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Telebehavioral Health Developments: 2023 and Beyond

Hospital Association of Southern California – 2023 Annual Meeting

May 18, 2023

Alicia Macklin, JD, MPH; Partner
Andrea Frey, JD, MPH; Senior Counsel

Disclaimer Slide

Sometimes lawyers put the fine print first

This presentation is solely intended for educational purposes and the matters presented herein do not constitute legal advice.

Attendees should consult with legal counsel and/or risk management professional(s) for advice and guidance regarding particular situations.

Agenda

1. **Current Context: Exponential Rise in Telebehavioral Health**
2. **Federal Considerations around Use of Telebehavioral Health/OUD treatment**
   - End of the Public Health Emergency (PHE)
   - Medicare Telehealth Services
   - DEA/SAMHSA Temporary Controlled Substances Rule
   - Enforcement Scrutiny
3. **California/State Developments**
   - DHCS's Medi-Cal Telehealth Policy
   - Telehealth parity (and mental health parity laws)
   - State licensure requirements and other considerations with telebehavioral health

Current Telebehavioral Health Landscape

- Telehealth-delivered behavioral health services **spiked 45-fold** since the onset of the pandemic, driven in part by surge in anxiety and depression
  - Telehealth more accessible for patients during pandemic
  - Unprecedented workforce shortage of behavioral health providers

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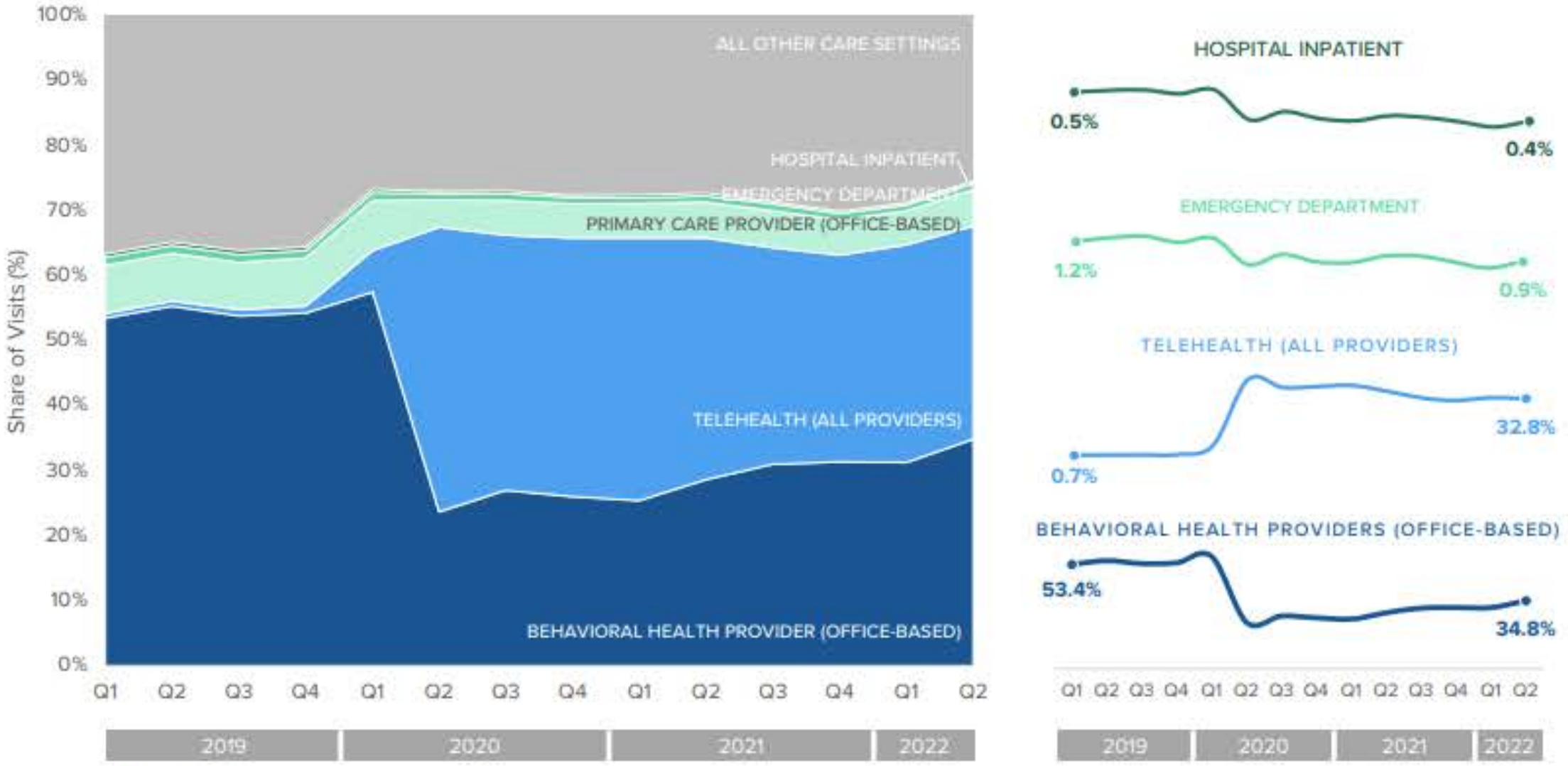
SHARE OF BEHAVIORAL HEALTH VISITS IN MAJOR CARE SETTINGS, Q1 2019-Q2 2022



