PRACTICING TELEHEALTH POST-PUBLIC HEALTH EMERGENCY

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01
INTRODUCTION

On May 11, 2023, the COVID-19 Public Health Emergency ("PHE") officially expired, bringing with it an end to the many regulatory waivers and flexibilities put in place to ease access to health care during the PHE. Many of these regulatory changes aimed to increase access to telehealth as COVID-19 made in-person healthcare increasingly risky. With these regulatory waivers in place, telehealth quickly became a widespread and integral part of medical care. In fact, a nationwide study of telehealth usage between 2019 and 2020 saw telehealth usage increase from approximately .3 percent of all medical interactions in 2019 to 23.6 percent of all medical interactions in 2020.[2] While telehealth usage rates fluctuated throughout the pandemic, overall use continues to be higher than pre-pandemic rates.[3] The regulatory changes that made this shift possible include changes to Medicare and Medicaid policies, changes to state and federal prescribing requirements, waivers of administrative and federal sanctions for copayment waivers and reductions, and HIPAA-related enforcement discretion.[4] While some of these waivers and flexibilities remain in place, some have expired and are no longer available following the expiration of the PHE. This article will describe the current telehealth policy landscape and what practitioners need to know to practice telehealth compliantly in a post PHE environment.

02
MEDICARE

Some of the most significant changes to telehealth regulations occurred via waivers or discretionary enforcement of Medicare-related regulations. Prior to the PHE, telehealth for Medicare beneficiaries was restricted to specific types of health care services in limited geographic settings. PHE-related waivers removed many such barriers and expanded telehealth care access to a wider variety of health care providers and Medicare beneficiaries. On December 29, 2022, President Biden signed the Fiscal Year 2023 Consolidated Appropriations act and extended many of these flexibilities through December 31, 2024.

A. Geographic and Originating Site Requirements

Pre-PHE, health care practitioners were restricted to providing telehealth services to patients who were physically located in designated *originating sites* (such a doctor's offices, critical access hospitals, rural health clinics, or federally qualified health centers ("FQHCs")) in an appropriate *geographic area* designated as a rural health professional shortage area.[5] For behavioral health services, the originating site has been expanded to include a beneficiary's home and geographic requirements have been waived **permanently**.[6] Any Medicare beneficiary can continue to receive behavioral health therapies from the comfort of their home indefinitely. For all other non-behavioral health care, the geographic and originating site requirements for telehealth services have been waived through December 31, 2024.

B. Extending Telehealth Services for all Federally Qualified Health Centers and Rural Health Clinics

Prior to the PHE, FQHCs and Rural Health Clinics ("RHCs") were prohibited from serving as *distant site* telehealth providers.[7] Distant site refers to the site at which the provider is located at the time the telehealth service is rendered.[8] This requirement made it impossible for providers in in FQHCs and RHCs to be reimbursed by Medicare for their telehealth services. FQHCs and RHCs are now **permanently** eligible to serve as the distant site for behavioral and mental telehealth services. Further, FQHCs and RHCs can serve as distant sites for all non-behavior and mental telehealth services through December 31, 2024.

2 Jonathan P. Weiner et al., *In-Person and Telehealth Ambulatory Contacts and Costs in a Large US Insured Cohort Before and During the COVID-19 Pandemic*, 4(3) JAMA 1,1 (2021).

3 Robin Gelburd, *Telehealth Utilization Grew 7% Nationally in January 2023,* Am. J. Managed Care (Apr. 4, 2023), https://www.ajmc.com/view/contributor-telehealth-utilization-grew-7-nationally-in-january-2023.

4 The Health Insurance Portability and Accountability Act of 1996.

5 42 USC §1395m(m)(4)(C).

6 https://telehealth.hhs.gov/providers/telehealth-policy/policy-changes-after-the-covid-19-public-health-emergency#permanent-medicare-changes.

7 42 USC §1395m(m)(4)(A).

