McDERMOTT HEALTH 2023 ANNUAL REPORT

DIGITAL HEALTH: 2022 YEAR IN REVIEW

McDermott Will & Emery

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SPECIAL REPORT

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OVERVIEW

Digital health is one of the fast-growing segments of the healthcare market, with patients, clinicians and regulators increasingly aligned behind the opportunities that digitization presents.

Over the last three years, patients and clinicians alike have embraced digitally delivered care and telehealth-related flexibilities. In 2022, we saw state legislative and regulatory activity centered around states making key temporary COVID-19 flexibilities permanent or adjusting previously enacted telehealth laws and regulations. The increase in digitally delivered healthcare activity has led to an increased focus on the privacy and security of patient and consumer data in 2022. We also observed increasing federal attention to fraud and abuse risks associated with telehealth. Separately, the ruling in *Dobbs v. Jackson Women's Health Organization* forced digital women's health providers to examine, and sometimes change, their operations in response to state law requirements.

As the federal COVID-19 public health emergency (PHE) winds down (now slated to end on May 11), we can expect in 2023 to see the federal government and state governments continuing to implement some of these flexibilities on a permanent basis, while setting new standards for telehealth and digital care in a post-PHE world, along with a continuing focus on the privacy and security of patient and consumer data.

On the transactional front, deal flow may be muted in 2023 while compared against record-high activity in 2021 and 2022, but it is also probable that investors will continue to get behind transformative digital health solutions that can enhance the patient experience, reduce cost, drive efficiencies and tackle workforce challenges, accompanied by a simultaneous and continuing level of focused regulatory diligence.

TELEHEALTH 2022 SUMMARY

STATE LEGISLATION AND REGULATORY TRENDS

In 2022, McDermott tracked more than 100 state-enacted bills and close to 90 final and emergency state regulations related to telehealth. Much of this legislative and regulatory activity centered around states making certain temporary COVID-19 flexibilities permanent or adjusting previously enacted telehealth laws and regulations. A key area of focus in this were statutes and regulations pertaining to health professionals. This included expanding the scope of practice for various professionals to include telehealth, updating telehealth-related definitions and implementing standards for the provision of services via telehealth.

A dominant trend was the adoption of laws and regulations addressing cross-state licensing. As most states have eliminated their COVID-19-related interstate license waivers, many states sought to address cross-state licensing on a permanent basis. Enacted legislation included licensure or registration processes for out-of-state providers, providing exceptions from licensing requirements where a prior provider-patient relationship exists, and licensure compacts. A significant amount of licensure compact activity continued, with states joining the Audiology and Speech Language Pathology Compact (eight states), Counseling Compact (15 states), EMS Compact (one state), Interjurisdictional Psychology Compact (eight states), Interstate Medical Licensure Compact (four states) and Occupational Therapy Compact (13 states).

Other areas of legislative and regulatory focus included telehealth prescribing (addressing prescribing of controlled substances, buprenorphine and cannabis, as well as standards for forming the

provider-patient relationship required for telehealth prescribing), Medicaid reimbursement (including coverage for audio-only and asynchronous modalities), payment parity and private payer reimbursement, and the provision of abortion medication via telehealth.

DOJ AND OIG FOCUS ON TELEHEALTH

Given the proliferation in telehealth since the start of the COVID-19 pandemic, 2022 saw the US Department of Justice (DOJ) and US Department of Health and Human Services (HHS) Office of Inspector General (OIG) turn increasing attention to fraud and abuse risks associated with telehealth.