Source: Trilliant Health national all-payer claims database.

Current Telebehavioral Health Landscape

Improvements around Behavioral Healthcare Quality During Pandemic

Brief Report

March 29, 2023

Association of Receipt of Opioid Use Disorder–Related Telehealth Services and Medications for Opioid Use Disorder With Fatal Drug Overdoses Among Medicare Beneficiaries Before and During the COVID-19 Pandemic

Christopher M. Jones, PharmD, DrPH[1]; Carla Shoff, PhD[2]; Carlos Blanco, MD, PhD[3]; et al

ORIGINAL ARTICLES

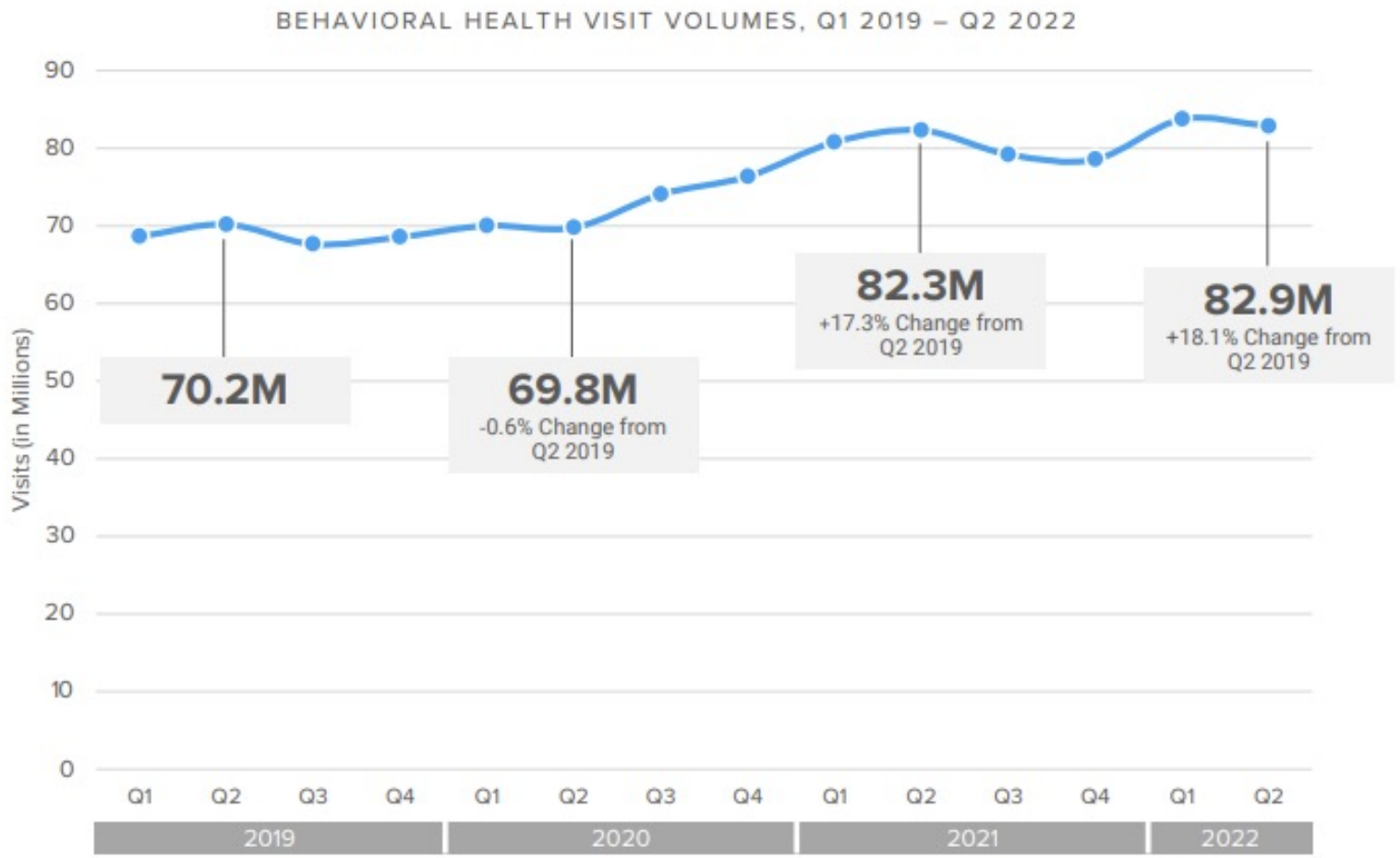
Health-care–Related Practices in Virtual Behavioral Health Treatment for Major Depression Before and During the COVID-19 Pandemic