8 42 CFR §410.78(a)(2).

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C. In-Person Requirements for Tele-Mental Health Services

Pre-PHE, Medicare beneficiaries who initiated mental or behavioral health services via telehealth or tele-communications technology were required to have an in-person visit with a provider within six months of their telehealth treatment. Additionally, they were required to have an in-person visit at least annually to continue their tele-mental health services. These requirements have been waived through December 31, 2024, for all providers and patients and through January 1, 2025, for providers in FQHCs and RHCs.[9]

D. Audio-Only Telehealth Services

Prior to the PHE, audio-only (i.e. telephone) telehealth services were covered for Medicare beneficiaries in only extremely limited circumstances. The requirement for synchronous two-way audio-video communication has been **permanently** waived for mental and behavioral telehealth services.[10] However, those using audio-only telehealth services for mental and behavioral health care are subject to the periodic in-person requirements described above after December 31, 2024. For other services, including evaluation and management services and educational services, audio-only care is covered for Medicare beneficiaries through December 31, 2024.

E. Telehealth for Recertification of Hospice Care Eligibility

The Centers for Medicare and Medicaid Services ("CMS") requires a face-to-face encounter with a physician or nurse practitioner for every hospice patient to determine continued eligibility for hospice care for that patient prior to the 180th day recertification and every recertification thereafter. Prior to the PHE that encounter was required to be in person. Face-to-face encounters for the purpose of recertification of hospice patients are now covered for Medicare beneficiaries through December 31, 2024.[11]

F. Practitioners Eligible to Furnish Telehealth Services

Pre-PHE, only a narrow subset of providers were eligible to deliver health care services via telehealth. This included physicians, nurse practitioners, physician assistants, nurse midwives, clinical nurse specialists, certified registered nurse anesthetists, clinical psychologists, clinical social workers, and registered dieticians or nutrition professionals. During the PHE, the list of eligible provider types was expanded to include all providers that are eligible to bill Medicare for their services. Importantly, this included physical therapists, occupational therapists, speech language pathologists, and audiologists. The waiver allowing expansion of eligible provider types expires on December 31, 2024. Unless a permanent modification is made, providers eligible to bill Medicare for telehealth services will return to the original nine provider types described above.

G. Acute Hospital Care at Home ("H@H") Program

During the PHE, the H@H program, an initiative that allowed hospitals to provide acute hospital-level care to patients requiring inpatient services via telemedicine in the patient's home, allowed hospitals to expand their inpatient capacity to care for more COVID-19 patients. The H@H program combines telemedicine with at-home nurse visits or visits by appropriate medical professionals to provide inpatient care outside of the hospital setting. This program allows eligible hospitals to apply to waive certain Medicare conditions of participation in order to implement H@H initiatives. The H@H program has been extended such that the United States Department of Health and Human Services Secretary ("HHS") may grant H@H waivers and flexibilities for H@H admissions occurring through December 31, 2024.[12]

> ***Some of the most significant changes to telehealth regulations occurred via waivers or discretionary enforcement of Medicare-related regulations***

H. Virtual Supervision

During the PHE, the regulatory definition of "direct supervision," which requires physicians to be "immediately available" during the provision of services, was modified to include "virtual presence" of the supervising physician with appropriate use of synchronous audiovisual technology. The modified definition has been extended to apply through December 31, 2023. Further, during the PHE, the requirement for direct supervision of non-surgical extended duration therapeutic services provided either in the hospital's outpatient department or in a critical access hospital was eliminated. Instead, the supervising physician is only required to provide

9 42 USC §1395m(o)(4)(B); 42 USC §1395m(y)(2).

10 42 USC §1395m(o)(4)(B); 42 USC §1395m(m)(9).

11 Coronavirus Aid, Relief, and Economic Security Act, Public Law 116-136 Sec. 3706.

12 For additional information about the H@H program and impacts of the continued waivers and flexibilities, see Health Care Law Today's "Acute Hospital Care at Home": Omnibus Bill Extends Flexibility Period to December 31, 2024.

