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THE FUTURE OF TELEHEALTH - PART 1

The legal and regulatory boundaries of telehealth and remote medicine changed almost overnight as the COVID-19 pandemic set in. Those boundaries are set to change again – and again and maybe again – over the next 18 months.

Currently, telehealth is largely unrestrained compared to the pre-pandemic regulatory and medical care industry.

The COVID-19 national emergency, first declared by President Trump in March 2020 and maintained ever since by President Biden, loosened Medicare, Medicaid, HIPAA, and various other restrictions on telehealth.

Before the pandemic, Medicare only reimbursed providers for certain narrow uses of telehealth. But Medicare offered pandemic-related flexibilities[1], including:

- Reimbursing health care providers for telehealth services provided to patients in their homes outside of designated rural areas.
- Allowing health care provider to treat patients in different states[2].
- Permitting health care providers to establish relationships with new patients through telehealth.
- Expanding the types of telehealth services covered by Medicare.

Further temporary regulatory waivers, including a formal notification of enforcement discretion regarding telehealth issued by the U.S. Department of Health and Human Services ("HHS")[3], allowed covered health care providers to:

- Use virtually any non-public remote communication technology to communicate with patients.
- Examine patients exhibiting COVID-19 symptoms using video or audio chat applications.
- Treat or assess any other medical condition, such as a sprained ankle, dental problem or psychological evaluation.
- Follow up with patients through text-based applications such as Facebook Messenger, Apple iMessage, Signal, WhatsApp, and more.

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[1]Policy Changes During COVID-19: Medicare and Medicaid Policies, Telehealth.HHS.Gov, last updated February 16, 2023. Available at https://telehealth.hhs.gov/providers/policy-changes-during-the-covid-19-public-health-emergency/medicare-and-medicaid-policies.

[2]A physician's treatment of a patient in another state nonetheless remained, and remains, subject to applicable state laws and regulations.

[3]Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency, U.S. Department of Health & Human Services, January 20, 2021. Available at https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html

HHS made it clear to covered providers that, during the national emergency, they could treat their patients using popular video applications "without risk that OCR might seek to impose a penalty for noncompliance" with HIPAA and various other federal regulations and rules[4].

The medical industry responded to the relaxed regulatory environment. Patients reacted too. Large swaths of the public turned to telehealth in new and far more expansive ways. In fact, telehealth services increased more than 15 times from March 2020 to February 2021, according to a study by the U.S. Government Accountability Office ("GAO")[5]. In this study covering five states, the GAO found that the number of Medicaid beneficiaries accessing telehealth services increased from 2.1 million to 32.5 million in that one-year period.

Now, however, the emergency declaration is set to end. President Biden announced last month that the emergency declaration, and all of its waivers and deferments, will expire on May 11, 2023.

Consequently, the legal and regulatory contours of telehealth likely will change – potentially in substantial ways – during the course of the next year to 18 months.

TELEHEALTH SERVICES INCREASED MORE THAN 15 TIMES FROM MARCH 2020 TO FEBRUARY 2021

Congress kick-started this timeline when it passed a short-term extension of most of the temporary waivers and authorizations.

However, the extension of key telehealth provisions is only temporary and currently is set to expire by the end of 2024. Many observers have concluded that the debate over the telehealth measures, including coverage of telehealth services for Medicare and Medicaid beneficiaries, indicated opposition to making many of the changes permanent[6].

Politicians and some administration officials expressed concerns that expanded telehealth services could expose Medicare and Medicaid to potential fraud or significantly increased treatment costs. Accordingly, the 2022 omnibus budget bill, which contained the telehealth extension, mandated a study and report examining telehealth quality of care and program integrity[7]. In an earlier study, as summarized in a 2021 GAO report, the GAO already determined that the telehealth waivers increased spending in both Medicare and Medicaid[8]. Further, the GAO study noted that the quality and efficacy of telehealth services "has not been fully analyzed"[9].

The Biden administration signaled plans to restrict some telehealth services even before the congressional extension of the pandemic waivers ends in 2024. For example, the Drug Enforcement Agency currently is considering a new rule to require in-patient medical evaluations before a covered provider may prescribe most prescription medications[10]. DEA Administrator Anne Milgram said in a press release that the DEA is "committed to the expansion of telemedicine **with guardrails**"[11](emphasis added).