Weinfield, Nancy S. PhD[*]; Tavel, Heather M. MPH[†]; Goodrich, Glenn MS[†]; McCracken, Courtney E. PhD[‡]; Basra, Sundeep MPH[*]; Gander, Jennifer C. PhD[‡]; Davis, Teaniese L. PhD[‡]; Ritzwoller, Debra P. PhD[†]; Roblin, Douglas W. PhD[*]

DEMAND: VOLUME

Behavioral Health Demand Continues To Grow Post-Pandemic

In Q2 2020, behavioral health volumes were 0.6% lower than in Q2 2019. By Q2 2022, volumes were 18.1% above pre-pandemic levels. Increasing prevalence of behavioral health conditions can exacerbate other medical comorbidities and drive higher spending.



Source: Trilliant Health national all-payer claims database.

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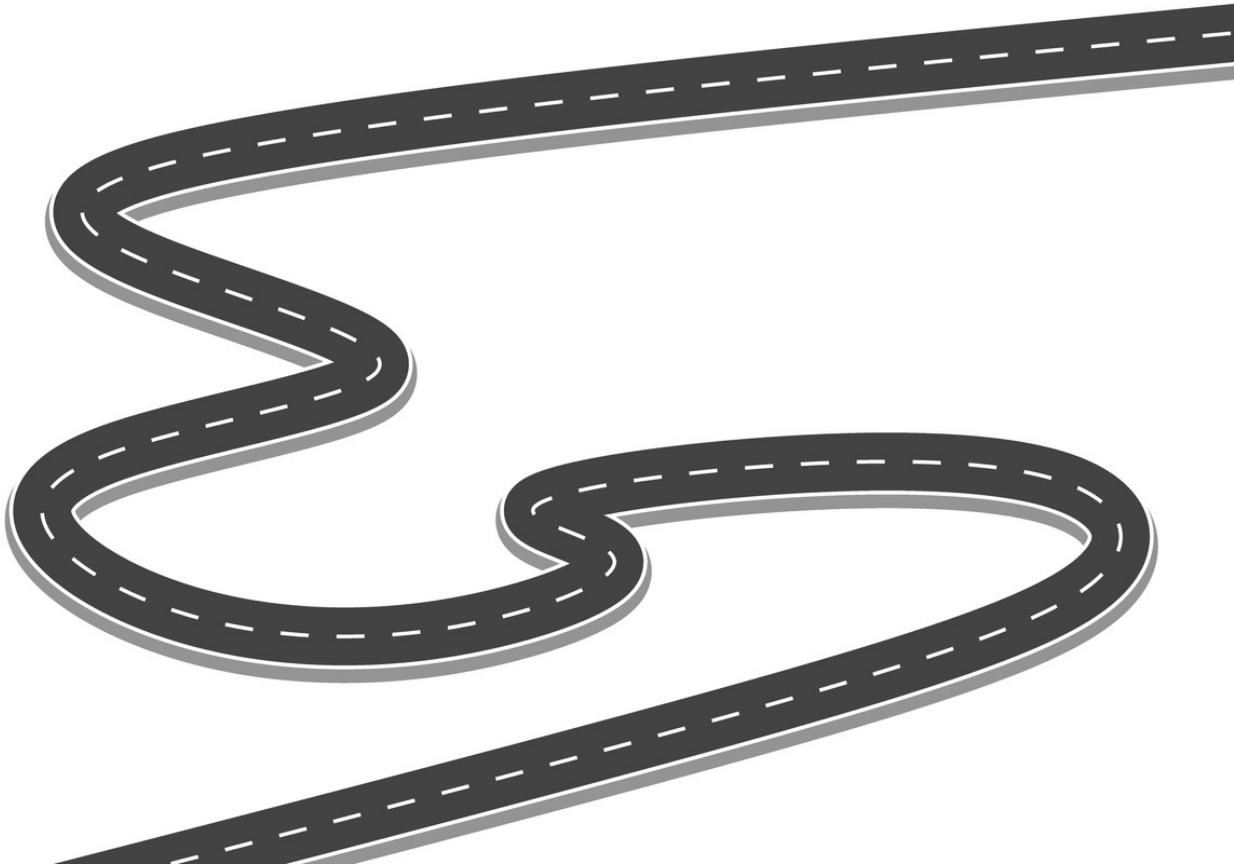
Federal Developments

