Top Issues in Behavioral Health for 2023

ANNUAL NEWSLETTER FROM THE BEHAVIORAL HEALTH LAW GROUP

Investment in Behavioral Health Will Remain Strong in 2023

Paul A. Gomez
Shareholder | Chair,
Behavioral Health
Law Group
Los Angeles

Investment and M&A activity in behavioral health has been growing for years. The sector saw its most active year in terms of deal volume in 2021. Although 2022 did not quite hit the heights of 2021, it remained by any measure a very strong year for investment in behavioral health. Economic headwinds may contribute to some further decrease in M&A activity as we move through 2023, but the same factors and tailwinds that have driven investment in behavioral health in past years (and the last few years in particular) are still expected to result in 2023 being another strong year for investment in behavioral health. A brief summary of those factors follows below.

Factors Continuing to Drive Investment in Behavioral Health

Growing Demand. Unfortunately, the U.S. experienced significant levels of substance use disorder (SUD) and mental health conditions for years before the pandemic. COVID-19 and responses to same, while aiming to help contain and limit the terrible effects of that virus, also undoubtedly resulted in other health and mental health-related damage on many levels. Substance use disorder, suicides and mental health conditions have grown substantially from already serious pre-pandemic levels. People of all ages and backgrounds have been impacted by this, but children may have been the most severely impacted, and long-term effects are probably not yet fully understood. The demand and need for greater access to mental health services in particular is so great that it triggered a U.S. Surgeon General Advisory in late 2021 and a declaration of a national emergency in child and adolescent mental health by pediatric health experts.

Decrease in Stigma. Although more work needs to be done, progress has been made to decrease the stigma that has historically be associated with SUD and mental health conditions. Both research data and anecdotal evidence reveal that more people feel more comfortable talking with others about mental illness (including their own), and fewer people report that they would be or are reluctant to pursue help and treatment for behavioral health needs than has historically been the case.[1] However, data also shows that most people with mental health conditions do not seek or receive treatment, which tends to indicate that there must be a push to further remove this barrier to care, but that does negate the importance of the progress that has been made on this front.

Access Through Telebehavioral Health. As discussed in more detail within this Newsletter (below), the convergence of technology, growing patient demand, greater regulatory flexibility and greater availability of payment for behavioral health care continue to converge to support telehealth as a driver of greater access to behavioral health services. As also discussed further below, telebehavioral health seems to have particular appeal, remaining an important and steady means of accessing care when compared with declining use of telehealth in many other sectors of healthcare. Legislative developments also continue to buoy the use and expansion of telehealth as a critical component of rendering behavioral healthcare, including (not exhaustive) extended flexibilities in providing such care, removal of geographic restrictions, loosening of certain healthcare supervision requirements and extension of greater flexibility for prescribing controlled

[1] *See infra "Despite Additional Funding, Staffing Shortages Will Continue to Reduce Access to Behavioral Health"* (documenting that over half of the U.S. population with mental illness do not receive treatment.).

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substances in connection medication assisted treatment (MAT).[2]

Greater Recognition of Importance of Integrating Behavioral Health and Physical Health. As discussed in more detail within this Newsletter (below), leveraging partnerships to further integrate behavioral health services into primary care and other levels of health care while also collecting and analyzing data on a greater and more integrated scale may better enable providers to improve health care outcomes, increase patient satisfaction, improve quality and control costs. With the continued rise of interest and investment in value-based care models, both in traditional physical health and behavioral health,[3] behavioral health care providers with sound fundamentals that could further benefit from significant additional resources, a disciplined organizational structure and experience in analyzing data and reporting metric-related success may be particularly attractive to private equity, strategic buyers and health system partners.

Fragmented Market and Insufficient Resources. Like many other health care sectors, the behavioral health market is still relatively fragmented and often rendered by small providers that have no national presence and are not part of a larger continuum of care. Great potential remains for private equity-backed companies and other investors and stakeholders to engage in further acquisitions to drive significant economies of scale, greater standardization of both clinical and administrative practices and better, more accessible and more efficient care as an additional means to try to address chronic staffing shortages.

For more detail regarding the foregoing factors that will continue to drive investment in behavioral health, please refer to our Top Issues in Behavioral Health for 2022 Newsletter.

New Developments Driving Investment in Behavioral Health

Bipartisan Legislative Tailwinds. As discussed in more detail further below in this Newsletter, despite our current highly partisan political climate, the level of bipartisan interest and achievement with respect to behavioral health needs and investment in 2022 was noteworthy. Passage of the Bipartisan Safer Communities Act in mid-2022 and the Fiscal Year (FY) 2023 Omnibus Spending Bill at the end of 2022, are prime, though not exhaustive examples of this.

The FY 2023 Omnibus Spending Bill contained several important provisions for behavioral health providers and investors. These included coverage of marriage and family therapists and counselors, improved payment for mental health mobile crisis units, coverage of intensive outpatient mental health care and a two-year extension of certain pandemic telehealth flexibilities. Dozens of mental health and SUD programs that were set to expire were reauthorized, and improved provider prescribing flexibilities regarding medication assisted treatment (MAT) were extended. The foregoing examples and combination of increased flexibility and greater availability of payment should not only enhance access to care for patients but incentivize private equity firms and other stakeholders who are looking to invest in resilient and impactful services and sectors.

Moreover, notwithstanding that we now have divided government with Democrats controlling the White House and the Senate and Republicans controlling the House of Representatives, it is expected that there will be continued opportunity for bipartisan achievement going forward as legislators look to build upon recent behavioral health legislative wins.[4]

[2] *See infra "Telehealth Will Continue to Improve Access to Behavioral Health Services"* (noting these significant legislative and regulatory developments taking place within the past year that continue to drive greater access to behavioral health services).
[3] *See infra "Making the Jump: 3 Steps to Value-Based Care"* (discussing interest in value-based care models and considerations for implementation of same in more detail).
[4] *See infra,* "New Congress, New Realities and New Opportunities: Welcome to the Federal Behavioral Health Landscape for the New Year" (explaining some of the key areas of potential bipartisan achievement, building on certain recent legislative and regulatory accomplishments).

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Specter of Recession and Resiliency of Behavioral Health. Notwithstanding the tremendous amounts of "dry powder" that many private equity firms continue to have to deploy, concern is growing among investors about a potential recession in 2023 and related economic circumstances. These include continued inflation, rising interest rates, tighter debt markets and geopolitical turmoil.[5] Many investors, advisors and commentators believe these factors are likely to contribute to a shift of more investment dollars toward middle market deals, away from big platform deals (in part because values will not be maximized in the current market) and toward more add-on deals.[6] Given that healthcare and behavioral healthcare specifically are often middle-market opportunities with plentiful add-on prospects, and that they have generally proven to be among the more resilient sectors, this should bode well for continued substantial investment and M&A activity in behavioral health throughout 2023.[7]

Mental Health, SUD and Joint Ventures Among the Most Active Segments of Behavioral Health

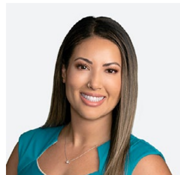
Mental health and SUD treatment deals are expected to remain among the most active components of the behavioral health sector. That was true of 2022 and many of the same factors driving that investment activity and growth remain in place today. Add to that the potential relative shift of additional investment dollars toward middle market, resilient sectors that offer long-term value propositions as noted above, greater flexibilities in provision of treatment via telehealth and certain prescriptions practices, reimbursement for services and continued potential for bipartisan legislative support for behavioral health, there is ample reason to believe that these will be among the most active components of behavioral health activity in 2023.[8] Joint ventures should also continue to grow among behavioral health providers and health systems, largely for the same reasons noted in our article about behavioral health joint ventures in our Top Issues in Behavioral Health for 2022 Newsletter. The economic headwinds noted above that are contributing to a move away from larger market and platform deals may also help drive greater interest in joint ventures as a means to further leverage the relative strengths of potential partners and share some degree of risk in making behavioral health investments and endeavoring to increase access to and quality of care.

In sum, although not likely to hit the heights of 2021, a combination of the health needs of the U.S. population, increased consensus about the need for better integration of behavioral health and physical health, economic factors, significant "dry powder" to deploy and legislative/regulatory tailwinds should support substantial, continued investment and activity in behavioral health throughout 2023.

[5] *See https://www.pwc.com/us/en/industries/financial-services/library/private-equity-deals-outlook.html* (noting several factors that are likely to contribute to shifts in investment strategy and flow of investment capital); *see also https://www.blackrock.com/institutions/en-us/literature/investor-guide/2023-private-markets-outlook.pdf* (discussing factors contributing to market instability and potential resulting further shifts in investment to resilient sectors with long-term value potential).
[6] *See id. See also* https://www.bdo.com/insights/industries/private-equity/bdo-s-7-private-equity-predictions-for-2023 (noting that merger and acquisition activity will remain substantial, but emphasis and relative volume will shift toward middle market deals and sectors that are generally resilient even in tougher economic climates and that show potential for building long-term value).
[7] *See id.*
[8] *See supra* FN 2-3 (describing legislative tailwinds and telehealth flexibilities that should help continue to drive M&A activity in mental health and SUD); *see also "2023 Behavioral Health M&A Outlook" Webinar,* BEHAVIORAL HEALTH BUSINESS (providing support through panel discussion of experts that outpatient mental health and SUD are and will probably continue to be among the most active in terms of behavioral health M&A in 2023).

Telehealth Will Continue to Improve Access to Behavioral Health Services

Joelle M. Wilson
Shareholder
Chicago



Jasmine C. González
Counsel
Denver | Seattle

Telehealth has played a particularly significant role in meeting the need for behavioral health services, especially over the past few years as a result of waivers and flexibilities introduced to combat the impacts of the COVID-19 Public Health Emergency ("PHE"). A recent report by the Kaiser Family Foundation found that during the height of the pandemic (March - August 2020) telehealth visits represented 40% of mental health and substance use outpatient visits, compared with only 11% of other visit types. Now that in-person care has resumed, non-mental health and substance use claims have dropped to around 5% of outpatient visits, however, telehealth use for mental health and substance abuse treatment has remained strong, representing 36% of these outpatient visits.[1] While, in general, telehealth visits seem to be leveling off as we move away from the PHE, which is slated to end on May 11, 2023, behavioral healthcare seems to be one prominent exception. One recent study, looking at data from January 2020 to March 2022, found that mental health conditions were the most common telehealth diagnoses at a national level.[2]

Stakeholders continue to find that the use of telehealth behavioral health is valuable, and broader adoption of such services is likely in the coming years. Much of this change can be attributed to federal legislative and administrative changes aimed at increasing access to mental health and behavioral health care furnished via telehealth. Theses much

[1] Kaiser Family Foundation and Epic Research analysis of Cosmos data, March 2022, available at: https://www.kff.org/coronavirus-covid-19/issue-brief/telehealth-has-played-an-outsized-role-meeting-mental-health-needs-during-the-covid-19-pandemic/
[2] The Evolution of Telehealth during the COVID-19 Pandemic, June 14, 2022, available at: https://s3.amazonaws.com/media2.fairhealth.org/brief/asset/The%20Evolution%20of%20Telehealth%20during%20the%20COVID-19%20Pandemic-A%20FAIR%20Health%20Brief.pdf

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needed changes were accomplished through statutory updates in the SUPPORT Act, the Consolidated Appropriations Act ("CAA") of 2021, as well as administrative changes by the Centers for Medicare and Medicaid Services ("CMS"), as outlined below.