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[4]Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency, U.S. Department of Health & Human Services, January 20, 2021. Available at https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html

[5]"Telehealth in the Pandemic – How Has It Changed Health Care Delivery in Medicaid and Medicare?," WatchBlog, U.S. Government Accountability Office, September 29, 2022. Available at https://www.gao.gov/blog/telehealth-pandemic-how-has-it-changed-health-care-delivery-medicaid-and-medicare#:~:text=We%20found%20that%2the%20number,March%202020%20to%20February%202021).

[6]"It's 'Telehealth vs. No Care': Doctors say Congress Risks Leaving Patients Vulnerable", Sarah Jane Tribble, Kaiser Health News, January 31, 2023. Available at https://khn.org/news/article/its-telehealth-vs-no-care-doctors-say-congress-risks-leaving-patients-vulnerable/.

[7]See The Consolidated Appropriations Act, 2022 (H.R. 2471), available at https://www.congress.gov/bill/117th-congress/house-bill/2471/text.

[8]"Medicare and Medicaid: COVID-19 Program Flexibilities and Considerations for their Continuation," U.S. Government Accountability Office, May 19, 2021. Available at https://www.gao.gov/products/gao-21-575t.

[9]"Medicare and Medicaid: COVID-19 Program Flexibilities and Considerations for their Continuation," U.S. Government Accountability Office, May 19, 2021. Available at https://www.gao.gov/products/gao-21-575t.

[10]See "Biden Administration Moves to Establish 'Guardrails' for Telehealth Prescriptions", Andrew Millman, CNN.com, Feb. 25, 2023. Available at https://www.cnn.com/2023/02/25/politics/telehealth-drug-enforcement-agency-biden/index.html#:~:text=The%20Biden%20administration%20has%20proposed,a%20statement%20released%20on%20Friday.

[11]See "Biden Administration Moves to Establish 'Guardrails' for Telehealth Prescriptions", Andrew Millman, CNN.com, Feb. 25, 2023. Available at https://www.cnn.com/2023/02/25/politics/telehealth-drug-enforcement-agency-biden/index.html#:~:text=The%20Biden%20administration%20has%20proposed,a%20statement%20released%20on%20Friday.

The end of the public health emergency also will bring changes to COVID-19 requirements on private and employer group health plans, including to benefits such as coverage of over-the-counter COVID-19 tests, telehealth, and health savings accounts[12].

The extent of these potential new guardrails will be critical to the practices of many doctors, dentists, hospitals, and rural health clinics. New rules, such as the DEA's proposed regulation mentioned above, and other potential efforts to walk back telehealth services likely could substantially define the care providers are able to offer patients in the months and years ahead. Consider that CMS issued more than 200 Medicare waivers related to telehealth, remote, and off-site care during the pandemic emergency period, which allowed: The expansion of hospital capacity as more than 100 new facilities were added through the waivers that provided hospitals to provide care in non-hospital settings;

- Expansion of the medical workforce through waivers that relaxed provider enrollment requirements and allowed certain non-physician providers, such as nurse practitioners to provide additional services; and
- Substantially more opportunities for reimbursement related to remote services that previously had to be provided in-person to be eligible for payment[13].

Please watch the Lashly & Baer web site for updates on the proposed new regulations, status of telehealth waivers, and related issues. Furthermore, our healthcare attorneys are available to answer your specific questions about these pending new regulations and will help you implement any requirements as they continue to develop.

For more information, please reach out to your Lashly & Baer attorney with any questions.

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[12] See generally "Employers Look to End of Covid Emergency for Benefit Adjustments," Sara Hansard, Bloomberg Law, Feb. 13, 2023. Available at https://news.bloomberglaw.com/health-law-and-business/employers-look-to-end-of-covid-emergency-for-benefit-adjustments.
[13] "Medicare and Medicaid: COVID-19 Program Flexibilities and Considerations for their Continuation," U.S. Government Accountability Office, May 19, 2021. Available at https://www.gao.gov/products/gao-21-575t.

This summary and legal alert is an overview of the new developments in the health care industry. It is not intended to be, and should not be construed as, legal advice for a specific factual situation.

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