The PHE is Over

Federal PHE Terminated May 11, 2023

Based on current COVID-19 trends, the Department of Health and Human Services (HHS) let the federal PHE for COVID-19, expire **at the end of the day on May 11, 2023**.



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Medicare Telehealth Services

What We Know

Historically, telehealth services only covered by Medicare when:

1) The service is on the approved “Medicare telehealth services” list
2) The patient is in -
    1) a qualifying originating site facility, and
    2) in a qualifying rural (or otherwise qualifying) area
3) Rendered by “qualified practitioner”
4) Furnished via an “interactive telecommunications system.”

See 42 U.S.C. § 1395m(m); 42 C.F.R. § 410.78

Medicare Telehealth Services

What We Know

During PHE, CMS approved following flexibilities:

1) The service is on the approved “Medicare telehealth services” list
   → *Significantly Expanded*
2) The patient is located in -
   1) a qualifying originating site facility, and → *Waived*
   2) in a qualifying rural (or otherwise qualifying) area → *Waived*
3) Rendered by “qualified provider” → *Significantly Expanded*
4) Furnished via an “interactive telecommunications system” → *Waived*

Medicare Telehealth Services

What We Know – Post-PHE

*Temporary Medicare Changes thru **December 31, 2024***

- Extended reimbursement of **certain non-behavioral/mental health telehealth services** regardless of where the patient or provider is located (i.e., the patient can be at home)
- Medicare payment parity
- Delayed the imposition of the pre-requisite in-person requirement for mental health services furnished through telehealth until after December 31, 2024

Medicare Telehealth Services

What We Know – Post-PHE

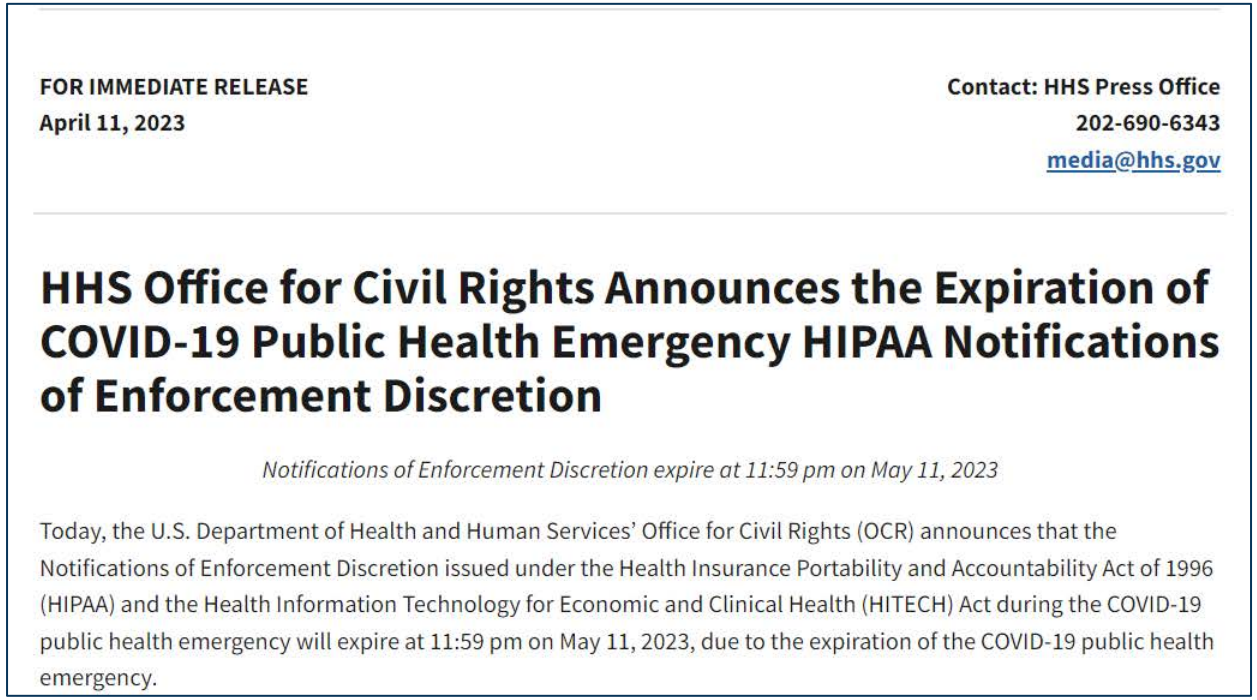
- Even after December 31, 2024, **mental health services may still be furnished through telehealth** by clinical psychologists, clinical social workers, or other practitioners to patients located at their homes, subject to the following:
  - the patient must have an **in-person mental health visit 6 months before** the telecommunications visit; and
  - there generally must be an in-person mental health visit at least every twelve months during active treatment.