- **SUPPORT Act:** Effective July 1, 2019, the SUPPORT Act statutorily removed the geographic limitations for telehealth services furnished to patients who with a diagnosed substance use disorder ("SUD") or co-occurring mental health disorder, if the telehealth service is used to treat the SUD or co-occurring mental health disorder. The SUPPORT Act also removed telehealth originating site restrictions, which enables patients to receive SUD treatment at any location, including the patient's home.
- **Consolidated Appropriations Act of 2021:** In December 2020, Section 123 of the CAA of 2021 expanded access to mental health services furnished via telehealth beyond substance use disorder treatment. As a result of this legislation, Medicare covers telehealth services furnished for the purposes of diagnosis, evaluation, or treatment of a mental health disorder. The Act removes restrictive telehealth originating site restrictions, which include geographic barriers, enabling patients to receive care from any location, including the patient's home. Importantly, and somewhat surprisingly, the Act also places a condition on the reimbursement of mental health services furnished through telehealth and requires beneficiaries to have at least one in-person (non-telehealth) mental health visit during the six months prior to the telehealth visit, and subsequent in-person visits thereafter.
- **PFS Final Rule 2022:** In November 2021, CMS implemented provisions of the CAA 2021 in the 2022 Physician Fee Schedule ("PFS") Final Rule which include the removal of telehealth geographic limitations and authorizing the patient's home as a permissible originating site for telehealth services furnished to Medicare beneficiaries with a substance use or mental health disorder. As required by the CAA, an initial in-person visit must take place within the 6 months prior to the telehealth visit, and every 12 months thereafter. However, and importantly, CMS clarified in the 2023 PFS Final Rule that the initial 6 month in-person visit does not apply to beneficiaries who began receiving mental health telehealth services in their homes during the PHE. If a beneficiary began receiving mental health telehealth services during the PHE or the 151-day extension period (CMS has yet to release guidance as to whether this guidance will apply to services furnished during the December 31, 2024 extension period) , the prior 6 month in-person visit requirement will not apply because the individual will be considered an established patient. These services will however continue to be subject to the requirement that at least one in-person visit be furnished every 12 months. As a result of the CAA 2023, the behavioral/mental telehealth visit in-person requirement, along with several other telehealth flexibilities, is waived through December 31, 2024.

  The 2022 PFS Final Rule also revised the regulatory language for mental health visits furnished in Rural Health Clinics (RHCs) and Federally Qualified Health Clinics (FQHCs). This change enables RHCs and FQHCs to provide mental health visits using telecommunication audio-video technology or audio-only technology when the patient can't access video or doesn't consent to the use of audio-video technology. CMS clarified that telecommunication services are different from telehealth services and allow FQHCs to report and receive payment for mental health visits in the same way they currently do when visits take place in-person. The rule requires that an in-person mental health service be furnished within 6 months prior to the furnishing of the telecommunications service and every 12 months thereafter (subject to certain exceptions based on patient circumstance).
- **PFS Final Rule 2023:** In November 2022, CMS amended "incident to" direct supervision requirements to allow behavioral health services to be furnished under the general supervision of a physician or non-physician practitioner. CMS notes that individual practitioners are in the best position to determine whether particular treatments or diagnostic services are behavioral health services. However, generally, behavioral health services include services furnished for the diagnosis, evaluation, or treatment of a mental health disorder, including substance use disorders (e.g., psychotherapy, Screening, Brief Intervention and Referral to Treatment (SBIRT) services, and psychiatric diagnostic evaluations, among others). Auxiliary personnel providing incident to services under general supervision are required to meet all of the applicable requirements to provide such services, including any applicable licensure requirements imposed by the State in which the services are being furnished. In practical terms, this new rule would no longer require supervising clinicians to be on-site for certain behavioral health services to be billable to Medicare. Thus, allowing beneficiaries needing behavioral services such as counseling or cognitive behavioral therapy easier access to more providers in various settings. While the increase in access to behavioral health services will allow for additional resources for behavioral health teams, there will be an increased need for care coordination among providers. Behavioral health facilities may have to evaluate their current systems to ensure providers are able to coordinate appropriately.

In addition to the aforementioned federal changes, private payers and state Medicaid programs continue to expand coverage for mental health and substance use services furnished through telehealth. Equally as important are the legislative efforts pertaining to the prescribing of controlled substances via telehealth. The Drug Enforcement Administration ("DEA") recently released a long-anticipated proposed rule that seeks to permanently extend controlled substance

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prescribing flexibilities beyond the PHE. Prior to the PHE, controlled substance prescribing via telemedicine was extremely restrictive as a result of the Ryan Haight Online Consume Privacy Act of 2008, which amended the Controlled Substances Act to prohibit the prescribing of controlled substances without a prior in-person medical evaluation. As a result of the PHE, the DEA suspended the in-person requirement, allowing practitioners to issue prescriptions for Schedule II-V controlled substances via telemedicine, as long as certain prerequisites are met.

The proposed rule does not make permanent the flexibilities instituted as a result of the PHE; however, it offers certain limited options in which practitioners can prescribe controlled substances via telemedicine without an in-person medical evaluation. If approved, the proposed rule will allow practitioners to prescribe a 30-day supply of non-narcotic Schedule III-V controlled substances via telemedicine without an in-person medical evaluation. The proposed rule also creates a “qualifying telemedicine referral,” which allows a prescribing practitioner that receives the referral to prescribe any controlled substance, including Schedule II controlled substances, without have conducted an in-person medical evaluation of the patient, as long as the referral is from a DEA-registered practitioner who has conducted a medical evaluation of the patient. The DEA also released a separate Notice of Proposed Rulemaking titled, ‘The Expansion of Induction of Buprenorphine via Telemedicine Encounter.’ This rule proposes to allow prescribing of certain narcotic-controlled substances, such as buprenorphine via telemedicine for the treatment of opioid use disorder. See Polsinelli’s full summary of the DEA’s proposed rule here.

Access to health care plays a tremendous role in an individual’s overall health, and importantly their mental health. As the PHE has taught us, telehealth has the unique ability to connect patients with care providers that they otherwise do not have access to, due to geography, technology limitations, and innumerable other reasons. While further efforts are needed to combat the ever present and increasing mental and behavioral health crisis, the changes that have taken place are a step in the right direction.

New Congress, New Realities, and New Opportunities: Welcome to the Federal Behavioral Health Landscape for the New Year

Sylvia Kornegay
Policy Advisor
Washington, D.C.

Tim Perrin
Policy Advisor
Washington, D.C.

As the books closed on 2022 and revelers finalized their midnight plans, Congress and President Biden pulled one last gift from behind the tree and enacted a final Fiscal Year (FY) 2023 omnibus spending bill that featured several wins for mental and behavioral health stakeholders. These included Medicare provisions such as coverage of marriage and family therapists and counselors, improved payment for mental health mobile crisis units, coverage of intensive outpatient mental health care, and a two-year extension of pandemic telehealth flexibilities. The legislation also reauthorized over 30 mental health grant programs under the Substance Abuse and Mental Health Services Administration (SAMHSA) and Health Resources and Services Administration (HRSA) that were slated to expire and improved provider prescribing flexibilities regarding medication assisted treatment (MAT).

Passage of the FY 2023 funding bill in December and the Bipartisan Safer Communities Act in June – landmark legislation enacted immediately following the Uvalde, TX school shooting tragedy – marked decisive action by federal policymakers on behavioral health despite a particularly heightened partisan climate. The next two years in Washington promise to be just as consequential for these policies and the patients, providers, and communities impacted by them, regardless of this new era of divided government.

COVID-19 Public Health Emergency “Unwinding” and its Impact on Behavioral Health

In late January, the Biden Administration formally announced that both the COVID-19 national emergency and public health emergency (PHE) will expire on May 11. The Administration expressed that a sudden, disorderly end to these declarations would have serious consequences for our healthcare system and noted particularly that a loss of telehealth access would “most acutely impac[t]…individuals with behavioral health needs and rural patients.”[1] There are

[1] White House Statement of Administration Policy (January 30, 2023), available at <https://www.whitehouse.gov/wp-content/uploads/2023/01/SAP-H.R.-382-H.J.-Res.-7.pdf>.

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several dimensions of behavioral healthcare that stand to be affected by the COVID-19 PHE unwinding.

Virtual prescribing of Opioid Use Disorder (OUD) and mental health drugs. The PHE granted practitioners the flexibility to prescribe controlled substances, such as buprenorphine, via telehealth without first requiring an in-person evaluation. Referred to as the Ryan Haight Act waiver, this measure was not extended through 2024 alongside Medicare telehealth flexibilities in the FY 2023 omnibus. The Drug Enforcement Administration (DEA) additionally broadened the universe of patients eligible to receive prescriptions via telemedicine during the PHE to include those who are not being treated at DEA-registered hospitals or clinics. Absent executive action, these restrictions would snap back into place for patients requiring treatment of substance use disorder (SUD), mental health, and other conditions that necessitate prescribed drug interventions.

DEA recently signaled two forthcoming Notices of Proposed Rulemaking (NPRMs) that seemingly would avert this regulatory cliff: one addressing virtual prescribing and special telemedicine registration requirements in general, and a second specifically focusing on buprenorphine prescribing via telehealth.[2] On February 24, DEA announced two proposed regulations addressing these topics and provided notice of corresponding 30-day public comment periods.[3],[4] These measures would impact the prescribing of controlled substances in instances where a provider and patient previously have not held an in-person evaluation by limiting prescribing to a 30-day supply of Schedule III-V non-narcotic controlled medications/a 30-day supply of buprenorphine for the treatment of opioid use disorder. Additionally, they would provide for continued access to buprenorphine via telehealth and update DEA's definition of the "practice of telemedicine" to be consistent with regulations advanced by the Centers for Medicare and Medicaid Services (CMS).

Telehealth and HIPAA compliance*.* In March 2020, the Office for Civil Rights (OCR) at the Department of Health and Human Services (HHS) issued "Notification of Enforcement Discretion for Telehealth Remote Communications" exempting telehealth providers from penalties for noncompliance with HIPAA Rules, per the good faith provision of telehealth during the COVID-19 PHE. This notification expresses that OCR will exercise enforcement discretion during the PHE in instances of telehealth using non-public facing remote technologies, even if these communications and how they are used may not be fully HIPAA compliant.[5] Though HHS issued subsequent guidance in June 2022 covering the use of audio-only telehealth once the PHE expires[6], this document pertains to only one type of telehealth communications utilized by behavioral health patients and providers and is silent on others.

Medicaid beneficiaries. Congress enacted a measure as part of the FY 2023 omnibus to sunset the PHE's Medicaid continuous coverage requirement on March 31, 2023. States will have at least 12 months to initiate Medicaid eligibility redeterminations and may terminate enrollments as early as April 1. While this legislative action effectively delinked pandemic-era Medicaid coverage from the formal PHE declaration, the Centers for Medicare & Medicaid Services (CMS) announced its own "unwinding" mechanism to accommodate affected beneficiaries and smooth transitions off Medicaid rolls. CMS will create an Unwinding Special Enrollment Period (SEP) during which individuals who lose their Medicaid coverage after March 31 will be permitted to enroll in a marketplace plan on HealthCare.gov outside of the annual sign-up period.[7] The success of these disruption mitigation efforts, such as their ability to reach impacted individuals or update missing or incomplete contact information, directly will determine whether Medicaid beneficiaries experience a lapse in behavioral health access or coverage.

