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SUPPORT FOR PERMANENT EXPANSION OF TELEHEALTH REGULATIONS AFTER COVID-19

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Committee on Telepsychiatry, and Council on Healthcare Systems and Financing*

EXECUTIVE SUMMARY

The purpose of this paper is two-fold: first, to highlight effective and liberalizing changes to telehealth regulations that enabled healthcare to continue during the COVID-19 pandemic; and second to provide the basis for the American Psychiatric Association's (APA's) advocacy on behalf of continuing and, in some cases, expanding further the changes made during the pandemic. While changes ultimately were effectuated during COVID-19, we lost precious time in treating patients waiting for regulatory guidance and implementing the technology needed to effectuate the changes. Because the changes proved effective in expanding access to care, they should be continued after the crisis ends, and temporary regulations with some additional changes should become permanent to avoid lost time and confusion in the next crisis.

During the COVID-19 pandemic, federal and state restrictions that previously provided barriers to telehealth were temporarily lifted. This helped to facilitate the expansion of telehealth during the COVID-19 crisis, and greatly enhanced access to patient care and physician wellbeing when both groups were required to shelter in place for safety reasons.

Policy Recommendations:

As Federal and state officials and payers consider policy changes that have improved access to care during this pandemic, we make the following recommendations to ensure patients with mental health and substance use disorders continue to receive appropriate quality care.

- 1) Extend the telehealth waiver authority under COVID-19 beyond the emergency deceleration to study its impact.
- 2) Remove geographic restrictions for mental health and allowing the patients to be seen in the home.
- 3) The Drug Enforcement Agency should finalize regulations for Ryan Haight Act to allow for the prescribing of controlled substances via telehealth without a prior in-person exam.
- 4) Continue to pay telehealth services on par with in person visits.
- 5) Allow for the use of telephone (audio) only communications for evaluation and management and behavioral health services to patients with mental health and substance use disorders when it is in the patient's best interest, and should be paid at no less than an in person visit.
- 6) Maintain coverage and increased payment for the telephone evaluation and management services.
- 7) Remove frequency limitations for existing telehealth services in inpatient settings and nursing facilities.
- 8) Include all services on the expanded Medicare-approved telehealth list including group psychotherapy.
- 9) Allow teaching physicians to provide direct supervision of medical residents remotely through telehealth.

- 10) Telehealth consultations should include any synchronous or asynchronous consultation with a patient by regular telephone, text, or videoconferencing employed at the clinical discretion of the physician who is providing treatment within professionally accepted standards of care.
- 11) The Federal government should fund research to understand the successes, challenges, barriers, innovations, safety, training needs, and workforce utilization of telehealth across the healthcare delivery landscape during the public health emergency. New research methodologies and funding mechanisms should be advanced that are rapid, flexible, and adaptive to provide timely information in the current dynamic environment.

THE IMPORTANCE OF TELEHEALTH DURING A DISASTER

Telehealth is a crucial tool for optimal disaster management of mental and physical health, but its full potential cannot be realized if it is put into place only in response to a disaster. This important modality was used extensively for the first time in the recent US hurricane disasters, prior to the COVID-19 pandemic. However, modifications in regulations at that time were temporary, and regulatory changes, which inevitably cause delays in disaster support, should not need to be reinstated each time there is a disaster.

The use of telehealth in disaster situations has been extensively described in the literature, especially in the military. A recent, large NATO project described how multinational telemedicine systems could be used in disaster response.¹ In brief, telehealth can provide rapid access to much-needed quality care for both victims and responders in all manner of disasters; in individual and group settings; and across multiple specialties ranging from emergency medicine, to surgical assessments and consultations, to mental health. Telehealth is also demonstrably useful to improve communications across the disaster management scenario and has a substantial place in the recovery and re-adjustment phases. To ensure the ready availability of these important telehealth functions, regulations initiated in response to the pandemic need to be permanent.