… *unless* patient isn't capable of or does not consent to video technology.

HIPAA Flexibilities

OCR Enforcement Discretion Ended

- Flexibility ended for covered entities under HIPAA to use *any* non-public facing application in connection with the "good faith provision of telehealth" without risking federal penalties
- OCR providing covered entities 90-calendar day transition period



FOR IMMEDIATE RELEASE
April 11, 2023

Contact: HHS Press Office
202-690-6343
media@hhs.gov

HHS Office for Civil Rights Announces the Expiration of COVID-19 Public Health Emergency HIPAA Notifications of Enforcement Discretion

Notifications of Enforcement Discretion expire at 11:59 pm on May 11, 2023

Today, the U.S. Department of Health and Human Services' Office for Civil Rights (OCR) announces that the Notifications of Enforcement Discretion issued under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act during the COVID-19 public health emergency will expire at 11:59 pm on May 11, 2023, due to the expiration of the COVID-19 public health emergency.

Remote Prescribing: Controlled Substances

Pre-Pandemic Regulatory Landscape

- **Ryan Haight Online Pharmacy Consumer Protection Act of 2008**
  - Enacted in response to “pill mills” of the late 90’s and early 2000’s.
- Ryan Haight Act only allows practitioners to prescribe controlled substances **for a legitimate medical purpose**, in the usual course of practice, after performing **an in-person examination of the patient**, unless an exception is satisfied.

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Remote Prescribing: Controlled Substances

Pre-Pandemic Regulatory Landscape, continued

- **Telemedicine exceptions to in-person examination requirement:**
  - Treatment in a hospital or clinic
  - Treatment in the physical presence of a practitioner
  - Indian Health Service or tribal organization
  - PHE
  - Special Registration
  - Dep't of Veteran Affairs medical emergency
  - Other circumstances specified by regulation

See 21 C.F.R. § 1300.04

Telemedicine Special Registration

2008
Ryan Haight Act

2015
DEA and DOJ Proposed Rule to Permit Special Registration?

2016

2018
The SUPPORT Act: gave DEA one-year deadline

2020
COVID-19 PHE and DEA Waiver

Remote Prescribing: Controlled Substances

PHE Changes

- During the COVID-19 PHE, DEA waived:
  - the prior in-person examination requirement, *and*
  - the state-specific DEA registration requirement under a “practice of telemedicine” exception which applies during PHE

U.S. Department of Justice
Drug Enforcement Administration

Drug Enforcement Administration

Headquarters

March 20, 2020 **For Immediate Release**

Contact: Media Relations

Phone Number: (571) 776-2508

DEA’s response to COVID-19

DEA is protecting the nation’s prescription drug supply chain

Remote Prescribing: Controlled Substances

March 1 Proposed Rules for Post-PHE

- **Telemedicine Prescription:** 30-Day Rule for Schedule III-V controlled substances (and buprenorphine).
- **Qualified Telemedicine Referral:** Prescribing physician can treat via telehealth relying upon in-person exam performed by another physician.
- **3-Way Consultation Prescription**: Physician not present with the patient can prescribe based on in-person physician's examination.
- **180 Days Off-Ramp:** for Relationships established during the PHE.
- **Audio-Only Pathway:** Prescriptions may be issued for controlled medication pursuant to an audio-only interaction if requirements satisfied.