Legislative Opportunities for Behavioral Health Policy Amidst Divided Government

Ending and unwinding the COVID-19 PHE and implementing the numerous behavioral healthcare provisions included in the FY 2023 omnibus appropriations bill will dominate the Administration's executive actions in this space over the next several months. While some may worry that Republicans and Democrats will not collaborate or cooperate with one another in the new divided Congress, or that lawmakers will ignore new behavioral health proposals because of the large package of MH/SUD policies Congress passed in December, fear not! There will be opportunities this year for federal lawmakers to move several behavioral healthcare policy solutions, no matter what the media says.

Despite headlines decrying the inability of Congress to work together, behavioral healthcare is among the few issues on Capitol Hill that boast support from lawmakers in both parties. In fact, both the Bipartisan Safer Communities Act passed by Congress last summer, and many of the provisions included in the FY 2023 omnibus appropriations bill (as passed by the House in June 2022), enjoyed broad bipartisan support. As a result, it should not be surprising that Members of Congress want to build on this momentum this year by advancing policy proposals

[2] *See supra, "Telehealth Will Continue to Improve Access to Behavioral Health Services"* (discussing similar developments in further detail).
[3] 88 FR 12890 (March 1, 2023), available at <https://www.federalregister.gov/documents/2023/03/01/2023-04217/expansion-of-induction-of-buprenorphine-via-telemedicine-encounter>.
[4] 88 FR 12875 (March 1, 2023), available at <https://www.federalregister.gov/documents/2023/03/01/2023-04248/telemedicine-prescribing-of-controlled-substances-when-the-practitioner-and-the-patient-have-not-had>.
[5] 85 FR 22024-25 (April 21, 2020), available at <https://www.govinfo.gov/content/pkg/FR-2020-04-21/pdf/2020-08416.pdf>.
[6] "Guidance on How the HIPAA Rules Permit Covered Health Care Providers and Health Plans to Use Remote Communication Technologies for Audio-Only Telehealth (Last reviewed June 13, 2022), available at <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-audio-telehealth/index.html>.
[7] "Temporary Special Enrollment Period (SEP) for Consumers Losing Medicaid or the Children's Health Insurance Program (CHIP) Coverage Due to Unwinding of the Medicaid Continuous Enrollment Condition – Frequently Asked Questions (FAQ) (January 27, 2023), available at <https://www.cms.gov/technical-assistance-resources/temp-sep-unwinding-faq.pdf>.

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that fight the national opioid epidemic and increase access to behavioral healthcare services, among other priorities.

Reducing illicit fentanyl abuse. Opioid deaths impact every state and Congressional district in the nation and the destruction has reached record levels. Each Senator and House Member wants to stop the opioid epidemic, especially the use of illicit fentanyl. Even before the House of Representatives' Energy & Commerce Committee had officially named its members for the 118th Congress, the panel convened two roundtable discussions to address the illegal trafficking of fentanyl across the southern border and the role big tech plays in facilitating the trade and abuse of illicit fentanyl. These roundtables signal that stopping fentanyl abuse is a top issue and portend official action from the committee this year. In fact, the committee held formal hearings on the fentanyl issue in mid-February and is expected to consider legislative solutions this year. Public health concerns are a top priority for Energy & Commerce Committee Chair Cathy McMorris Rodgers (R-WA) and reducing fentanyl abuse is a tailormade issue ripe for bipartisan collaboration. In his recent State of the Union address, President Biden called on Democrats and Republicans to work together to "launch a major surge to stop fentanyl production, sale, and trafficking, with more drug detection machines to inspect cargo and stop pills and powder at the border." Look for bipartisan collaboration on this issue this year.

Increasing access through telehealth. Telehealth proved effective at increasing patient access to services during the pandemic and Congress recognized this fact. By loosening limitations on telehealth during the pandemic and extending those flexibilities in Medicare in the FY 2023 omnibus bill, Congress has significantly elevated the successes of telehealth. The MH/SUD stakeholder community applauds these moves and is now calling on Congress to make those flexibilities permanent. Lawmakers are also eager to capitalize on these successes within Medicaid so patients can reap the benefits of easier access to MH/SUD providers. These lawmakers are considering ways to support state Medicaid programs as they consider program enhancements. With questions remaining about the quality of behavioral healthcare delivered via telehealth during the pandemic, expect the consideration of programmatic guardrails to be debated alongside moves to expand telehealth services and providers.[8]

Building on the omnibus. After the FY 2023 omnibus package was enacted, many behavioral healthcare stakeholders acknowledged that the size and scope of the MH/SUD provisions that Congress passed in December was historical in nature. Yet while the omnibus package did so much, stakeholders are urging lawmakers to go further by building on the workforce, mental health parity, suicide prevention, and coordinated care provisions included in the omnibus. Stakeholders rightly note the great and unmet demand for MH/SUD services and are highlighting the need to further expand the number of educated and trained providers to treat patients, give states and the federal Department of Labor more tools to enforce the requirements of the mental health parity law, create a sustainable funding source for the 988 suicide prevention hotline and associated wrap-around services, and promote more ways for behavioral healthcare services to be integrated within primary health.

Despite the many MH/SUD policy victories in 2022, several of which we predicted in last year's edition of this Newsletter, significant portions of the work done last Congress by the Senate Finance Committee and the Senate Health, Education, Labor and Pensions (HELP) Committee were not enacted into law. Both Senate panels spent a great deal of time and effort researching and producing policy papers, issue briefs, and legislative proposals. Committee leaders, working in a bipartisan fashion, say they will continue working on MH/SUD issues in this new Congress. In fact, HELP Committee Chair Bernie Sanders (I-VT), in announcing his agenda for the year, noted that unresolved issues from last Congress, including bipartisan mental health parity legislation championed by Sens. Chris Murphy (D-CT) and Bill Cassidy (R-LA), will be a priority.

Divided government means there will be heated debates that make for eye-catching headlines. But it also means that Democrats and Republicans will have to work together to move their respective agendas. These collaborations are the conversations to watch. This year Congress will have to reauthorize several major federal programs. These legislative vehicles, combined with a Constitutional requirement to fund the federal government through the appropriations process, set up a number of opportunities for bipartisan behavioral healthcare priorities to be attached and enacted.

[8] *See supra* FN 2, above (discussing similar developments in further detail).

Making the Jump: 3 Steps to Value-Based Care

Lori A. Oliver
Shareholder
Seattle

Kathleen Snow Sutton
Associate
Denver

Behavioral health has enjoyed a renaissance of interest and investment from the broader health care industry, creating opportunities to integrate behavioral and physical healthcare and to progress toward value-based care.

Behavioral health providers face unique challenges to integration and value-based care, such as the lack of consensus on meaningful quality and outcome metrics; limitations on the ability to bill for services by certain providers; and interoperability and sharing of data. Nevertheless, recent federal policy initiatives support a broader adoption of value-based care. For example, the most recent Medicare physician fee schedule adopted an exception to the "incident to" rules to provide for general (rather than direct) supervision of licensed professional counselors and licensed marriage and family therapists; authorized reimbursement for clinical psychologists and licensed social workers as part of a primary care team; and approved access from mobile units and the use of telecommunications technology in connection with certain opioid use disorder treatments.[1] Further, as described in Alignment of 42 CFR Part 2 with HIPAA Impact on Behavioral Health, proposals to align data privacy protections would streamline providers' ability to use and share clinical data. There is also ongoing work to develop consensus on meaningful behavioral health quality and outcome measures that will drive efficiency and incentives for population health and value-based care.[2]

These changes position behavioral health providers to engage in strategies to capitalize on the momentum and to stay ahead of the curve as the industry evolves to embrace value-based behavioral healthcare:

- Step 1: Continue to prepare the infrastructure necessary to succeed;
- Step 2: Partner with physical health providers who are already engaged in value-based care; and
- Step 3: Negotiate your own value-based contracts.

These strategies can be staged or engaged in individually or collectively.

1. Prepare the Infrastructure

To benefit from opportunities for value-based reimbursement and population health management, providers must ensure that they have an infrastructure in place to track and share information between providers and payors. Specifically, providers must have systems in place to:

- access and integrate claims and practice data,
- report on quality metrics,
- identify care gaps,
- inform intervention strategies,
- support real-time patient engagement,
- manage population health, and
- align clinician compensation to drive objectives.[3]

Providers who already have an established infrastructure to access, use, and report data on patient care and outcomes are prepared to jump as opportunities arise to capitalize on value-based care opportunities and they are prepared to engage with other providers and payors and to clearly communicate the value they bring through measurable, high-quality care. Importantly, preparing to participate in value-based care also supports the management of your existing patient populations for improved outcomes.

2. Partner with Physical Health Providers

Partnering with physical health providers and networks can provide a first step into value-based care for behavioral health providers who are not yet ready to engage with payers directly. Many physical health care providers have already launched value-based care activities and population health management.[4] Effectively managing behavioral health can reduce costs for co-occurring physical health conditions and may reduce continued fragmentation of health care services.[5] While the research on integrated behavioral health in primary care is not new,[6] the industry has only recently begun to adopt measures to harness the remarkable potential of integrating behavioral health care to provide whole person care for their patients' physical and mental health needs.[7] See our 2022 Newsletter article "Value-Based Payments and Behavioral Health Integration Begin to Take Center Stage" for orientation on behavioral health integration generally." In addition, CMS's Behavioral Health Strategy emphasizes ongoing integration of behavioral health into primary care, continued emphasis

[1] 87 Fed. Reg. 69404 (Nov. 18, 2022), https://www.govinfo.gov/content/pkg/FR-2022-11-18/pdf/2022-23873.pdf

[2] *See, e.g.,* Lauren Niles and Serene Olin, Behavioral Health Quality Framework: A Roadmap for Using Measurement to Promote Joint Accountability and Whole-Person Care, THE NATIONAL COMMITTEE FOR QUALITY ASSURANCE (NCQA) (May 2021), https://www.ncqa.org/wp-content/uploads/2021/07/20210701_Behavioral_Health_Quality_Framework_NCQA_White_Paper.pdf.

[3] *See, e.g.,* Integrating Clinical Care through Greater Use of Electronic Health Records for Behavioral Health (Chapter 4), MACPAC (June 2021), https://www.macpac.gov/publication/integrating-clinical-care-through-greater-use-of-electronic-health-records-for-behavioral-health/.

[4] *See* Jennifer Rabiner, History of Value-Based Care, Pearl Health (June 2021), https://pearlhealth.com/blog/healthcare-insights/history-of-value-based-care.

[5] *See* Ken Thorpe, Sanjula Jain & Peter Joski, Prevalence and Spending Associated With Patients Who Have A Behavioral Health Disorder And Other Conditions, Health Affairs (Jan. 2017), https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0875.

[6] *See, e.g.* Behavioral Health Integration Program, UW Medicine: AIMS Center, https://aims.uw.edu/behavioral-health-integration-program-bhip (last visited Feb. 6, 2023).

[7] *See* Susan Foosness, Opening the door: Are behavioral health providers ready for value-based care? (Jul. 25, 2022), https://medcitynews.com/2022/07/opening-the-door-are-behavioral-health-providers-ready-for-value-based-care/

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on parity, and Medicaid reimbursement of inter-professional consultations.[8]

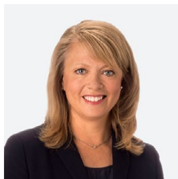
Partnerships between behavioral and physical health providers can benefit both types of providers and pave the way for future opportunities for behavioral health care providers. By addressing behavioral health, physical health providers may be able to achieve incentives available under their value based care or population health management arrangements with payors, particularly in the case of total cost of care models.[9] In addition to value-based incentives and bonuses, the recent addition of a new billing code for behavioral health integration (G0323)[10] suggests that additional reimbursement may be available for behavioral health providers engaging in integration services. For behavioral health providers, partnering with physical health providers may provide a bridge to payors as the industry works to adapt to develop metrics and payment models that work for behavioral health care.