To its credit, the federal government recognized the potential usefulness of telehealth for the COVID-19 pandemic and took swift and decisive action to dramatically reduce, waive, or suspend regulations that impede implementation of important telehealth activities. The result was widespread rapid utilization of telehealth in multiple medical specialties, especially mental health.² Ready availability of telehealth practice has many advantages during disasters. For example, primary care assessments are far safer for both patients and providers and can also enhance continuity of care nationally. Use of telehealth also enables flexible culturally competent care (e.g., clinician skill, language) for refugees when there is an international disaster or upheaval.

We applaud the rapid, decisive government action to make needed regulation changes during the pandemic. However, valuable time was still lost in getting clinicians and healthcare systems up to speed in their ability to provide these services because providers and patients needed to learn new regulations and new ways of interacting. Agencies could not have adequate telehealth disaster plans in place

¹ Doarn, CR, Latifi R, Hostiu C, Arafat R, Zoicas C. A multinational Telemedicine Systems for Disaster Response: Opportunities and Challenges. 2017. Vol 130 of NATO Science for Peace and Security Series.

² Yellowlees P, Nakagawa, K et al. Rapid Conversion of an Academic Outpatient Psychiatric Clinic to a 100% Virtual Telepsychiatry Clinic: Lessons Learned in Response to COVID-19. April 2020 Psychiatric Services. Published online.

because they could not know what changes the government would make to regulations. If telehealth regulations are permanently changed, and telehealth becomes a regular part of ongoing medical care, there will be a much larger workforce prepared to provide telehealth services both faster and more effectively at the time of the next crisis. This is especially important for mental health care where the ability to establish and maintain a strong connection to patients is crucial to effective interventions. Permanent regulatory changes would enable clinicians to develop a comfort level with telehealth and the regulations to be able to use it most effectively in response to a disaster. Additionally, healthcare organizations can have effective disaster management plans in place without having to wait to see what the regulations will be. This could make a critical difference in our ability to optimize the provision of immediate healthcare during a disaster. Effective early intervention is one of the most important ways to manage disasters.

SUMMARY OF THE HISTORY OF RECENTLY LIFTED REGULATIONS IN FOUR MAIN AREAS

1. LICENSING

Prior to the current pandemic response, a complex web of state licensure laws, policies, and regulations substantially obstructed the progress of telemedicine. As a result, many Americans in need of medical care were left untreated.

Through a Waiver or Modification of Requirements Under Section 1135 of the Social Security Act, the "requirement that physicians or other health care professionals hold licenses in the State in which they provide services, if they have an equivalent license from another State (and are not affirmatively barred from practice in that State or any State a part of which is included in the emergency area)" was waived.³ This waiver is only for the purposes of Medicare reimbursement and only applies to federal and not state requirements for licensure. In effect, the waiver has mostly served to set a precedent for state medical boards to consider. Physicians are still beholden to restrictive rules from individual state medical boards.

Fortunately, many state medical boards have recognized the need to make licensure requirements easier to navigate during the public health emergency. The Federation of State Medical Boards (FSMB) is tracking states that are modifying their physician licensure requirements or renewals in the context of COVID-19 at FSMB.org.⁴ While this may help reduce some hurdles to practicing across state lines, physicians and other healthcare professionals have found it extremely difficult to navigate the complex patchwork of state laws and regulations related to these waivers during the crisis. COVID-19 related waiver of licensure rules varies from state-to-state and involve factors such as:

1. Which entity is issuing the waiver (e.g., governor's executive order, a regulatory body, existing law regarding licensure during a state of emergency)?
2. The type of care that can be provided through the waiver (e.g., telehealth, in-person, unspecified).
3. The types of providers that qualify for the waiver.

³. <https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx> (last accessed on June 18, 2020).