What about the telemedicine registration?

DEA did not propose to establish highly anticipated telemedicine special registration

- In the Proposed Rule, DEA explains that it felt the registration process would be "unduly burdensome."
- DEA suggests that the new pathways satisfy their statutory obligation to create a registration (without explanation).

Remote Prescribing: Buprenorphine

March 1 Proposed Rules for Post-PHE

- Contains similar technical requirements to those in DEA's Telehealth Proposed Rule
- No remote prescribing for pain or any other purpose besides treatment of opioid use disorder

OTP and OUD Treatment

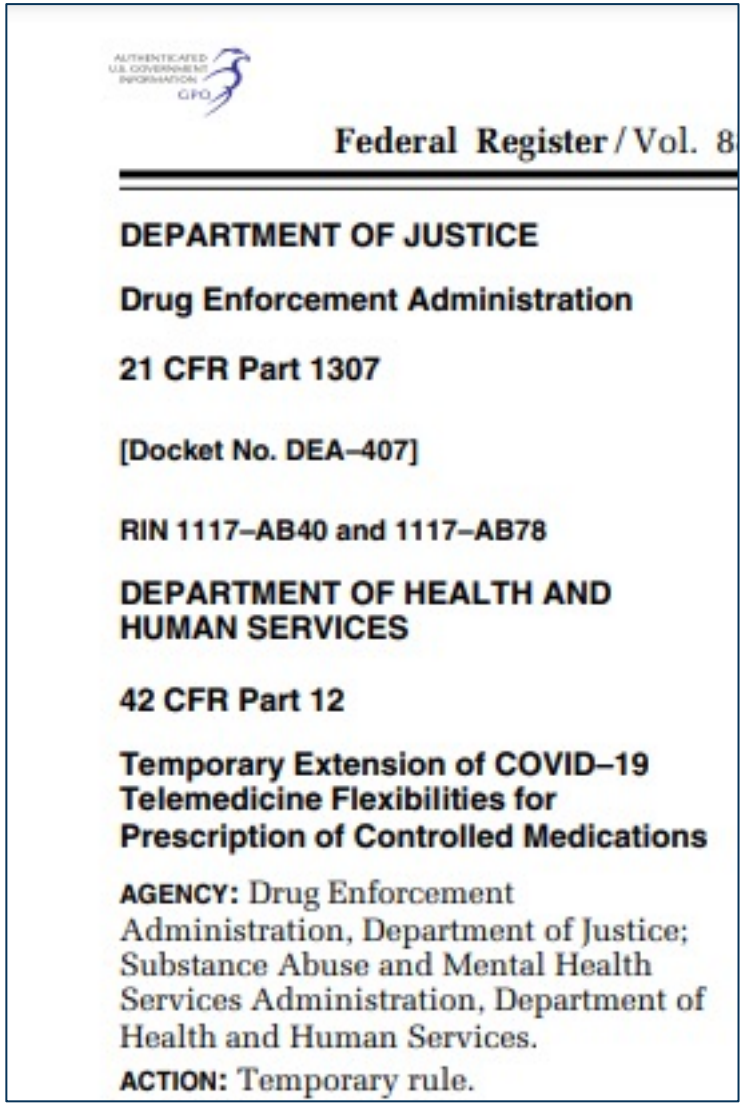
Opioid Treatment Programs and Prescribing Buprenorphine via Telehealth

- During PHE, SAMHSA:
  - Allowed prescribers to initiate MAT for *new* patients using audiovisual or audio-only connection (not methadone)
  - Increased amount of take-home methadone a patient may receive, up to a 28-day supply
- December 2022:
  - SAMHSA issued proposed modifications that would make PHE medication flexibilities permanent, and update standards for OTPs
- January 2023:
  - DEA and SAMHSA release guidance confirming CAA of 2023 eliminated DATA-Waiver program (including associated patient caps)

What's Next for DEA and SAMHSA?

Temporary Rule extends flexibilities

- DEA received a record ***38,000 comments*** on its proposed telemedicine rules, according to a statement from DEA Administrator Anne Milgram issued May 3
- Given the record number of comments, the DEA, in concert with SAMHSA, issued a Temporary Rule extending COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications on May 10



Federal Register / Vol. 8

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1307

[Docket No. DEA–407]

RIN 1117–AB40 and 1117–AB78

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 12

Temporary Extension of COVID–19 Telemedicine Flexibilities for Prescription of Controlled Medications

AGENCY: Drug Enforcement Administration, Department of Justice; Substance Abuse and Mental Health Services Administration, Department of Health and Human Services.