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general supervision for the duration of treatment, even at initiation of treatment. This modification is **permanent.**[13]

I. Payment Parity

For the duration of the PHE, CMS initiated higher reimbursement rates for telehealth services provided in non-facility settings, such as the patient's home. In other words, CMS has been reimbursing telehealth services at the same rates as if they were administered as in-person care. This payment parity flexibility was extended through December 31, 2023, in the 2023 Physician Fee Schedule Final Rule. Absent any further rulemaking, distant-site telehealth providers will begin being reimbursed based on facility rates as of January 2024. This will result in some services reverting to the lower pre-PHE payment rates.[14]

J. Remote Patient Monitoring ("RPM")

Remote patient monitoring ("RPM"), sometimes called remote physiological monitoring, is a form of telehealth that allows the provider to monitor certain health conditions remotely for patients who have difficulty traveling or otherwise accessing health care.[15] It is useful for monitoring conditions such as high blood pressure, diabetes, weight loss or gain, heart conditions, chronic obstructive pulmonary disease, sleep apnea, and asthma. It requires the use of medical devices such as scales, pulse oximeters, heart monitors, breathing apparatuses, and others. CMS has issued guidance statements reiterating the requirement for RPM to only be used for *established* patients, that is, patients who have already established a provider-patient relationship. However, for the duration of the PHE, CMS waived this requirement and allowed RPM to be used for new and established patients alike.

This waiver, like many others, ended on May 11, 2023, with the end of the PHE. In addition to requiring an established relationship, CMS requires that the billing provider be eligible to furnish evaluation and management services in order to receive reimbursement for RPM. Establishing an appropriate provider-patient relationship for the purposes of rendering RPM generally requires the provider to furnish the patient with new patient evaluation and management ("E/M") services.[16] This E/M service allows the provider an opportunity to collect patient history and conduct a patient examination.

03
MEDICAID

Another major source of telehealth related policy comes from changes in Medicaid administration. However, because Medicaid is administered through both state and federal regulation, changes in telehealth regulation are largely state dependent. Nonetheless, virtually every state and most United States territories expanded telehealth Medicaid coverage in some way during the PHE. Many of the common regulatory changes include expanded coverage of health care services delivered via telephone, electronic and other virtual means; including the home as the originating site for telehealth care services; and pay parity for some or all services delivered via telehealth.[17] State adoption of such changes has been variable, for example:

- All 50 states and Washington, D.C. reimburse synchronous two-way audiovisual telehealth communication for at least some health care services.
- 28 states reimburse store-and-forward telehealth services whereby health information is electronically transmitted to a provider (usually a specialist) who renders a health care service outside of a real-time interaction.
- 34 states reimburse remote patient monitoring, or using synchronous or asynchronous digital technology to collect or monitor patient health data at an originating site, transmit the data to a distant site provider and enable the provider to diagnose, treat, educate, or otherwise provide care to the program beneficiary.
- 35 states reimburse some forms of audio only telehealth.[18]

Notably, many states confine the types of telehealth care that is reimbursable through Medicaid and other state-level programs to *synchronous* or *real-time audio-video* care. This restriction limits widescale acceptability of store-and-forward telehealth practices and remote monitoring.

Finally, Medicaid guidelines require all providers to practice within the scope of their state licensure or State Practice

13 85 FR 85866.

14 2023 Physician Fee Schedule Final Rule, available at https://www.federalregister.gov/documents/2022/11/18/2022-23873/medicare-and-medicaid-programs-cy-2023-payment-policies-under-the-physician-fee-schedule-and-other#p-555.

15 Telehealth and Remote Patient Monitoring. See https://telehealth.hhs.gov/providers/preparing-patients-for-telehealth/telehealth-and-remote-patient-monitoring.