In July, OIG issued a Special Fraud Alert concerning the fraud and abuse risks associated with healthcare practitioners entering into arrangements with telemedicine companies, see our *On the Subject* (OTS) here. The alert followed dozens of civil and criminal investigations into alleged fraud schemes involving companies that claimed to provide telehealth, telemedicine or telemarketing services but allegedly engaged in kickbacks and substandard medical practices to generate medically unnecessary orders and prescriptions for items or services, resulting in submissions of fraudulent claims to Medicare, Medicaid and other federal healthcare programs. The alert also came on the heels of a nationally coordinated DOJ takedown involving more than $1 billion in allegedly fraudulent telemedicine schemes. Based on the OIG and DOJ's telemedicine enforcement experience, the alert identifies a non-exhaustive list of seven "suspect characteristics" that could suggest a telemedicine arrangement presents potential risk for fraud and abuse. While the characteristics highlighted in the alert are not representative of the legitimate and crucial telemedicine services offered by most healthcare providers, the alert and the government's sustained focus on potential telemedicine-related fraud cases provide an important opportunity for healthcare providers to evaluate their telemedicine offerings and arrangements and strengthen their telemedicine compliance activities.

In September, OIG released a data brief analyzing telehealth services covered by Medicare and related program integrity risks, evaluating the impact that the regulatory flexibilities implemented during COVID-19, and corresponding hikes in utilization rates for telehealth services by Medicare beneficiaries, had on program integrity, see OTS here. OIG found that of the 742,000 providers evaluated, 1,714 had "concerning billing" on at least one of the seven measures that OIG considers to be potential indicators of fraud, waste and abuse. Providers should continue to ensure that telehealth services are properly billed in accordance with applicable billing policies. As the PHE winds down, providers should be aware of flexibilities that may be modified or cease to exist, and should update their billing practices accordingly.

Visit our Telehealth Transformation Resource Center for more on telehealth regulatory developments.

POST-DOBBS AND WOMEN'S HEALTH

One of the biggest news items to come out of 2022 in the United States was the Supreme Court's ruling in *Dobbs v. Jackson Women's Health Organization*. Digital health companies that in any way touch on women's health were forced to grapple with the legal fallout from the Court's ruling that no federal constitutional right to abortion exists. Women's digital health providers and those that pay for these services were required to examine their operations in connection with relevant state law(s) (often across multiple states), and engaged in a number of risk-mitigation strategies. These measures included reducing ties to restrictive states, taking advantage of

state-level shield laws in protective states, conducting internal reorganizations and examining data strategies.

In 2023, we expect to see additional enforcement activity in restrictive states as well as additional legislative measures in protective states. Those digital health providers whose operations touch in any way on women's health who have not engaged in corporate hygiene measures should consider doing so as soon as practicable in the new year.

More broadly, the Court's ruling in *Dobbs* has energized companies and investors focused on women's health. Many companies were prompted by the ruling to expand travel benefits for women seeking care. There is increased awareness of the importance of enabling women's and family health, and female-focused companies have continued raising capital to expand services focused specifically on women's health. This includes not only the more traditional categories such as pregnancy, childbirth and menopause, but also has extended to conditions that affect men and women differently, such as cardiovascular conditions and migraines. There has been significant focus on investment in women's health over the past year and we expect this to continue into 2023.

Stay current on the evolving post-*Roe* landscape and its impact on organizations across the US.

OCR GUIDANCE ON TRACKING TECHNOLOGIES

Of particular interest to digital heath companies, on December 1, 2022, the HHS Office for Civil Rights (OCR) issued a bulletin on the obligations of covered entities and business associates (regulated entities) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security, and Breach Notification Rules (HIPAA Rules) when using online tracking technologies, such as cookies, web beacons and pixels. The bulletin aims to provide further clarity on when identifiable information collected by such tracking technologies may also constitute protected health information (PHI) as defined and interpreted under the HIPAA Rules.

In such instances, the bulletin instructs that the technology vendor may be seen as providing a service to the regulated entity that would, in light of the use and disclosure of PHI, create a direct or downstream business associate relationship. Accordingly, the bulletin states that the regulated entities would need to enter into a business associate agreement (BAA) with the vendor of the technology (and the vendor would, in turn, become a regulated entity) and meet other requirements under the HIPAA Rules. The bulletin provides long-awaited guidance to help regulated entities review their positions and procedures concerning tracking technologies to ensure that the trackers they implement either do not collect PHI or meet the prerequisites outlined in the bulletin.