⁴. <https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf> (last accessed on June 18, 2020)

4. Whether or not the state allows prescribing of controlled substances through this waiver; whether there is an application or attestation that must be completed; and
5. Variation in reciprocity for telemedicine during the pandemic varies per state (i.e., California allows physicians licensed in other states to provide health services via telemedicine whereas Texas requires a Texas medical license even when using telemedicine).

Some believe that a separate action at the federal level that would prevent treatment providers from having to navigate these complex state-by-state waiver variations would provide all Americans with the opportunity for continuity of care and to establish new treatment relationships during this challenging time. Australia implemented a National Medical License over a decade ago to solve many issues raised in this document.

2. REIMBURSEMENT

Compensation for services delivered over communications technology can vary widely from state to state. Some states solved this to a degree by enacting parity legislation to assure that reimbursement for services delivered via telemedicine would not be disadvantaged compared to those delivered in person. Prior to the crisis, 42 states had some form of commercial insurance coverage law, but only about 10 states had true payment parity for telehealth. True payment parity enables telehealth to be reimbursed at the same rate as in-person for that same service.

Commercial payers and Medicaid often follow the lead of Medicare with respect to coverage and reimbursement, although rates vary significantly. Medicare has traditionally imposed numerous restrictions around the location, type, and number of services that can be rendered over video teleconferencing.

The COVID-19 pandemic provoked several important changes relating to payments. CMS began allowing reimbursement (though a token amount) for patient-initiated “brief check-ins” via telephone (lasting around 5 – 10 minutes). Medicare also provided for coverage of “e-visits” into all types of locations, including the patient’s home, and in all areas, not just rural ones. This allowed for established Medicare patients to have non-in-person, patient-initiated communications with their doctors without going to the doctor’s office by using online patient portals. The patient is required to initiate the inquiry, and communications can occur over a 7-day period. The patient must verbally consent to receive virtual check-in services. The Medicare coinsurance and deductible apply to these services.⁵

These changes helped correct some of the long-standing disincentives for telemedicine that had previously characterized the major federal payer—Medicare. By removing limitations around originating site disparities and the practical prohibition against services delivered into inpatient settings, access greatly improved. In the past, some rural sites (e.g. those in health professional shortage areas or outside of a metropolitan statistical area) had been covered while most urban sites were not, which often resulted in urban underserved populations being denied access to treatment. Inpatient services were covered in an inconsistent and highly impractical fashion. By eliminating these barriers, Medicare beneficiaries, many of whom are at a higher risk for COVID-19, are able to visit their doctor safely from their home, without having to go to a doctor’s office or hospital and can avoid putting themselves and

⁵. <https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet> (last accessed on June 18, 2020)

others unnecessarily at risk. Likewise, in inpatient settings, specialists could use technology from a safe environment and eliminate the need to don extensive personal protective equipment (PPE) to conduct a visit. This not only helps to extend the initially limited inventory of PPE, but also protects both patient and physician from risk of cross-contamination.

This change almost certainly helped already disadvantaged rural hospitals in obtaining desperately needed specialty services. CMS had earlier rejected the addition of initial hospital care as a covered telehealth service and would cover only certain subsequent hospital care services delivered via telemedicine. However, the frequency limitations around such services (once every three days for hospital inpatient, and once every thirty days for skilled nursing facility resident) were highly unrealistic and rarely, if ever, used. Had the goal been to limit utilization, the previous regulations made perfect sense because they were a significant barrier to telemedicine adoption and limited basic access to appropriate care.⁶

With the 1135 waiver, CMS will currently pay for any patient on Medicare to be seen over video by any provider who is correctly licensed in any state in the US as of March 6, 2020. Moreover, a wider range of providers are now able to deliver telehealth services. In addition to doctors, nurse practitioners, clinical psychologists, and licensed clinical social workers, distant site practitioners who can furnish and get payment for covered telehealth services (subject to state law) can also include physician assistants, nurse midwives, certified nurse anesthetists, clinical psychologists, clinical social workers, registered dietitians, and nutrition professionals. Telehealth visits are considered the same as in-person visits and are reimbursed with parity to in-office, in-person care. This expansion of Medicare telehealth services will continue for the duration of the COVID-19 public health emergency.