16 Health Care Law Today's 2021 Medicare Remote Patient Monitoring FAQs: CMS Issues Final Rule. See https://www.foley.com/en/insights/publications/2020/12/2021-remote-patient-monitoring-cms-final-rule.

17 CMS Toolkit. See https://www.cms.gov/files/document/telehealth-toolkit-providers.pdf.

18 CCHP Telehealth Coverage Summary Chart. See https://www.cms.gov/files/document/telehealth-toolkit-providers.pdf.

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Act.[19] While State Practice Acts vary both by state and by type of provider, they generally define practice standard, including whether and when practitioners are required to conduct an in-person exam, how practitioners establish a clinician-patient relationship, and what limitations might exist applicable to the rendering of a diagnosis or treatment recommendation.[20] The state-level requirements may limit what types and forms of telemedicine are reimbursable by Medicaid in any given state.

In determining which telehealth regulatory changes will remain in place post PHE, it is important to note that Medicaid waivers and flexibilities are not tied to the end of the PHE. In fact, many state Medicaid programs had some level of telehealth coverage before the PHE. This reflects the notion that Medicaid views telehealth not as a medical service itself, but as a method of a healthcare delivery. CMS has encouraged states to implement policies that will allow for continued Medicaid coverage of telehealth services.[21]

04

PRESCRIBING FLEXIBILITIES FOR CONTROLLED SUBSTANCES

Significant telehealth-related changes to prescribing post-PHE were enacted on May 10, 2023, in the Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications.[22] This rule extended the "full set" of the DEA's PHE-related waivers for prescribing controlled substances via telemedicine through November 11, 2023. Additionally, the waivers will continue to apply for an additional year to any provider-patient relationship established within the initial extension period. Put another way, for those established provider-patient relationships, the extension will apply through November 11, 2024.

Prior to the PHE, pursuant to the Ryan Haight Act, providers prescribing controlled substances were required to conduct at least one in-person examination of a patient before prescribing a controlled substance to that patient. The Act further provides DEA registration requirements for providers who prescribe medications via telehealth. This Act was put in place to prevent the proliferation of "rogue internet sites" that unlawfully dispensed controlled substances without ensuring that a proper provider-patient relationship had been established.[23] During the PHE, and now through November 11, 2023, the DEA waived three significant requirements of the Ryan Haight Act relating to in-person examinations and DEA registration requirements.

First, DEA-registered providers who are authorized to prescribe to a patient in a different state are no longer required to register with the DEA in the patient's local state. Put another way, DEA-registered providers are only required to be registered in one state if they are authorized to prescribe medications in both the state in which the practitioner is registered and the state in which the medication dispensing actually occurs. Prior to the PHE, the prescribing provider was required to obtain DEA registration in both the state in which they practice and the state in which the medication is dispensed if the patient is being prescribed via telemedicine.

The second and third waivers relate to in-person examination requirements for providers prescribing via telemedicine. Under the Controlled Substances Act, a prescription for a controlled substance must generally be predicated on an in-person examination.[24] However, during the PHE, the requirement that patients first have an in-person examination was waived. For the duration of the PHE and now through November 11, 2023, prescribers are authorized to prescribe all schedule II-V controlled substances in all areas of the United States for new or existing patients without first conducting an in-person examination. The third and final waiver applies the in-person examination exception to the prescribing of buprenorphine. Similar to the second waiver, providers prescribing buprenorphine for the treatment of opioid use disorder may do so without a preliminary in-person examination. However, unlike other schedule II-V controlled substances, a

19 State Medicaid and CHIP Telehealth Toolkit. Available at https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit.pdf.

20 For additional information, see Foley & Lardner's Telemedicine and Scope of Practice Issues. Available at https://www.foley.com/en/services/industry-teams/health-care-life-sciences/telemedicine--digital-health/telemedicine-and-scope-of-practice-issues.