3. **Negotiate Value-Based Care Contracts**

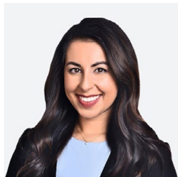
Finally, armed with data from an established infrastructure and experience from partnerships with physical health providers, behavioral health providers can seek to contract directly with payors. Health insurers have signaled increasing interest in providing behavioral health benefits as part of its value based care programs.[11] When entering into value-based arrangements, providers should ensure that the models recognize the ongoing challenges that are unique to behavioral health, are simple to track and execute, and have a significant enough benefit to drive adoption. Models should have sufficient flexibility to leverage activities that are not always independently reimbursed by payers—such as peer counseling or digital health—while also having a significant impact on the overall cost and outcomes of care provided to patients. Behavioral health providers should be prepared to invest for the long term.

[8] *See* CMS Behavioral Health Strategy, CMS.gov, https://www.cms.gov/cms-behavioral-health-strategy.
[9] *See* Ken Thorpe, Sanjula Jain & Peter Joski, *Prevalence and Spending Associated With Patients Who Have A Behavioral Health Disorder And Other Conditions,* Health Affairs (Jan. 2017), https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0875
[10] CY 2023 Medicare Physician Fee Schedule Final Rule (Nov. 18, 2022) 87 Fed. Reg. 69404, 69551.
[11] *See, e.g.,* Michael Rolfsen, *Healthcare providers are now including mental and behavioral healthcare in the patient experience,* Humana, Outcomes-Utilization: Behavioral Health Article, https://www.humana.com/provider/news/value-based-care/value-based-care-report/outcomes-utilization/outcomes-utilization-behavioral-health (last visited Feb. 6, 2023); Jakob Emerson, *UnitedHealth to integrate behavioral health, home health into growing number of value-based care models,* Becker's Payer Issues (Jan. 17, 2023), https://www.beckerspayer.com/payer/unitedhealth-to-integrate-behavioral-home-health-into-growing-number-of-value-based-care-models.html; *Better health at lower costs: Why we need Value-Based Care now,* Aetna, https://www.aetna.com/employers-organizations/resources/value-based-care.html (last visited Feb. 6, 2023).

Medicaid Enrollment Overtakes Medicare – But Challenges are Around the Corner for Behavioral Health Providers Continuous Enrollment Ends April 1, 2023



Jennifer L. Evans
Office Managing Partner
Denver



Sidra S. Galvin
Associate
Los Angeles

Behavioral health providers who serve Medicaid beneficiaries will face four significant issues over the next several years as Medicaid policy implemented in response to the COVID-19 Public Health Emergency ("PHE") winds down in 2023: elimination of Medicaid coverage for millions of beneficiaries, coordination of benefits risk, increased regulatory scrutiny and financial risk for Medicaid providers resulting from new financial pressures on States to fund Medicaid, and potential changes to Medicaid flexibilities for telehealth services. These changes are especially salient for behavioral health stakeholders that expanded operations to include Medicaid as a line of business just as demand for behavioral health and substance use disorder services surged during the pandemic.

Recent figures from the Centers for Medicare and Medicaid Services (CMS) show that as of August 2022, the number of individuals enrolled in Medicaid exceeded the number of individuals enrolled in Medicare by more than 25 million leading to an astonishingly unprecedented expansion in Medicaid coverage. In states that expanded Medicaid with the Affordable Care Act, Medicaid is likely to be one of the largest payors in that state.

Medicaid enrollment grew to historic levels from 2020-2022 thanks to the Families First Coronavirus Response Act (the Act). The Act was a response to health and economic needs arising from the PHE and increased federal Medicaid funds to states in exchange for continuous enrollment of all Medicaid beneficiaries. Any individual who was enrolled in Medicaid during or after March of 2020 has enjoyed continuous Medicaid enrollment without redetermination of eligibility and potential loss of Medicaid enrollment. When continuous enrollment ends on April 1, 2023, states will be required to redetermine an

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individual's eligibility for Medicaid for the first time in three years. The Department of Health and Human Services estimates approximately 9.5% of Medicaid enrollees (8.2 million people) will lose eligibility, and another 7.9% (6.8 million people) could lose Medicaid coverage through "administrative churning," describing individuals who are still eligible for Medicaid but will lose coverage due to administrative hurdles, such as difficulty navigating the renewal process. A significant percentage of people losing coverage will have continuing behavioral health care and substance use disorder needs after losing Medicaid: data from 2020 indicate that approximately 39% of Medicaid enrollees were living with a mental health or substance use disorder.[1] Risks for Medicaid providers arising from these changes, as well as advice to manage those risks, are set forth below.

First, continuous enrollment in Medicaid ends for beneficiaries on April 1, 2023. As described above, in response to the COVID-19 PHE, Congress increased the amount of federal funds available to states to fund the Medicaid program as long as the State's Medicaid program maintained continuous enrollment for beneficiaries until the end of the PHE. Congress recently decoupled increased Medicaid funding and continuous eligibility requirements from the end of the PHE. Consequently, while the PHE declaration may be extended, regular redetermination of Medicaid eligibility will soon resume, resulting in the disenrollment of millions of Medicaid beneficiaries who will no longer qualify or who may face enrollment hurdles.

State Medicaid programs must begin eligibility redeterminations in February, March, or April 2023, and can initiate policies for disenrollment as early as February 1, 2023, with eligibility terminations effective as soon as April 1, 2023. Redeterminations and renewals must be completed by May 31, 2024.

In late January 2023, CMS announced a Marketplace Special Enrollment Period (SEP) for qualified individuals and families who lose Medicaid or Children's Health Insurance Program (CHIP) coverage due to the end of the continuous enrollment condition. The SEP will allow affected individuals to enroll in private marketplace coverage outside of the annual open enrollment period between March 31, 2023 and July 31, 2024.[2]

Given the extended compliance time for states, anticipated enrollment churn, and lengthy transition to other coverage, providers must be diligent when verifying Medicaid eligibility. We also recommend review of and possible revisions to assignment of benefits and other patient responsibility documents in case a state retroactively determines that a patient was not eligible for Medicaid, or that Medicaid was not the primary payor at the time services were rendered.

Second, continuous Medicaid enrollment may have resulted in billing mistakes if a Medicaid enrollee obtained new, private health coverage during the PHE but failed to inform a health care provider. Coordination of Benefits rules require Medicaid to be the payor of last resort. We anticipate that State Medicaid Agencies may want to "look back" for claims paid by the Medicaid program when an individual had secured other primary health insurance coverage through an employer or family member during the PHE. Providers should maintain all insurance documentation in case of future audits or overpayment demands.

In addition to careful insurance verification and documentation, Medicaid providers should consider proactively identifying Coordination of Benefits errors. Timely identification of these errors may permit a provider to affirmatively make Medicaid repayments and file a timely claim to a patient's primary insurance. If providers wait until Medicaid demands repayment for services furnished to a patient who acquired primary insurance during the PHE, these repayment demands are likely to be made well past timely filing for the primary coverage and could result in providers going unpaid for those services.

Third, Congress is phasing out additional federal funds to states for Medicaid over 2023, renewing pressure on state budgets that could result in provider reimbursement rate cuts. The additional 6.2% of federal financial participation (FFP) available since 2020 will only remain through March 2023. Additional FFP will fall to 5% through June 2023, 2.5% through September 2023 and an additional 1.5% that will expire at the end of December 2023. State policy makers may feel pressure to cut provider rates. Consider advocacy about negative impacts to Medicaid providers and beneficiaries at risk of reduced access to care if provider rates are cut.

Finally, behavioral health stakeholders should monitor state changes to telehealth flexibilities.[3] The rapid expansion of Medicaid coverage during the PHE brought with it expanded coverage and access to telehealth in state Medicaid programs. For example, nearly all state Medicaid programs permitted audio-only telehealth coverage during the PHE. While most states have plans to adopt more lasting Medicaid telehealth expansions after the PHE ends, some may curtail access, especially to audio-only telehealth. Apart from changes to Medicaid coverage, restrictive telehealth policies would likely have a cascading effect on state law requirements for scope of practice, licensure and supervision requirements. State law restrictions on telehealth combined with the end of continuous Medicaid enrollment may significantly impact Medicaid-based revenue for behavioral health stakeholders that have more recently invested in telehealth services for the Medicaid population. Behavioral health care providers should consult with qualified legal counsel if they have questions or need assistance planning for the end of the PHE and to avoid or defend Medicaid repayment demands.

[1] https://www.kff.org/medicaid/issue-brief/medicaid-what-to-watch-in-2023/
[2] https://www.cms.gov/technical-assistance-resources/temp-sep-unwinding-faq.pdf
[3] *See also, supra "Telehealth Will Continue to Improve Access to Behavioral Health Services"* (noting both challenges and opportunities presented by current and anticipated changes in telehealth-related flexibilities).

HHS and FTC Guidance for Website Tracking Technologies – Tracking Technologies Should be Assessed Now

ILIANA L. PETERS
Shareholder
Washington, D.C.

As individuals are increasingly interacting with behavioral health services providers online, the Department of Health & Human Services ("HHS") Office for Civil Rights ("OCR") has issued new guidance for HIPAA regulated entities to address privacy concerns stemming from the use of tracking technologies. Further, the Federal Trade Commission ("FTC") issued similar guidance, as part of a recent fine of a health care entity, as well.

While the OCR or the FTC guidance do not state specifically what technologies meet the definition of website tracking technology, OCR clarifies that tracking technologies include applications used to gather information about users' interactions with websites, which is then analyzed to create insights about users and their online activities. While the definition is not exhaustive, it specifically includes cookies, web beacons or tracking pixels, session replay scripts and fingerprinting scripts.

OCR further clarifies that HIPAA "[R]egulated entities are not permitted to use tracking technologies in a manner that would result in impermissible disclosure of PHI to tracking technology vendors or any other violations of the HIPAA Rules."[1] The FTC guidance similarly indicates that FTC-regulated entities cannot engage in similar disclosures of information without consent.[2]

The definition of HIPAA protected health information ("PHI") is exceedingly broad and includes information reasonably able to identify the individual, be created or received by a HIPAA Regulated Entity, and relate to the past, present, or future condition, provision of, or payment for healthcare of an individual. Accordingly, information that is sufficiently de-identified per the HIPAA Privacy Rule's requirements or that cannot reasonably be associated with healthcare is arguably outside the scope of the guidance.

Further, the guidance distinguishes between web services that require authentication. In instances where authentication is required, OCR notes that tracking technologies on a user-authenticated webpage will generally have access to PHI, and accordingly, that the use of tracking technologies on user-authenticated pages will likely violate the HIPAA Privacy Rule. By contrast, if unauthenticated web pages do not generate PHI, they may but outside the scope of the guidance, except that OCR states that PHI would be at issue in many unauthenticated websites, including a webpage "that addresses specific symptoms or health conditions…or that permits individuals to search for doctors or schedule appointments."