ACTION: Temporary rule.

Remote Prescribing: Controlled Substances

Pre-Pandemic Regulatory Landscape, continued

Reminder:

- States have their own Controlled Substances Act; most are less strict than the federal CSA.
- About **half of states** have an independent controlled substances registration requirement, separate from the federal DEA requirement (not California).

Oversight and Enforcement Actions

Hint: Enforcement Likely!

DEA United States Drug Enforcement Administration

THE UNITED STATES DEPARTMENT of JUSTICE

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JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE — Wednesday, July 20, 2022

Justice Department Charges Dozens for $1.2 Billion in Health Care Fraud

Nationwide Coordinated Law Enforcement Action to Combat Telemedicine, Clinical Laboratory, and Durable Medical Equipment Fraud

The Department of Justice today announced criminal charges against 36 defendants in 13 federal districts across the United States for more than $1.2 billion in alleged fraudulent telemedicine, cardiovascular and cancer genetic testing, and durable medical equipment (DME) schemes.

The nationwide coordinated law enforcement action includes criminal charges against a telemedicine company executive, owners and executives of clinical laboratories, durable medical equipment companies, marketing organizations, and medical professionals. In connection with the enforcement action, the department seized over $8 million in cash, luxury vehicles, and other fraud proceeds.

Additionally, the Centers for Medicare & Medicaid Services (CMS), Center for Program Integrity (CPI) announced today that it took administrative actions against 52 providers involved in similar schemes.

"The Department of Justice is committed to prosecuting people who abuse our health care system and exploit telemedicine technologies in fraud and bribery schemes," said Assistant Attorney General Kenneth A. Polite, Jr. of the Justice Department's Criminal Division. "This enforcement action demonstrates that the department will do everything in its power to protect the health care systems our communities rely on from people looking to defraud them for their own personal gain."

Oversight and Enforcement Actions

Hint: Enforcement Likely!

Why OIG Did This Audit

In response to the COVID-19 public health emergency (PHE), CMS temporarily expanded access to health services provided via telehealth. From March 2020 through February 2021 (audit period), Medicare Part B paid $1 billion for psychotherapy services, including telehealth services, provided to Medicare enrollees nationwide. Prior OIG audits of four psychotherapy providers identified high improper payment rates for psychotherapy services furnished before the PHE. We conducted this nationwide audit to determine whether compliance issues identified in the prior audits occurred during our audit period. To understand the challenges that providers faced when furnishing telehealth services, we also surveyed providers on their experience with providing those services to people enrolled in Medicare.

Our objective was to determine whether providers met Medicare requirements and guidance when billing for psychotherapy services, including services provided via telehealth.

- May 2023 OIG Report found Medicare improperly paid for some psychotherapy services, including those provided via telehealth, during the first year of COVID-19 PHE
  - Reviewed services provided from March 1, 2020 through February 28, 2021
  - ~ 57% of the total amount Medicare Part B paid for psychotherapy services was for telehealth services (compared with less than 1% in 2019)
  - Also included findings on providers' experience with telehealth services

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State Developments

DHCS Medi-Cal Telehealth Policy

Behavioral Health (SMHS, DMC-ODS, DMC)

Substantive Area	Continues PHE Policy?	Additional Detail
Baseline coverage of synchronous telehealth	✅	• Continue coverage of synchronous video, audio-only telehealth • Medi-Cal covered services are reimbursable for SMHS, DMC-ODS, and DMC
Payment parity	✅	• "Rendering services via telehealth does not change the payment methodologies or reimbursement rates to Medi-Cal behavioral health delivery systems." *BHIN No. 23-018.* Still excludes virtual communications.

Establish New Patients via Telehealth	❌	• New patients = in-person or via synchronous video telehealth visits
		• Exceptions for audio-only synchronous interaction:
		  • when the visit is related to sensitive services (including covered SMHS, DMC-ODS, and DMC),
		  • when the patient requests audio-only or attests they do not have access to video, or
		  • when the visit is otherwise designated by the Department.

Patient Consent	❌ + additional requirements	• New consent requirements:
		  • Right to in-person services
		  • Voluntary nature of consent
		  • Availability of transportation to access in-person services
		  • Limitations/risks of receiving services via telehealth
		  • Notification of the right to make complaints

DHCS Medi-Cal Telehealth Policy

Behavioral Health (SMHS, DMC-ODS, DMC), cont.