21 CMS Waivers, Flexibilities, and the Transition Forward from the COVID-19 Public Health Emergency. See https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit.pdf.

22 Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications. See https://www.federalregister.gov/documents/2023/05/10/2023-09936/temporary-extension-of-covid-19-telemedicine-flexibilities-for-prescription-of-controlled.

23 Health Care Law Today's DEA Extends Telemedicine Flexibilities for Prescribing of Controlled Medications. See https://www.foley.com/en/insights/publications/2023/05/dea-telemedicine-controlled-medications.

24 21 U.S.C. Sec. 829 (e)(1).

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provider need only provide an assessment via telephone and is not required to use any visual or video medium to support the underlying provider-patient relationship and ensuing prescription.

Prior to issuing the extensions described above, the DEA proposed rules on February 24, 2023, that would permanently enshrine some telemedicine flexibilities while eliminating others. In response to their proposed rule, the DEA received 38,369 public comments. The DEA has stated that this temporary extension was issued to allow them the necessary time to review all comments and move forward with one or more of the rules proposed earlier. Based on earlier statements, it is likely that the DEA will issue a new final rule based on the previously proposed rule prior to the expiration of the extension on November 11, 2024.[25]

05

HEALTH INSURANCE AND PORTABILITY AND ACCOUNTABILITY ACT ("HIPAA") DISCRETIONARY ENFORCEMENT

For the duration of the PHE, the Office of Civil Rights ("OCR") at HHS issued guidance that it would be using its enforcement discretion to not impose penalties for HIPAA-related noncompliance in connection with good faith use of telehealth services.[26] This discretion was applied to all uses of non-public facing telehealth, for any type of health service related to diagnosis or treatment. This guidance allowed covered health care providers to use any form of digital communication including Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, Teams, Zoom, or Skype to provide healthcare services without risking OCR enforcement for HIPAA noncompliance. Notably, this discretion did not apply to public facing telecommunications platforms such as TikTok, Facebook live, Twitch, or public chat rooms.

Throughout the PHE, OCR issued three additional notices describing their use of enforcement discretion to limit enforcement related to Community Based COVID-19 testing Centers , COVID-19 vaccination appointment portals, and business associates who disclose protected health information in the course of performing COVID-19-related health oversight activities.[27] On April 11, 2023, OCR announced its intention to resume enforcement relating to each of the above described activities upon the expiration of the COVID-19 PHE.[28] On May 11, 2023, OCR resumed regular enforcement of telehealth-related HIPAA noncompliance. Telehealth providers are encouraged to ensure use of appropriate video communications platforms and vendors that that provide HIPAA-compliant video communication products. Additionally, providers should ensure that all vendors enter into an appropriate HIPAA Business Associate Agreement to ensure complete compliance with HIPAA requirements.

25 Health Care Law Today's DEA Extends Telemedicine Flexibilities for Prescribing of Controlled Medications.

26 Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19. See https://www.foley.com/en/insights/publications/2023/05/dea-telemedicine-controlled-medications/ Nationwide Public Health Emergency. See https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html#:~:text=OCR%20is%20exercising%20its%20enforcement,19%20nationwide%20public%20health%20emergency.

27 Enforcement Discretion Under HIPAA To Allow Uses and Disclosures of Protected Health Information by Business Associates for Public Health and Health Oversight Activities in Response to COVID-19, available at https://www.govinfo.gov/content/pkg/FR-2020-04-07/pdf/2020-07268.pdf; Enforcement Discretion Regarding COVID-19 Community-Based Testing Sites (CBTS) During the COVID-19 Nationwide Public Health Emergency, available at https://www.govinfo.gov/content/pkg/FR-2020-05-18/pdf/2020-09099.pdf ; Enforcement Discretion Regarding Online or Web-Based Scheduling Applications for the Scheduling of Individual Appointments for COVID-19 Vaccination During the COVID-19 Nationwide Public Health Emergency available at https://www.govinfo.gov/content/pkg/FR-2021-02-24/pdf/2021-03348.pdf.