Finally, the use of the collected data implicates a behavioral health care services provider's relative exposure. For example, besides the recent FTC action, we also continue to see an explosive growth in litigation and investigations by OCR and State Attorneys General arising out of the use of website tracking tools, including session replay, chatbots, and pixel technologies being framed as "wiretapping" by class-action plaintiffs' counsel. In essence, plaintiffs' attorneys and these regulators argue that the use of these technologies to collect PHI, including IP addresses, dates of interaction, and other website identifiers, may be an impermissible disclosure of PHI under the HIPAA Privacy Rule, and a "breach" as defined by the HIPAA Breach Notification Rule and state law.

Accordingly, behavioral health services providers must engage in a detailed analysis of what data is collected by any website tracking tools, whether that data can reasonably be considered "PHI" under HIPAA, and whether the use of this data could be construed as an impermissible use or disclosure under the HIPAA or FTC regulations. This exercise should include an analysis of the types of technologies utilized to collect information, the specific websites where these technologies are used, as well as the historical and persistent nature of the data collected.

In practice, behavioral health care providers can mitigate their exposure by restricting the use of tracking technologies and, to the extent that such technologies are utilized, by taking effective measures to de-identify the data such that it falls outside the scope of the definition of PHI.

Finally, behavioral health care providers can greatly mitigate their exposure by entering into business associate agreements governing the use and disclosure of PHI with third parties that provide services online or confirming the HIPAA authorization of individuals before PHI is shared with these parties.

[1] The Guidance points out that entities and activities outside this scope may still be subject to regulatory oversight and intervention by the Federal Trade Commission and other regulators.
[2] https://www.ftc.gov/news-events/news/press-releases/2023/02/ftc-enforcement-action-bar-goodrx-sharing-consumers-sensitive-health-info-advertising?utm_source=govdelivery.

CMS Proposes Improved Access to Behavioral Health Care Under Medicare Advantage Plans

C. Ryan Morgan
Shareholder
Denver

Matthew T. Lin
Associate
Los Angeles

In 2022, the Centers for Medicare & Medicaid Services ("CMS") twice solicited comments from the public on ways to improve and expand the Medicare Advantage ("MA") program. The first, in January 2022 sought comments on the extent to which behavioral health services should be available and provided to enrollees. The second was broader, seeking comments on ways to achieve CMS's goals of advancing health equity, expanding access to affordable care, driving high-quality, person-centered care, and promoting sustainability of the Medicare program. On December 22, 2022, after reviewing almost 4,000 comments, CMS published a proposed rulemaking several important changes to the MA program, including new provisions expanding access to behavioral health care. The proposed rule seeks to build Medicare Advantage behavioral health networks and improve access to behavioral health service. If finalized, the rule could have significant implications for behavioral health providers.

The portions of the proposed rule addressing behavioral health care are detailed below:

1. Adding Clinical Psychologists, Licensed Clinical Social Workers, and Prescribers of Medication for Opioid Use Disorder as Specialty Types

MA plans are currently required to demonstrate that they meet objective network adequacy requirements (e.g. distance standards, time standards, etc.) for only two behavioral health specialty types: psychiatry and inpatient psychiatric facility services.[1] The proposed rule seeks to strengthen network adequacy requirements for MA plans for behavioral health providers in the following three ways.

First, the proposed rule would add three new behavioral health providers to the list of provider specialty types subject to objective network adequacy standards, including clinical psychology, clinical social work, and "Prescribers of Medication for Opioid Use Disorders" (providers with waivers under section 303(g)(2) of the Controlled Substances Act (CSA) and Opioid Treatment Programs). The proposed rule also included maximum travel time and distance standards and minimum provider-to-beneficiary ratios for each of the three new provider specialty types.

Second, the proposed rule would require MA networks to include providers that specialize in behavioral health services by amending the list of health care providers in the existing access to service standards under 42 C.F.R. § 422.112(a)(1)(i).

Third, the proposed rule would expand incentives for MA plans to include behavioral health telehealth providers. Existing rules provide for a 10-percentage point credit towards the percentage of beneficiaries that reside within published time and distance standards if the MA plan includes one or more telehealth providers for certain specialty types that provide additional telehealth benefits in their contracted networks. The proposed rule would add clinical psychology, clinical social work, and Prescribers of Medication for Opioid Use Disorders to the list of specialty types eligible for this 10-percentage point credit.

2. Including Behavior Health Services to General Access to Service Standards

MA plans are currently required to have programs in place to ensure continuity of care for certain types of services. The proposed rule would extend the continuity of care standards to behavioral health services.

3. Codifying Standards for Behavioral Health Appointment Wait Times

MA plans are currently subject to timeliness requirements for the provision of care to enrollees. CMS has provided guidelines for MA plans for appointment wait times. The proposed rule would codify the appointment wait times standards described in the CMS guidance for primary care services and make those standards equally applicable to behavioral health services. The minimum appointment wait times would be added to existing requirements for MA plans such that wait times for each organizations' respective network of providers meet or exceed the proposed wait time standards.

[1] *See* 42 C.F.R. § 422.116(b).

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CMS stated that it is also considering establishing wait time standards for primary care and behavioral health specialty types similar to those for Qualified Health Plans ("QHPs). These wait time standards for QHPs include maximum wait times of 10 business days for behavioral health appointments, 15 business days for primary care (routine), and 30 days for specialty care (non-urgent). Additionally, CMS is considering requiring new and expanding service area applicants to attest to their ability to provide timely access to care consistent with the CMS appointment wait time standards.

4. Codifying Mandatory Reimbursement Requirements for Behavioral Health Emergency Services

MA plans are currently required to reimburse providers of emergency services without imposing prior authorization requirements and without regard to the emergency care provider's contractual relationship with the MA plan. The proposed rule would modify the definition of "emergency medical condition" to include both physical and behavioral health conditions that satisfy a prudent layperson standard. This interpretation would improve access to care for behavioral health emergency by requiring MA plans to reimburse providers for emergent behavioral health services without regard to prior authorization or the organization's contractual relationship with the provider.

5. Enhanced Disclosure Requirements When MA plans Terminate Contracts with Behavioral Health Providers

CMS next proposed enhancements to enrollee disclosure requirements when MA plans terminate contracts with primary care and behavioral health providers. The proposed rule would require MA plans to provide enrollees who are treated by a provider on a regular basis at least 60 days' notice when terminating the contract with that provider without cause, and to make a "good faith effort" to notify the enrollee when the contract is terminated for cause.

The proposed rule would also add specific notice requirements for contract terminations with behavioral health providers. First, when an MA plan terminates a contract with a behavioral health provider, the MA plan must notify all enrollees who were ever treated by the terminated behavioral health provider, rather than just the enrollees treated by the terminated provider on a regular basis. Second, the proposed rule would require MA plans to provide notice to enrollees at least 45 days before the termination effective date for contract terminations that involve a primary care or behavioral health provider, which is longer than the 30-day standard for all other specialty types. Third, the proposed rule would require both written and telephonic notice for contract terminations that involve a primary care or behavioral health provider, while only written notice is required for all other specialty types. Fourth, MA plans would have to provide telephonic notice 45 days in advance of a primary care or behavioral health provider contract termination that contains the same information as the written provider termination notice described in 42 C.F.R. 422.2267(e)(12)(ii).

These proposed enhancements to current notice requirements reflect CMS' intent to protect the stability of enrollee's primary care and behavioral health treatment. The proposed rule cited a study that showed that disruptions to behavioral health treatment could be especially severe compared to other provider types because behavioral health treatment could be longer in duration than that of physical health and because behavioral health providers need more time to develop mutual trust with their patients. The proposed rule would give enrollees greater notice and flexibility in preserving their behavioral health care if MA plans terminate contracts with their behavioral health providers.

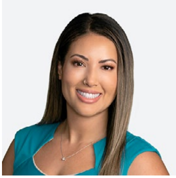
6. Including Behavioral Health Services in Care Coordination Programs

Finally, the proposed rule requires MA plans offering coordinated care plans to ensure continuity of care and integration services through arrangements with contracted providers. These coordinated care plans must include programs for coordination of plan services with community and social services generally available through contracting and noncontracting providers in the area served by the MA plan, including nursing home and community-based services. The proposed rule would add behavioral health as a category of service required to be provided under these coordinated care plans.

Conclusion

If CMS adopts these proposed rules, behavioral health providers should be ready to take advantage of potential benefits of expanded MA plan coverage but also be aware of new compliance challenges the rules may present. As proposed, these new rules have the potential to provide greater access to behavioral health services for MA plan beneficiaries and facilitate participation by new types of behavioral health providers. But such providers should ensure that their respective practices are compliant with all regulations governing MA plans and beneficiaries, including new potential regulations like the proposed service standards and wait time standards discussed above.

Certain Fraud and Abuse Risks for Behavioral Health Providers



Jasmine C. González
Counsel
Denver | Seattle

Matthew T. Lin
Associate
Los Angeles

Behavioral health has grown in the healthcare space in recent years, but with that growth comes increased scrutiny from government enforcement agencies. Recent enforcement trends show that the government and *qui tam* whistleblowers have increased their focus on behavioral health providers. Regulatory changes in the coming year, including the expiration of the COVID-19 Public Health Emergency ("PHE") present fraud and abuse risks for behavioral health providers, entities, and investors.

Background

Healthcare practitioners need little reminder that penalties under fraud and abuse laws can be devastating. The federal False Claims Act ("FCA"), Civil Monetary Penalty law, and Exclusion Statute impose severe penalties for submitting false claims for payment to the federal government, including civil penalties, treble damages and exclusion from participation in federal programs like Medicare and Medicaid. The FCA also has high enforcement risk because it allows private plaintiffs ("relators") to bring whistleblower claims to the government. The federal government has long used the FCA as its primary civil tool for addressing fraud on the government and has primarily focused its enforcement efforts on the healthcare industry. Not only can liability stem from kickback and self-referral violations under the Anti-Kickback Statute ("AKS") and the Stark Law—the government and whistleblowers frequently bring FCA enforcement action based on false certifications (including implied false certifications) of compliance with federal health care regulations. Most states have adopted their own versions of the FCA and actively enforce them for violations of healthcare regulations.

Behavioral health providers should also be wary of the Eliminating Kickbacks in Recovery Act ("EKRA"). EKRA, passed by Congress in 2018, prohibits kickbacks for patient referrals in relation to recovery homes, clinical laboratories, and "clinical treatment facilities", meaning a licensed or certified medical setting other than a hospital that provides detoxification, risk reduction, outpatient treatment and care, residential treatment, or rehabilitation for substance use. Violations of EKRA are punishable by up to 10 years' imprisonment and/or up to $200,000 in fines per occurrence. EKRA has fewer safe harbors (or exceptions) than the AKS and the Stark Law, and, unlike those statutes, can apply even where the government funds are not implicated. EKRA also has much less enforcement history than the AKS and the Stark Law, but even that limited enforcement history demonstrates government attention to kickbacks related to addiction treatment and to an increasingly broad set of defendants.

Recent enforcement trends show the importance of fraud and abuse enforcement to the federal government and to the healthcare industry. The federal government collected over $2.2 billion in False Claims Act settlements and judgments in the fiscal year ending September 30, 2022.[1] As expected, the vast majority of those recoveries—over $1.7 billion—resulted from enforcement actions in the health care industry, including enforcement against fraudulent kickback schemes, drug pricing schemes, and fraudulent billing for unnecessary services or substandard care. A significant portion of those recoveries also came from enforcement against pandemic relief fraud, including fraud against the Paycheck Protection Program and Provider Relief Fund. Notably, qui tam whistleblowers initiated 652 FCA actions in fiscal year 2022, up from 598 in fiscal year 2021, and whistleblower-initiated FCA actions accounted for $1.9 billion in total recoveries.

