achieve their business goals.

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

Many companies of all different types, including behavioral health care providers, may not be aware of the substantial HIPAA and state-law data privacy and security-related legal risk associated with deploying third-party tools of all types to their websites. These tools include tools for social media, analytics, translation, mapping, chat, video replay, and other website functionality and send data to third-party vendors; such data includes information considered to be PHI under HIPAA and PII under state laws. These disclosures of PHI and PII are likely not considered to be permissible under HIPAA and applicable privacy laws, and there has been and continues to be significant activity from State AGs, HHS, the FTC, and plaintiffs' attorneys on these issues. Investigations related to privacy compliance where third-party tools are used are increasing, as are related multi-million dollar demands.

Links to the articles below contain more details. For more information and for assistance, please contact one of the members of our national Behavioral Health Law Group or your main Polsinelli lawyer contact.

HHS-OCR Guidance for Online Tracking Technologies

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EDITORIAL BOARD

Paul A. Gomez
Co-Chair, Behavioral Health Law Group
pgomez@polsinelli.com
310.556.6762

Nathaniel 'Tani' Weiner
Co-Chair, Behavioral Health Law Group
nweiner@polsinelli.com
415.248.2115

Ryan J. Mize
Attorney
rmize@polsinelli.com
816-572-4441

Bragg E. Hemme
Co-Chair, Behavioral Health Law Group
bhemme@polsinelli.com
303-583-8232

Jean Marie R. Pechette
Shareholder
jpechette@polsinelli.com
312-873-3690

Neal D. Shah
Shareholder
nshah@polsinelli.com
312-463-6233

Joelle M. Wilson
Shareholder
jmwilson@polsinelli.com
312.463.6219

Cat Kozlowski
Counsel
ckozlowski@polsinelli.com
310-203-5398

Matthew T. Lin
Associate
mlin@polsinelli.com
310.203.5312

Kathleen Snow Sutton
Shareholder
ksnowsutton@polsinelli.com
303-583-8275

Lori A. Oliver
Shareholder
loliver@polsinelli.com
206-393-5440

Jasmine C. González
Counsel
jgonzalez@polsinelli.com
720.931.1173

Michael T. Flood
Shareholder
mflood@polsinelli.com
314-552-6843