28 HHS Office for Civil Rights Announces the Expiration of COVID-19 Public Health Emergency HIPAA Notifications of Enforcement Discretion, available at https://www.hhs.gov/about/news/2023/04/11/hhs-office-for-civil-rights-announces-expiration-covid-19-public-health-emergency-hipaa-notifications-enforcement-discretion.html.

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06

DISCRETIONARY ENFORCEMENT OF COST SHARING WAIVERS AND REDUCTIONS FOR TELEHEALTH SERVICES

On March 17, 2020, HHS Office of Inspector General ("OIG") issued a policy statement indicating that it would refrain from enforcing administrative and civil sanctions ordinarily imposed for waiving or reducing patient cost sharing obligations.[29] Acknowledging the unprecedented circumstances, OIG explained that physicians and other practitioners who administer telehealth services and either reduce or waive cost sharing obligations such as copayments, coinsurance, and deductibles for Medicare beneficiaries would not be subject to Federal anti-kickback statute, civil monetary penalty, or exclusion laws related to potential associated kickbacks. The OIG limited the applicability of this policy statement to the duration of the PHE. On May 11, 2023, discretionary enforcement of civil and administrative sanctions relating to cost sharing waivers and reductions for Medicare beneficiaries receiving telehealth services officially ended with the end of the PHE.

will come to an end within the next two years. However, healthcare providers and others in the health care industry are pushing the government to reconsider abandoning these PHE provisions. Proponents argue that telehealth not only expanded access to high-demand services such as mental health care and health care in rural and underserved communities, it also defied many of the traditional concerns about telehealth creating opportunities for fraud and abuse.[30] In fact, a 2022 audit from the HHS OIG revealed that telehealth has similar rates of "upcoding," a practice of billing for more expensive services than were provided, as in-person medical care.[31] This finding was based on telehealth data from during the PHE, when regulation of telehealth was reduced.

For advocates who seek to enshrine PHE-era waivers and flexibilities, several bills are currently circulating in congress. For example, the Telemental Health Care Access Act (H.R.3432) seeks to eliminate the requirement that Medicare beneficiaries receive at least one in-person visit within six months of initiating treatment and annually thereafter. Further, the CONNECT for Health Act of 2023 seeks to remove many geographical barriers to telehealth by expanding allowable originating sites and expanding the authority of practitioners eligible to furnish telehealth services.[32] Additionally, the bill would provide resources and trainings for providers of telehealth services and would require that CMS publish data quarterly on use of telehealth services. These bills and more pose significant opportunity for the continued expansion of telehealth services in the near future.

07

CONCLUSION

While the end of the COVID-19 PHE brought a decisive end to some of the telehealth policies and regulations that have shaped the provision of health care over the past three years, much remains uncertain about the future of telehealth. The Centers for Medicare and Medicaid Services and HHS have issued guidance and regulations indicating that many of the waivers, flexibilities, and discretionary enforcement measures that have been influential throughout the PHE

"While the end of the COVID-19 PHE brought a decisive end to some of the telehealth policies and regulations that have shaped the provision of health care over the past three years, much remains uncertain about the future of telehealth

29 OIG Policy Statement Regarding Physicians and Other Practitioners that Reduce or Waive Amounts Owed by Federal Health Care Program Beneficiaries for Telehealth Services During the 2019 Novel Coronavirus (COVID-19) Outbreak, available at https://oig.hhs.gov/documents/special-advisory-bulletins/960/policy-telehealth-2020.pdf.

30 Bloomberg – Medical Industry Makes Push to Enshrine Telehealth Provisions, available at https://news.bloomberglaw.com/ip-law/medical-industry-makes-push-to-enshrine-telehealth-provisions.

31 *Id*.

32 H.R.4189, 118th Cong. (2023-2024).

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