Additionally, and of particular importance to the behavioral health sector, two FCA settlements in 2022 discussed below illustrate the how whistleblowers and the federal government have addressed enforcement in the behavioral health space.

1. Molina Healthcare

In June 2022, the United States Attorney's Office for the District of Massachusetts announced a $4.5 million settlement with Molina Healthcare, Inc. ("Molina") and Pathways of Massachusetts ("Pathways"), a former subsidiary of Molina. Molina, a managed health care services company based in California, owned and operated Pathways, a group of Massachusetts mental health centers, from November 2015 to March 2018.

Whistleblowers filed a qui tam action in the District of Massachusetts accusing Molina and Pathways of violating the federal and Massachusetts False Claims Acts by billing the Massachusetts Medicaid program for services provided in violation of mental health staffing regulations. Following an investigation of the whistleblowers' claims, the DOJ and the State of Massachusetts intervened in the case and accused Molina and Pathways of submitting false claims based on three types of regulatory violations between January 2016 and March 2018. First, the government alleged that the defendants violated licensure and supervision requirements for mental health staff by failing to provide and/or timely document adequate clinical supervision to clinicians requiring

[1] U.S. Department of Justice, *False Claims Act Settlements and Judgments Exceed $2 Billion in Fiscal Year 2022, February 7, 2023,* available at: https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-2-billion-fiscal-year-2022

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supervision and permitting unqualified clinicians to supervise social works and psychological associates. Second, they accused the defendants of submitting claims to Massachusetts managed care entities administering outpatient mental health services despite knowing that the services rendered did not comply with licensure and supervision requirements for mental health center staff. Third, the government alleged that the defendants received overpayments for claims to the Massachusetts Medicaid program and managed care entities and failed to return those overpayments. Molina and Pathways entered into a $4,625,000 settlement agreement with the government in June 2022 without admitting to liability.

2. OGCC Behavioral Health Services

On March 31, 2022, The U.S. Attorney's Office for the Northern District of Georgia announced a $750,000 settlement with OGCC Behavioral Health Services, Inc. ("OGCC") and its owner to resolve allegations that they violated the FCA by falsely billing the Georgia Medicaid program. OGCC is a CORE Services Provider for the Georgia Department of Behavioral Health and Development Disabilities, which requires it to provide services to individuals experiencing emotional and behavioral difficulties, mental health problems, and addiction.

A qui tam complaint filed by a former OGCC employee accused OGCC of submitting false claims to the Georgia Medicaid program between 2014 and 2016. The complaint specifically alleged that OGCC falsified the identity and qualifications of behavioral health care providers in order to claim reimbursement at a higher rate, inflated the amount of time spent with patients, submitted claims for encounters that never occurred, misrepresented the dates of service, and fabricated documents in response to government requests.

Both of these cases show that the government and whistleblowers are paying attention to behavioral health providers and will scrutinize their regulatory compliance. Those in the behavioral health space should think about the following fraud and abuse concerns going into 2023.

1. **Proper Licensing for Behavioral Health Providers**

   As in the Molina settlement, behavioral health providers should ensure that all of their providers are properly licensed before seeing patients. This may seem obvious as a matter of patient care, but behavioral health centers should be diligent in reviewing and confirming the licensure and qualifications of their employed providers in order to minimize enforcement risk based on care provided by unlicensed providers. Behavioral health providers and employers should know that FCA liability can apply even without actual knowledge of the falsity of claims if the person or entity submitting claims acted with deliberate ignorance or reckless disregard of the falsity of those claims.

2. **Regulatory Changes After the End of the Public Health Emergency**

   The Biden Administration plans to end the PHE in May 2023, so behavioral health providers must be conscious of the regulatory changes and fraud and abuse risks that may follow from that decision. The PHE dramatically changed the practice and regulation of behavioral health over the past three years, including flexibility in telehealth treatment, medication-assisted treatment ("MAT"), and expansion of behavioral health coverage under Medicaid.[2] The end of the PHE will bring a large mix of regulatory changes for behavioral health, so those in the behavioral health field must be prepared for those changes in order to avoid potential liability for non-compliance.

   Some regulations adopted during the PHE were adopted as permanent rules and will continue after the expiration of the PHE. However, the end of the PHE will bring significant changes to many other parts of the regulatory landscape for behavioral health. For example, many Section 1135 waivers are set to expire after the end of the PHE. Behavioral health providers should review whether they are operating under any such waivers and evaluate which regulations may change when such waivers expire. Continuing certain billing or patient care practices that are no longer permitted after such waivers expire could result in exposure to liability under the FCA.

   Behavioral health providers should also be aware of changes in state regulations and/or waivers that may end simultaneously with the end of the federal PHE. Similar to the federal PHE, changes in state regulations after the PHE may result in liability under state fraud and abuse laws.

3. **Fraud and Abuse Enforcement Risk for Private Equity Companies**

   Private equity is increasingly focused on behavioral health, but FCA enforcement has also become focused on private equity involvement in healthcare, particularly in recent years. The challenge for FCA enforcement with respect to private equity investment in healthcare is demonstrating that private equity companies acted with knowledge or intent in causing their portfolio company to submit false claims. Whistleblowers and the government may look to the private equity company's involvement in managing its portfolio company, changes in billing practices after acquisition, and/or information discovered during acquisition due diligence.

   Private equity companies have generally performed due diligence into target company's regulatory compliance in part to assess risk of the target company becoming subject to an enforcement action and the potential resulting financial liability. However, private equity should also be aware of the risk that they themselves may become subjects of such enforcement action if their involvement with portfolio

2 *See supra,"Telehealth Will Continue to Improve Access to Behavioral Health Services"* (noting both challenges and opportunities presented by current and anticipated changes in telehealth-related flexibilities); *see also "Medicaid Enrollment Overtakes Medicare – But Challenges Are Around the Corner for Behavioral Health Providers – Continuous Enrollment Ends April 1, 2023"* (analyzing difficulties that behavioral health providers may face when confronted with certain regulatory changes impacting relatively new services and payment challenges that may result due to likely drops in Medicaid enrollment and coverage for may behavioral health patients).

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companies could be construed as causing their submission of false claims. Accordingly, private equity companies should minimize their potential liability by continuing to probe target companies for their regulatory compliance during due diligence but also by maintaining a culture of compliance at portfolio companies after they are acquired. Private equity companies should also stay up to date on regulatory concerns in the behavioral health space, such as the concerns illustrated above and be mindful about how involved they become in management of portfolio company operations.

4. EKRA Enforcement: Commission-Based Remuneration to Marketing Personnel

The EKRA employee safe harbor permits payments made to employees or independent contractors with "bona fide" relationships with an employer, where the payment does not vary based on the number of individuals referred, tests performed, or amount Some early interpretations read this as arguably prohibiting recovery homes, clinical treatment facilities, or laboratories from paying sales commissions to employees or independent contractors.

However, a Hawaii district court recently concluded that EKRA does not apply to marketers. The case, *S&G Labs Hawaii, LLC vs. Graves,* an employment suit, involved a lab terminating a marketing contract in connection with failed compensation re-negotiations. The lab apparently sought to renegotiate the prior, commission-based compensation arrangement with its employed marketer, believing that it was illegal under EKRA. In attempting to resolve the subsequent resulting dispute and case between the lab and former employee, the court concluded that the prior commission-based arrangement did not violate EKRA. The court reasoned that although there was remuneration because the marketer was paid commission-based compensation for services, there was no inducement to refer because the lab's payment was to the employee, and not to a patient or to a physician or other person who was in a position to make referrals. Time will tell whether other courts find the reasoning and interpretation of the *S&G Labs Hawaii* persuasive in this regard, although at least apparently has not, as noted below

In *U.S. v. Schena,* a May 2022 case from California, the court held that EKRA prohibits both direct and indirect referrals of patients to clinical laboratories. Importantly, the court addressed the District of Hawaii's interpretation of EKRA and explicitly rejected it, stating that EKRA's prohibition on paying remuneration for referrals includes situations in unlawful payments are made to a marketer who, in turn, induces an inappropriate referral from a physician as a result. Behavioral health and other healthcare providers will need to continue to watch related cases and be on the lookout for any related regulatory or interpretive guidance that may be issued.

5. EKRA Enforcement: Substance Abuse Facilities

In U.S. v. Markovich the jury found that two owners of a South Florida addiction treatment facility violated EKRA by engaging in the following conduct:

- Giving illegal drugs to patients before admission and readmission to cause the patients to test positive for drugs and qualify for the highest and most expensive level of care;
- Paying patients and providing them free transportation, including long-distance flights, to the addiction treatment facility;
- Splitting fees with clinical laboratories that performed laboratory tests on patients referred from the addiction treatment facility; and
- Using social media to target potential patients by offering them cash to go to the addiction treatment facility.

Unlike AKS cases, the Markovich defendants defrauded commercial insurance companies, not federal health care programs. Markovich is useful in demonstrating and confirming the types of marketing practices that can give rise to an EKRA violation. It is also useful as a clear example of enforcement of EKRA in which only private insurance, and no government payment, was involved.

Conclusion

Behavioral health providers and investors will continue to be confronted with substantial fraud and abuse challenges throughout 2023. As discussed, above, these challenges and related legal requirements can be accompanied by severe punishment and fines in some cases, and a lack of clear interpretive guidance, particularly in the case of EKRA. As a result, providers and investors should consult with experienced regulatory counsel to help ensure that their current practices are compliant with fraud and abuse laws, to identify fraud and abuse risks in behavioral health transactions and operations, and to help mitigate those risks.

Alignment of 42 CFR Part 2 with HIPAA Impact on Behavioral Health

Rebecca Frigy Romine
Shareholder
St. Louis

Erica L. (Beacom) Reagan
Associate
Washington, D.C.

On December 2, 2022, the U.S. Department of Health & Human Services (HHS), through the Office for Civil Rights (OCR) and in coordination with the Substance Abuse and Mental Health Services Administration (SAMHSA), published a Notice of Proposed Rulemaking (Proposed Rule) proposing regulatory changes to 42 C.F.R. Part 2 (Part 2) in order to implement Section 3221 of the Coronavirus Aid, Relief, and Economic Security Act and to further align Part 2 with the Health Insurance Portability and Accountability Act of 1996 and the implementation regulations thereunder (HIPAA). While the comment period to the Proposed Rule closed January 31, 2023, it remains important for providers subject to Part 2 (Part 2 Programs) to understand the scope and content of the Proposed Rule, and to be aware of potential operational challenges and benefits that the Proposed Rule may present, when finalized.

If implemented in its entirety, the Proposed Rule would increase patient care coordination amongst SUD, other behavioral health, and physical health providers. As Secretary Xavier Becerra stated in the HHS press release, "[v]arying requirements of privacy laws can slow treatment, inhibit care, and perpetuate negative stereotypes about people facing substance use challenges... This proposed rule would improve coordination of care for patients receiving treatment while strengthening critical privacy protections to help ensure individuals do not forego life-saving care due to concerns about records disclosure."[1] Put simply, the Proposed Rule could improve care coordination, minimize patient privacy concerns and eliminate barriers to necessary information sharing by streamlining the current compliance standards.