However, the bulletin does not address how OCR will approach enforcement of these cases, including whether the regulated entity is more at risk because a BAA is not in place and/or the regulated entity should have known that it was sharing PHI with a vendor. This may cause some regulated entities to rethink their strategies when deploying tracking technologies from vendors that do not sign BAAs, are not currently set up to comply with the HIPAA Rules or publicly state that they do not comply with the HIPAA Rules.

RESPONDING TO CHANGES IN THE DIGITAL HEALTH ECOSYSTEM

On the heels of exponential growth and innovation during the PHE, digital health organizations were not

immune to the new pressures facing businesses in 2022, including international and domestic turmoil, inflation, healthcare professional burnout and other factors. These factors led to compression of valuation multiples for certain digital health companies, declines in certain publicly traded health companies' revenues and corresponding declines in share price. Private companies turned their focus to evaluating how to hone service delivery models and enhance revenues. McDermott offered its thought leadership in its video series Navigating Volatile Markets In The Digital Health Ecosystem, sharing timely insights and strategies to help organizations stay ahead of the curve and addressing critical areas of workforce management, financing and the potential for restructuring.

A LOOK AHEAD

DIGITAL HEALTH OUTLOOK FROM JPM 2023: CHALLENGES AND OPPORTUNITIES FOR DIGITAL HEALTH INVESTMENT

In January 2023, industry leaders, investors and entrepreneurs gathered at the 41st annual J.P. Morgan Healthcare Conference (JPM 2023). The panel "Digital Health: What's on the Horizon For 2023 and Beyond," moderated by McDermott partner Dale Van Demark, provided an outlook on investments in the digital health space in 2023. In light of the constrained market, the panelists observed that the same digital health companies that could have been funded just a few years ago are facing much more scrutiny today. In the current market, this means that digital health entrepreneurs need immediate use cases: ideas that that can serve immediate needs, can be monetized very quickly, and can show impact and identify cost-savings immediately. The panelists predicted that investment opportunities will be at the center of the established healthcare system, where digital health companies will need to engage with providers, payers and employers to create value. One panelist also observed that market conditions are ripe for a wave of digital health consolidation, which will see smaller startups that have not reached profitability consolidated on larger platforms. There is excitement for deal activity around complex diseases, improvements in efficiency and clinical workflow, enabling technologies for the transition to value-based care, and AI-driven patient navigation.

Driven both by lessons from the COVID-19 pandemic and the current market, the focus of entrepreneurs and investors has shifted to partnerships and collaborative models. Panelists discussed how the focus on value-based care will present digital health companies with more of an opportunity for collaboration with providers and payers, as well as opportunities to play matchmaker between partners. In particular, these collaborative opportunities may come with small- to medium-sized companies, who may be more willing to take on risk and be more flexible with their systems compared to incumbent health system companies.

Increased Focus on Privacy and Security

We expect to see continued focus on privacy and security at the federal and state level. For example, California, Virginia, Colorado, Utah and Connecticut have new privacy laws coming into effect in 2023. As part of our State Law Privacy Video Series, McDermott described how these laws will affect health data and healthcare entities—in particular, those entities that are regulated by HIPAA. In addition, at the end of 2022, HHS proposed long-

awaited changes to the regulations protecting the confidentiality of substance-use disorder patient records under Part 2 of Title 42 of the Code of Federal Regulations (42 CFR Part 2, or Part 2). Specifically, the proposed rule would implement provisions of Section 3221 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which required HHS to align Part 2 with certain provisions of HIPAA and to make certain changes to the HIPAA Notice of Privacy Practices, the form given to patients and plan members that describes patient privacy rights, covered entity duties, and the covered entity's uses and disclosures of protected health information.