The CMS fact sheet states that the “HHS Office of Inspector General (OIG) is providing flexibility for healthcare providers to reduce or waive cost-sharing for telehealth visits paid by federal healthcare programs.” CMS has also said it will not be conducting audits to ensure that an established relationship exists between the provider and the patient (a prior requirement for telehealth billing) during this public health emergency.

3. PRESCRIBING

Restrictions and uncertainties relating to prescribing that were caused by the Ryan Haight Act (RHA) had long been a cause of physician reluctance to adopt telemedicine modalities of care.⁷ The RHA allows for 7 exceptions to the requirement of an in-person evaluation prior to prescribing controlled substances. Much energy and advocacy effort had gone into making the 5th of these 7 become a reality though advocacy for *Telemedicine Special Registration* under Section 311(h) of the Act (21 U.S.C. 831(h)). Nothing has yet come of those efforts. However, by virtue of a declaration of a public health emergency by the Secretary of Health and Human Services, the 4th exception did come to pass allowing for the practice of telemedicine to be conducted during a public health emergency under Section 319 of the Public Health Service Act (42 U.S.C. 247d). It involves patients located in such areas, and such controlled substances, as the Secretary of the U.S. Department of Health and Human Services, with the concurrence of the Administrator, designates.⁸ This exception serves most of the same purposes sought

⁶. <https://www.foley.com/en/insights/publications/2018/08/medicare-proposes-and-rejects-new-telehealth-servi>

⁷. https://www.deadiversion.usdoj.gov/fed_regs/rules/2009/fr0406.pdf

⁸. https://www.deadiversion.usdoj.gov/coronavirus.html?fbclid=IwAR019vpJk11wyB_g4OL4KeofuHqTgPEhbQbL26Qud6Z5MOFAFtoZcJDCJlg

by the special registration for the duration of the designated public health emergency. With this roadblock removed, most any technologically capable physician could transfer some portion of their work to a telemedicine environment.

This change has proven to be especially helpful to those with substance use disorders. The waiver states that "practitioners in all areas of the United States may issue prescriptions for all schedule II-V controlled substances" — as long as it is for a legitimate medical purpose; real-time, two-way interactive communication with patients has been used; and the clinician "is acting in accordance with applicable Federal and State laws." As a practical matter, this makes it possible to prescribe all the usual psychiatric medications as well as benzodiazepines, psychostimulants, and, potentially, medication-assisted treatments for opioid use disorder, such as buprenorphine, via telemedicine without the requirement of an in-person evaluation. It is worth noting that the waiver is technically only in effect for 60 days unless extended. Specific information on use of telehealth techniques in opioid treatment programs can be found in an FAQ section on the Substance Abuse and Mental Health Services Administration (SAMHSA) website providing guidance for prescribing of methadone and buprenorphine treatments.⁹

Providers must also consider state rules around controlled substance prescribing and read those in harmony with changes that are being made at the federal level. This has limited the utility of changes made at the federal level as some states have not adopted federal language or have laws or regulations that are more stringent than that at the federal level.

4. SECURITY/HIPAA

In 1996, the Health Insurance Portability and Accountability Act (HIPAA) helped increase awareness and efforts to protect patient privacy and confidentiality. While there is little doubt about the importance of these protections, HIPAA regulations have, at times, created undue barriers to patient care, particularly during crisis situations. This sort of regulatory oversight is not always lethal but can seem challenging when the healthcare system is already under great strain.

HIPAA was passed almost a quarter of a century ago, for a very different day and world. Regardless of its intention, it has been an active barrier to the flow of information between clinicians. If it is confusing to clinicians (as it often can be), patients fare even worse. As an example, patients can and often do speak with clinicians (audio only) on an iPhone at one or both ends of the conversation without HIPAA concerns. Yet, the same device using its native videoconferencing software application (*FaceTime*) has never been considered HIPAA secure.