The following is a high-level summary of the most impactful parts of the Proposed Rule for Part 2 Programs, as well as the potential related practical implications. As a point of emphasis, the regulatory changes described below have been proposed – they have not been finalized by HHS and Part 2 Programs should not yet make operational changes to reflect the Proposed Rule changes or rely on the Proposed Rule changes in using or disclosing Part 2 records.

A. Single Patient Consent and Redisclosure

Most significantly, pursuant to the Proposed Rule, and as contemplated by the CARES Act, a Part 2 Program would be able to obtain a one-time, single patient consent for all future uses and disclosures for treatment, payment, and health care operations (TPO) activities. Not only would obtaining such a single consent from the patient ease the ability of a Part 2 Program to share Part 2 records for purposes of TPO without obtaining specific consents for each recipient, such proposed changes also provide additional flexibility and use of Part 2 records by the recipient of the records.

Notably, under the Proposed Rule, with the appropriate consent language, if Part 2 records are disclosed to a HIPAA covered entity or business associate for TPO purposes, such recipient can further use and disclose the Part 2 records in accordance with the HIPAA Privacy Rule (without any additional consent or other limitations), except in instances of civil, criminal, and legislative proceedings against the patient. In instances where the recipient of the Part 2 records is not a HIPAA covered entity or business associate and the disclosure is for TPO purposes, the Proposed Rule changes would allow the recipient/lawful holder to further use or disclose the Part 2 records consistent with the consent (and in some instances limited to the recipient's contractors, subcontractors, and legal representatives).

Under the current Part 2 regulations, recipients of Part 2 records are not permitted to further use and disclose the records without the patient's Part 2 compliant consent, unless an applicable Part 2 exception applies. Because of the current consent requirements and limits on disclosure, care coordination, care management, and quality improvement initiatives are often very difficult to manage and operationalize. If the Proposed Rule is finalized as proposed, based on a one-time patient consent, Part 2 Programs should more readily be able to participate in value-based care, alternative payment model, and integrated care initiatives.

1 U.S. Dept. of HHS, *HHS Proposes New Protections to Increase Care Coordination and Confidentiality for Patients With Substance Use Challenges* (Nov. 28, 2022), available at https://www.hhs.gov/about/news/2022/11/28/hhs-proposes-new-protections-increase-care-coordination-confidentiality-patients-substance-use-challenges.html.

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B. Expansion of Enforcement Authority to HHS

The Proposed Rule expands the enforcement authority of HHS to include enforcement of Part 2, and similarly extends the current HIPAA civil money penalty enforcement structure to Part 2. Currently, Part 2 enforcement sits with the U.S. attorney in the applicable jurisdiction of the Part 2 Program, and compliance with Part 2 has largely been unenforced, except in extreme instances. The proposed expanded enforcement jurisdiction to HHS will likely result in increased scrutiny of relevant providers' compliance with Part 2. As such, it will be increasingly important for behavioral health providers that provide SUD services to accurately determine whether their operations are subject to Part 2 – either in whole or in part - and to fully implement a Part 2 compliance infrastructure, when relevant.

C. Notice of Privacy Practices

Under the current Part 2 regulations, Part 2 Programs are required to provide patients with a Part 2 notice related to its obligations to comply with the standards of Part 2. This Part 2 requirement is separate and different from the HIPAA Notice of Privacy Practices (NPP) requirement, though some providers historically have combined the Part 2 notice and the NPP. The Proposed Rule proposes to amend both the Part 2 patient notice requirements, at 42 C.F.R. § 2.22, as well as the NPP requirements at 45 C.F.R. § 164.520. The result is to substantially align the content and structure requirements under both Part 2 and HIPAA.

D. De-Identification

Currently, Part 2 does not specify a standard for determining when Part 2 protected information is non-identifiable. The Proposed Rule would extend the HIPAA de-identification standards at 45 C.F.R. § 164.514 to Part 2 and instances where Part 2 addresses the use or disclosure of non-identifiable information. To the extent a Part 2 Program does not already have a de-identification policy in place (as part of its HIPAA compliance program), the Proposed Rule would require the formal implementation of policies and procedures related to de-identification.

E. Alignment with HIPAA Related to Certain Patient Rights, Complaints, and Breach Notification

While becoming increasingly less common in the behavioral health industry, there are still certain Part 2 Programs that are not subject to HIPAA because they do not conduct HIPAA standard transactions (e.g., bill third party payors electronically). The Proposed Rule applies and aligns certain obligations related to patient rights, handling of patient complaints, and breach notification obligations with HIPAA. Specifically, under the Proposed Rule:

- Part 2 Programs will be required to afford a patient with (i) the right to receive an accounting of disclosures of their Part 2 record (in line with the yet to be finalized modifications to the HIPAA regulations on accounting of disclosures), and (ii) the right to request restrictions on disclosures of Part 2 records for TPO, including required restrictions related to disclosures to health plans for services paid in full by the patient.
- Part 2 Programs will be required to establish a process to receive complaints related to its compliance with Part 2 and will be prohibited from discriminating or retaliating against a patient for making such a complaint.
- Part 2 Programs must comply with all notification requirements of the HIPAA Breach Notification Rule (45 C.F.R. Part 164, Subpart D) related to unsecure Part 2 records.

Part 2 Programs that already comply with HIPAA related to such obligations should not experience any (or at least any material) modifications to their operations as a result of this alignment; however, Part 2 Programs that are not currently subject to HIPAA will need to document and implement policies supporting compliance with these requirements.

Once the Proposed Rule is finalized, HHS proposed a 24-month timeframe for compliance. This timeframe encompasses a 60-day window for the rule to become effective after publication and an extended 22-month timeframe before enforcement. Undoubtedly, to the extent the proposed changes are finalized, Part 2 Programs will want to rely upon the general one-time consent and consent for redisclosure changes as soon as possible. Again, while operational changes should not be made prior to the publication and the effective date of a final rule, Part 2 Programs may want to start understanding what their current technical and operational capabilities are compared to what the Proposed Rule would allow and/or require, and whether there are limitations that may need to be addressed when the Proposed Rule is finalized.

Despite Additional Funding, Staffing Shortages Will Continue to Reduce Access to Behavioral Health

Paul A. Gomez
Shareholder | Chair, Behavioral Health Law Group
Los Angeles

Much has been written and reported about the ongoing shortages of available behavioral health care providers, including in the 2022 edition of this Newsletter. The shortages and associated challenges are not new and unfortunately, continue to grow. Growing demand for services that continues to outstrip access to available behavioral health professionals and services at an increasing rate is a major barrier to addressing the substantial behavioral health care needs of many Americans. For example, Mental Health Professional Shortage Areas identified by the federal government increased again in 2022, rising to 6,464, up from an already troubling level of 5,112 in 2018.[1] Most people with a substance use disorder in the U.S. do not receive any treatment. Well over half of all adults in the U.S. with a mental illness do not receive treatment and nearly sixty percent (60%) children in the U.S. with a major depressive disorder do not receive any treatment.[2] Further details about this these shortages and related unmet needs, including types and causes, can be found in our Top Issues in Behavioral Health Newsletter for 2022.

An infusion of qualified behavioral health providers is needed to increase behavioral health care access. Such an infusion is critical to drive down avoidable hospitalizations, reduce recidivism among those who have been in prison, address the substance use epidemic and reduce delays in access to evidence-based behavioral health services. As noted in last year's edition of this Newsletter, the solution may lie in a variety of short and long-term strategies, including: (i) increasing behavioral healthcare reimbursement rates to permit salary and benefit increases for providers, (ii) adopting tele-behavioral health care options, (iii) deploying educational stipends to spur students to enter the field, and (iv) pursuing provider consolidation and capital investment through M&A activity.

Over the past year there has been progress on at least some of the above noted fronts. M&A activity and investment in behavioral health providers remained at high levels in 2022, and is expected to continue at a strong pace in 2023.[3] Significant flexibilities in telehealth were further extended, including Medicare coverage for such modalities and removal of certain geographic and periodic in-person visit requirements.[4] Moreover, legislation was passed to allocate additional resources to training of new mental health professionals (particularly to increase access for young people and in schools) and Medicare coverage was extended to more types of behavioral health professionals.[5]

Notwithstanding these steps, more remains to be done to make a noticeable dent in persistent staffing and access challenges. It is also a reminder that efforts taken now may take years for in order for anticipated results to materialize, to be measurable and, most importantly, to be felt by those in need of help.

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1 *Mental Health Care Health Professional Shortage Areas (HPSAs),* KAISER FAM. FOUND. (Sept. 30, 2022) https://www.kff.org/other/state-indicator/mental-health-care-health-professional-shortage-areas-hpsas/?currentTimeframe=0&selectedRows=%7B%22wrapups%22:%7B%22united-states%22:%7B%7D%7D%7D-&sortModel=%7B%22colId%22:%22Percent%20of%20Need%20Met%22,%22sort%22:%22asc%22%7D

2 The State of Mental Health in America, MENTAL HEALTH AMERICA (last visited Feb. 20, 2023) https://mhanational.org/issues/state-mental-health-america#:~:text=Over%20half%20(54.7%25)%20of,illness%20did%20not%20receive%20care.

3 *See supra,* "Investment in Behavioral Health Will Remain Strong in 2023" (noting the active M&A behavioral health M&A climate in 2022 and continued and new factors that are expected to result in continued strong investment and growth in the behavioral health sector in 2023).

4 *See supra,* "New Congress, New Realities and New Opportunities: Welcome to the Federal Behavioral Health Landscape for the New Year" (summarizing key legislative developments designed to increase access to mental health professionals); *see also supra "Telehealth Will Continue to Improve Access to Behavioral Health Services" (summarizing key legislative and regulatory developments that are designed to promote greater access to telehealth services and may help address behavioral health professional shortages).*

5 *See Fact Sheet: Biden-Harris Administration Announces Two New Actions to Address Youth Mental Health Crisis, DEPT. OF EDUC. July 29, 2022* (summarizing several hundred million in grants to support training and availability of greater levels of mental health professionals in schools via both the Bipartisan Safer Communities Act of 2022 and FY 22 Omnibus bill.). https://www.ed.gov/news/press-releases/fact-sheet-biden-harris-administration-announces-two-new-actions-address-youth-mental-health-crisis (last visited February 21, 2023); *see also, supra "New Congress, New Realities and New Opportunities: Welcome to the Federal Behavioral Health Landscape for the New Year"* (summarizing key legislative developments designed to increase access to mental health professionals).

Predicting the Future of Psychedelic-Assisted Therapeutic Services Regulation: Ten Insights Gleaned from Oregon's Blueprint

Joelle M. Wilson
Shareholder
Chicago

Jasmine C. González
Counsel
Denver | Seattle

As scientific research on the therapeutic and medicinal potential of psychedelics grows, so does legal and political support. The Controlled Substances Act ("CSA"), signed into law in 1970, prohibits the use of many psychedelics in the United States. The CSA places regulated substances into one of five schedules according to their assessed risk. The most dangerous, addictive, and harmful substances that are believed to have little to no recognized medicinal use are considered "Schedule I," which include psychedelics such as psilocybin, a naturally occurring psychedelic in mushrooms that has shown significant promise for treating severe depression, post-traumatic stress disorder, end-of-life anxiety among the terminally ill, among other mental health conditions.