MAKING MEDICARE TELEHEALTH FLEXIBILITIES PERMANENT

The year-end omnibus legislative package passed in December 2022 extended key Medicare telehealth flexibilities implemented as part of the PHE waivers. The PHE remains in effect at least through January 2023 and is now expected to end May 11, 2023. However, stakeholders remained concerned about the potential termination of these flexibilities when the PHE ends and the instability it will cause for patients and providers. The healthcare provisions in the omnibus package continue the Medicare telehealth flexibilities for two calendar years, regardless of the status of the PHE, through December 31, 2024. These include:

- Waiving the geographic restrictions and originating site requirements
- Expanding the list of practitioners eligible to furnish telehealth services
- Allowing telehealth services for rural health clinics and federally qualified health centers
- Delaying the in-person visit requirement before a patient receives mental health services furnished through telehealth and telecommunications
- Allowing for telehealth services through audio-only telecommunications
- Allowing for telehealth to be used for a required face-to-face encounter prior to the recertification of a patient's eligibility for hospice care.

As these flexibilities are extended on a temporary basis through December 31, 2024, stakeholders will need to continue to engage with Congress on a more permanent solution.

Learn more about the omnibus package from our health policy colleagues at McDermott+Consulting.

CONTROLLED SUBSTANCE PRESCRIBING VIA TELEHEALTH

A key area to watch relates to enforcement of the Ryan Haight Act, which requires practitioners issuing a prescription for a controlled substance to conduct an in-person medical evaluation. During the PHE, the Drug Enforcement Agency (DEA) triggered an exception to the requirement for an in-person medical evaluation provided certain conditions are met, allowing practitioners to prescribe controlled substances via telehealth to the extent permitted by applicable state law. Stakeholders have continued to urge the DEA to issue regulations for a special telemedicine registration under the Ryan Haight Act, which was required by the Ryan Haight Act and would offer an exception to the Ryan Haight Act's in-person exam requirement on a permanent basis. It remains an open question when the DEA will issue such rules—and whether the rules, or an interim plan, will be finalized before the expiration of the PHE exception.

NEW TELEHEALTH RULES FOR METHADONE AND BUPRENORPHINE TREATMENT

The Substance Abuse and Mental Health Services Administration (SAMHSA) has proposed a new rule that would allow authorized physicians to treat patients with buprenorphine and methadone-assisted treatment via telehealth. The proposed rule would make permanent PHE flexibilities for the prescribing of buprenorphine via telehealth, allowing authorized clinicians to initiate buprenorphine through audio-only or audio-visual technology. The proposed rules would include new flexibilities for methadone-assisted treatment via audio-visual telehealth.

STATE TELEHEALTH LEGISLATIVE AND REGULATORY OUTLOOK

Continuing the trends in 2022, we expect to see more activity around regulating the use of telehealth by various provider types, as well as continued activity around cross-state licensing.

We are closely monitoring this space and have launched a weekly series to keep industry stakeholders informed on the complex state-level activity. Each week we highlight state legislative and regulatory developments that impact the healthcare providers, telehealth and digital health companies, pharmacists, and technology companies that deliver and facilitate the delivery of virtual care. We also look forward to providing quarterly reports on these important developments in 2023. Subscribe to stay in the know.

IN CLOSING

The regulatory landscape will be active as the federal government and state governments work to make permanent key telehealth flexibilities that so many came to depend on during the PHE, and to protect patient privacy and security. Providers will continue to react to the post-*Dobbs* environment, potentially developing more innovative care models for women's health. Digital health companies, providers and technology companies should continue to monitor the evolving regulatory and legislative landscape, particularly those changes at the state level, and take a proactive approach to compliance and due diligence. Regulatory changes could have significant impact on the way digital care is delivered across state lines, which may affect business lines, valuations and the ability to treat patients.

The 2023 economic outlook presents challenges for dealmakers and companies seeking funding, but companies with immediate use cases are still likely to find opportunity. Consolidation is expected as winners and losers emerge from the digital health funding frenzy of 2021 and 2022. Finding the right alignment between parties, conducting thorough due diligence and partnering with experienced counsel that can efficiently move deals forward will be paramount to success in a challenging year ahead.

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