Fortunately, in response to the public health emergency stemming from the COVID19 pandemic, a "Limited Waiver of HIPAA Sanctions and Penalties" was issued by the Secretary of the U.S. Department of Health and Human Services. This resulted in a waiver of sanctions and penalties against covered entities that do not comply with the certain provisions of the HIPAA Privacy Rule. Specifically, it allowed physicians to provide telehealth with their own phones.

Furthermore, as part of the effort to encourage citizens to stay home whenever possible, concrete steps were made to prevent certain Medicare policies from getting in the way. State Medicaid agencies were similarly allowed to expand their telehealth services without the approval of CMS during this

⁹. <https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf> (last accessed on June 19, 2020)

emergency. For the duration of this emergency declaration, the U.S. Department of Health and Human Services indicated that it would waive HIPAA penalties for using non-HIPAA compliant videoconferencing software. This allowed for popular platforms such as *Skype* (basic) and *FaceTime* to be used to conduct telehealth sessions via video.¹⁰

This has been a rapidly evolving area and it is by no means settled at this time. Online resources are in place to assist in staying up to date regarding these changes. The American Psychiatric Association provides a *Telepsychiatry Toolkit*,¹¹ and the American Telemedicine Association serves as a repository for many useful links to regulatory and administrative changes as they are announced.¹²

Most of the major adjustments needed to allow the system to respond optimally to the current crisis have by now been put in place. There are a few items remaining on the “telemedicine wish list” (most notably enabling legislation to move forward with more asynchronous modes of clinical care provision).

The chart below summarizes the evolution of telemedicine in mental health before and during COVID-19 and provides APA’s recommendations for the future.

TELEMENTAL HEALTH DOMAINS FOR ADVOCACY	What Happened Before COVID	What Happened During COVID	APA Recommendations Moving Forward
Licensing	Complex web of licensure laws, policies, and regulations obstructed telemedicine.	Despite waiver of licensing requirement for Medicare reimbursement and some states’ decision to follow suit, complex patchwork of laws and regulations remains.	Eliminate restrictions regarding geographic and “originating” site (i.e. where patient is physically at time of visit).
Reimbursement	Medicare, Medicaid and private insurers imposed restrictions on location, type and number of services; reimbursement varied widely and was not on-par with in-person care.	Expansion of reimbursement for types of service, “originating site” (e.g. patient at home, on inpatient service), range of providers, and parity with in-person visits.	Medicare, Medicaid, and private insurers should reimburse at the same rate as in-person for telehealth on the basis of care delivered.
Prescribing	Requirements of the Ryan-Haight Act posed obstacles to	HHS’ declaration of Public Health Emergency allowed	DEA should prioritize issuing waivers for telehealth prescribing of

¹⁰. <https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/index.html>

¹¹. <https://www.psychiatry.org/psychiatrists/practice/telepsychiatry/toolkit>

¹². <https://www.americantelemed.org/covid-19/>

	the prescribing of controlled substances.	for prescribing of Schedule II-V medications across the US for legitimate purpose, with 2-way (prescriber-patient) communication, and according to federal and state law.	controlled substances so that telehealth prescribing can be the same as in-person when conducted via live, interactive, audio-video technology.
HIPAA	Efforts to protect patient privacy and confidentiality enacted in 1996 created confusion and barriers to care, especially in a newly digital world.	HHS issued a limited HIPAA waiver allowing for use of phone and non-HIPAA-compliant videoconferencing platforms.	HIPAA technology should be used. Telehealth visits should include any synchronous or asynchronous consultation with a regular telephone, text, or videoconferencing at the discretion of the physician who provides treatment according to accepted standards of care. Any national and local standard for patient consent for telehealth should be verbal (nonwritten) consent.