Under federal law, psychedelics, including psilocybin, are illegal and subject to various criminal penalties. However, as clinical trial results show that psychedelics may be useful in treatment for certain illnesses, lawmakers in several states and cities have loosened or are considering loosening psilocybin restrictions. State considerations include the legalization of psilocybin treatment for adult patients, limiting psilocybin treatment to veterans or individuals with PTSD, or continued study of the issue. At the federal level, there has been movement via the introduction of House and Senate bills that would expand the uses of psychedelics for treatment of certain illnesses and research purposes. For example, the House introduced defense spending amendments that would support psychedelic-assisted PTSD treatment for veterans. Similarly, the Senate, in late December 2022, introduced a bill that seeks to expand access to therapeutic psychedelics that are designated as "Breakthrough Therapies," or a drug that clinical evidence indicates may demonstrate substantial improvement over available therapy on a clinically significant endpoint. While no legislative changes have been made to date, these legislative efforts seemingly foreshadow a shift in the federal governments approach to the therapeutic value of psychedelics.

In November 2020, Oregon became the first state to legalize the adult use of psilocybin. Two years later, in November 2022, with passage of Proposition 122, Colorado joined Oregon becoming the second state to legalize the use of psychedelics in therapeutic services. This article examines Oregon's first-in-the-nation psychedelic assisted services program, reviews the early efforts Colorado has engaged in to bring their program to life, and provides insight into other states' attempts to enact similar legislation.

Oregon

Oregon's Psilocybin Services Act (the "Act") legalizes the adult use of psilocybin, and authorizes the licensure and regulation of the manufacturing, laboratory testing, transportation, delivery, sale, and purchase of psilocybin products and the provision of psilocybin services. Effective January 1, 2023, Oregon began permitting the consumption of psilocybin at licensed service centers under supervision of trained facilitators. The Act does not legalize the recreational use or sale of psilocybin; psilocybin may only be purchased and consumed on-site at a licensed service center.

The parties involved in providing psilocybin services include Manufacturers (who produce whole fungi, homogenized fungi, psilocybin extract, or edible psilocybin product); testing laboratories (which test mushrooms for potency and perform quality control); service centers (where psilocybin/mushrooms are consumed), and facilitators (who administer psilocybin/mushrooms and watch over a person during their experience). The following list highlights ten unique features of Oregon's psilocybin regulatory framework which may serve as a blueprint for future state programs.

1. **Manufacturing.** Manufacturers may hold one or more endorsement types: fungi cultivation, psilocybin extraction, or edible psilocybin production. The cultivation, extraction, and production manufacturing phases have specific safety requirements including the prohibition against pesticides, limiting the types of solvents that may be used during extraction, and requiring production in licensed food establishments. In a likely effort to promote small cultivating operations, Oregon has prohibited the chemical synthesis of psilocybin. Similar to the packaging and labeling requirements for cannabis products, Oregon's psilocybin manufacturers have to comply with strict packaging and labeling rules for their psilocybin products. Manufacturers are required to include in their packaging a "Product Information Document", which contains manufacturer details, product details, laboratory test results, and other crucial information, which facilitators share with clients during the preparation session.
2. **Testing.** Oregon's psilocybin testing standards establish rules to protect consumer safety and health by certifying that psilocybin products are tested for psilocybin content, speciation, and contaminants.

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3. **Tracking.** Service center, manufacturer and laboratory licensees must use a psilocybin tracking system and appoint at least one administrator. Products must be tracked and reconciled with inventory. Unique identification numbers must be assigned and affixed to areas containing cultivation batches, and then to products in different phases of production. The Oregon Health Authority may conduct inventory audits at any time, and any discrepancy between the physical audit and tracking system which cannot be attributed to "normal moisture variation psilocybin products" is a violation. System-generated compliance notices may be generated, and licensees are charged with monitoring and addressing these in a timely fashion.
4. **Service Centers.** Psilocybin may only be consumed during an administration session at a licensed premise known as a "service center." Service centers may have multiple administration areas, including outdoor administration areas, if they have clearly defined borders and are free from hazards. Every service center must create and maintain an emergency plan which documents procedures for evacuating and relocating clients if the area becomes unsafe and general procedures for emergency response when a client experiences a medical or other emergency. Service centers are tasked with collecting the required taxes on the sale of psilocybin products, meeting specified security and surveillance requirements, and retaining records related to psilocybin services as specified in the regulations.
5. **Residency Requirements.** Through January 31, 2025, Oregon has instituted a minimum two-year residency requirement for manufacturing, service center and facilitator license applicants. Additionally, more than fifty percent of the shares, membership interests, partnership interests, or other ownership interests in a non-individual entity applicant must be held by persons who have been Oregon residents for a minimum of two-years. Starting in 2025, Oregonians (who did not meet the residency requirements previously) and out-of-state residents will be able to apply for psilocybin licenses in Oregon. Inventive contracting may be required to include Oregon residents of 2 or more years in the business endeavors in order to qualify to receive a psilocybin license under the parameters above.
6. **Facilitator Training.** Applicants for a facilitator license are required to complete an approved psilocybin training program consisting of at least 120 hours of instruction. Training program students are required to complete a minimum of 40 hours of in-person practicum training, including at least 30 hours of direct practice and 10 hours of consultation relating to the student's practice. At the conclusion of training, the student must satisfactorily pass a comprehensive skills-based examination. Oregon also requires applicants to pass a separate facilitator exam prior to licensure.
7. **Code of Ethics.** Oregon has developed a Code of Conduct for Facilitators that will guide the administration of psilocybin services. The Code of Conduct was inspired by ethical codes of the American Counseling Association, the American Psychological Association, and the Multidisciplinary Association for Psychedelic Studies. The Code of Conduct lays out the various duties owed to clients including the duties of loyalty, care, and confidentiality. Notable provisions include a discussion about the special considerations for non-ordinary states of consciousness and avoiding suggestion, manipulation, or exploitation of clients, and appropriate uses of touch during administration sessions. Licensees or licensee representatives have an affirmative duty to report misconduct involving a client that violates the Act; such conduct must be reported to the Oregon Health Authority within 24 hours.
8. **Social Equity Plans.** Applicants for a manufacturer, laboratory, service center, or facilitator license must submit a social equity plan with their initial application for licensure. Social equity plans must describe the application of diversity, equity, justice and inclusion principles to the licensee's internal practices and policies. The plan must also include objective performance measures that the licensee will use to evaluate their social equity plan.
9. **Psilocybin Services Procedure.** The process of ingesting psilocybin products occurs over various prescribed steps. First, during a preparation session, the prospective client meets with a trained and licensed facilitator at a service center at least 24 hours but not more than 90 days before the administration session. The facilitator must review a transportation plan, complete a client information form, obtain informed consent, review the client bill of rights, produce the product information document for the products to be consumed, document the fees to be collected, and review the service center emergency plan. Following the preparation session, the client partakes in the administration sessions, during which the client consumes the psilocybin products in the presence of a facilitator and within a service center's designated indoor or outdoor administration area. Following the administration session, the client may take part in an optional integration session, where they can talk about further support or other resources.
10. **Administration vs. Mental Health Services.** Oregon requires the strict separation of psilocybin facilitation from the provision of licensed mental health services. A facilitator may not perform any services that require a separate license (e.g., therapy, counseling, etc.), even if the facilitator holds such a license. The non-directive approach to facilitation is characterized by maintenance of a consistent, warm, and affirming disposition with clients, while avoiding giving clients direct advice or directly interpreting their statements or behaviors. The goal of nondirective facilitation is for clients to discover things about themselves for themselves with only minimal guidance from a facilitator. The pace and direction of facilitation are controlled by clients, while facilitators serve in a supportive role.

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Colorado

Proposition 122, Access to Natural Psychedelic Substances, won the popular vote in November 2022. The measure legalizes psilocybin and psilocin for use in therapeutic settings and paves the way for the establishment of "healing centers" where adults 21 years old and up can use the substances under the supervision of licensed facilitators. Over the next year, the Colorado Natural Medicine Advisory Board will make recommendations to the Colorado Department of Regulatory Affairs ("DORA") on areas related to the use of psilocybin and psilocin. DORA has until January 1, 2024 to adopt rules and establish qualifications for psilocybin and psilocin facilitators and adopt rules to implement the Natural Medicine Health Act. Proposition 122 also decriminalizes the personal growing, use, and sharing of psilocybin and psilocin for adult use.

Other Jurisdictions

Currently, Oregon and Colorado are the only states to legalize the adult use of psychedelics, such as psilocybin. However, lawmakers in several states have introduced bills that seek to decriminalize, legalize, or research use of psilocybin. Below is a list of actions that some state legislatures are taking with regard to psilocybin.

- Arizona: HB 2486 would appropriate $30 million from the state's budget for psilocybin research grants and establish a psilocybin research advisory council.
- California: On December 19, 2022, State Senator Scott Wiener introduced SB 58, which would legalize the possession, transportation, transfer, preparation, and obtaining allowable amounts of psilocybin, psilocyn, dimethyltryptamine (DMT), ibogaine and mescaline (excluding peyote) for personal, facilitated or supported use by persons 21 years old or older.
- Connecticut: On January 9, 2023, Rep. David Michel (D) and Sen. Gary Winfield (D) introduced HB 5102 which would amend the statutes to allow the use of psilocybin for medicinal and therapeutic purposes, including, but not limited to, the provision of physical, mental or behavioral health care.
- Illinois: On January 12, 2023, Reps. La Shawn Ford (D) and Jehan Gordon-Booth (D) introduced HB 0001, which would establish the Illinois Psilocybin Advisory Board within the Department of Public Health for the purpose of advising and making recommendations to the Department regarding the provision of psilocybin and psilocybin services.
- Massachusetts: In January 2023, State Rep. Lindsay Sabadosa (D) introduced HD.1450 in the House and Sen. Patricia Jehlen (D) introduced SD.949 in the Senate. The text for both bills is the same, removing penalties for people over 18 years old to possess, ingest, obtain, grow, and give away, "without financial gain," "no more than two grams of psilocybin, 8 psilocyn, dimethyltryptamine, ibogaine, and mescaline."

The results of these state bills are yet to be seen but one thing remains true and that is that interest in the use of psychedelics, namely psilocybin, for treatment of mental health and behavioral health illnesses is rapidly growing and gaining interest across the country. Increased interest in the use of psychedelic substances will present unique legal issues. We will continue to track state and federal advancements related to the use of psychedelics.

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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

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

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Editorial Board

Paul A. Gomez
Shareholder | Chair, Behavioral Health Law Group
pgomez@polsinelli.com
310.556.6762

Lori A. Oliver
Shareholder
loliver@polsinelli.com
206.393.5440

Iliana Peters
Shareholder
ipeters@polsinelli.com
202.626.8327

Rebecca Frigy Romine
Shareholder
rromine@polsinelli.com
314.889.7013

Erica L. (Beacom) Reagan
Associate
ebeacom@polsinelli.com
202.772.1487

Kathleen Snow Sutton
Associate
ksnowsutton@polsinelli.com
303.583.8275

Tim Perrin
Policy Advisor
tperrin@polsinelli.com
202.626.8321

Sylvia Kornegay
Policy Advisor
skornegay@polsinelli.com
202.626.8341

Jennifer L. Evans
Office Managing Partner
jevans@polsinelli.com
303.583.8211

Joelle M. Wilson
Shareholder
jmwilson@polsinelli.com
312.463.6219

C. Ryan Morgan
Shareholder
rmorgan@polsinelli.com
303.583.8208

Jasmine C. González
Counsel
jgonzalez@polsinelli.com
720.931.1173

Matthew T. Lin
Associate
mlin@polsinelli.com
310.203.5312

Sidra S. Galvin
Associate
sgalvin@polsinelli.com
310.203.5323

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