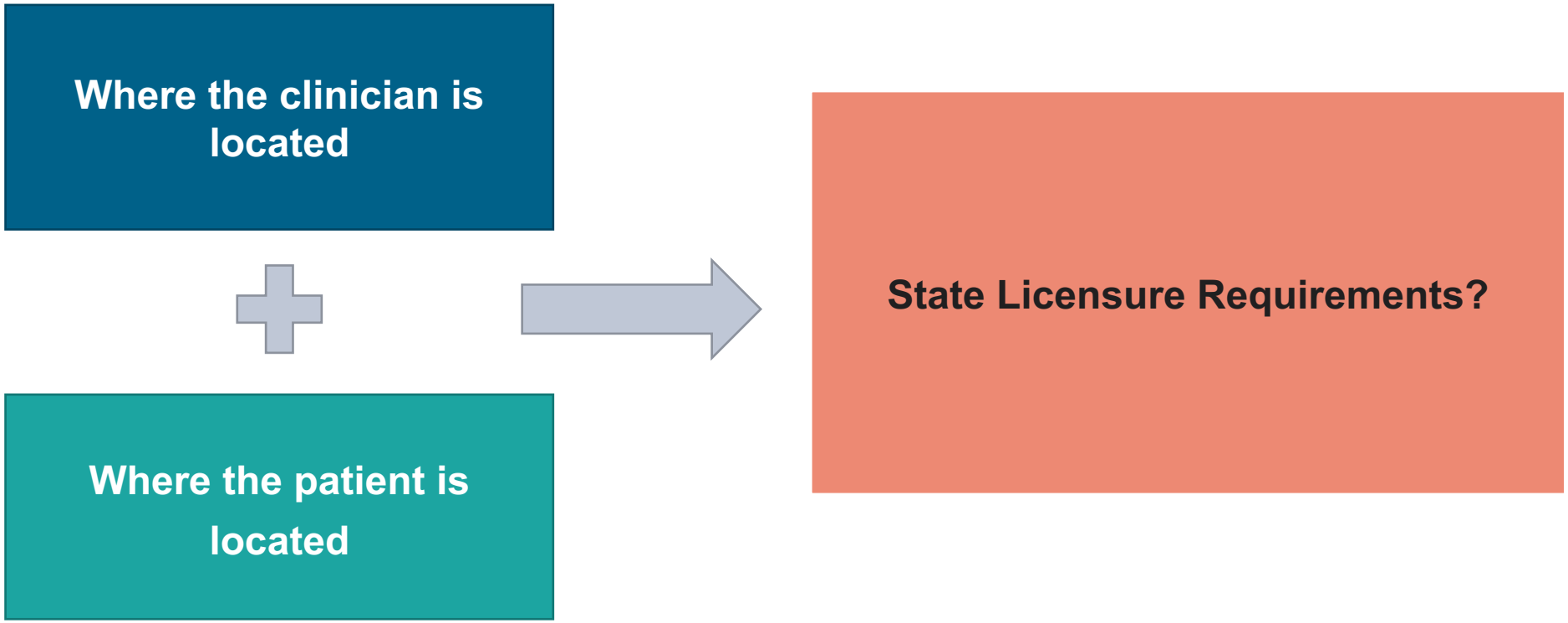
Substantive Area	Continues PHE Policies?	Additional Details
New Video Requirement	*New policy*	• No sooner than January 1, 2024, provide patients the choice of a video telehealth modality when care is provided via telehealth. • If a provider offers audio-only telehealth services, must provide option for video services to preserve beneficiary choice.
New In-Person Services Requirement	*New policy*	• No sooner than January 1, 2024, any provider furnishing services through telehealth to also either offer services (1) via in-person face-to-face contact or (2) link the beneficiary to in-person care. • If linking the beneficiary to in-person, must provide for a referral to and a facilitation of in-person care.
Network Adequacy	*New policy*	• County Mental Health Plans and DMC-ODS plans can use clinically appropriate telehealth services as a means of demonstrating compliance with the network adequacy time or distance standards. • All members have the right to an in-person appointment still and telehealth can only be provided when medically appropriate.

Parity Laws

Mental Health and Telehealth

- **Mental Health Parity**
  - Federal & State
- **Telehealth Parity**
  - Coverage/Service vs. Payment
  - Federal & State

State Licensure Considerations



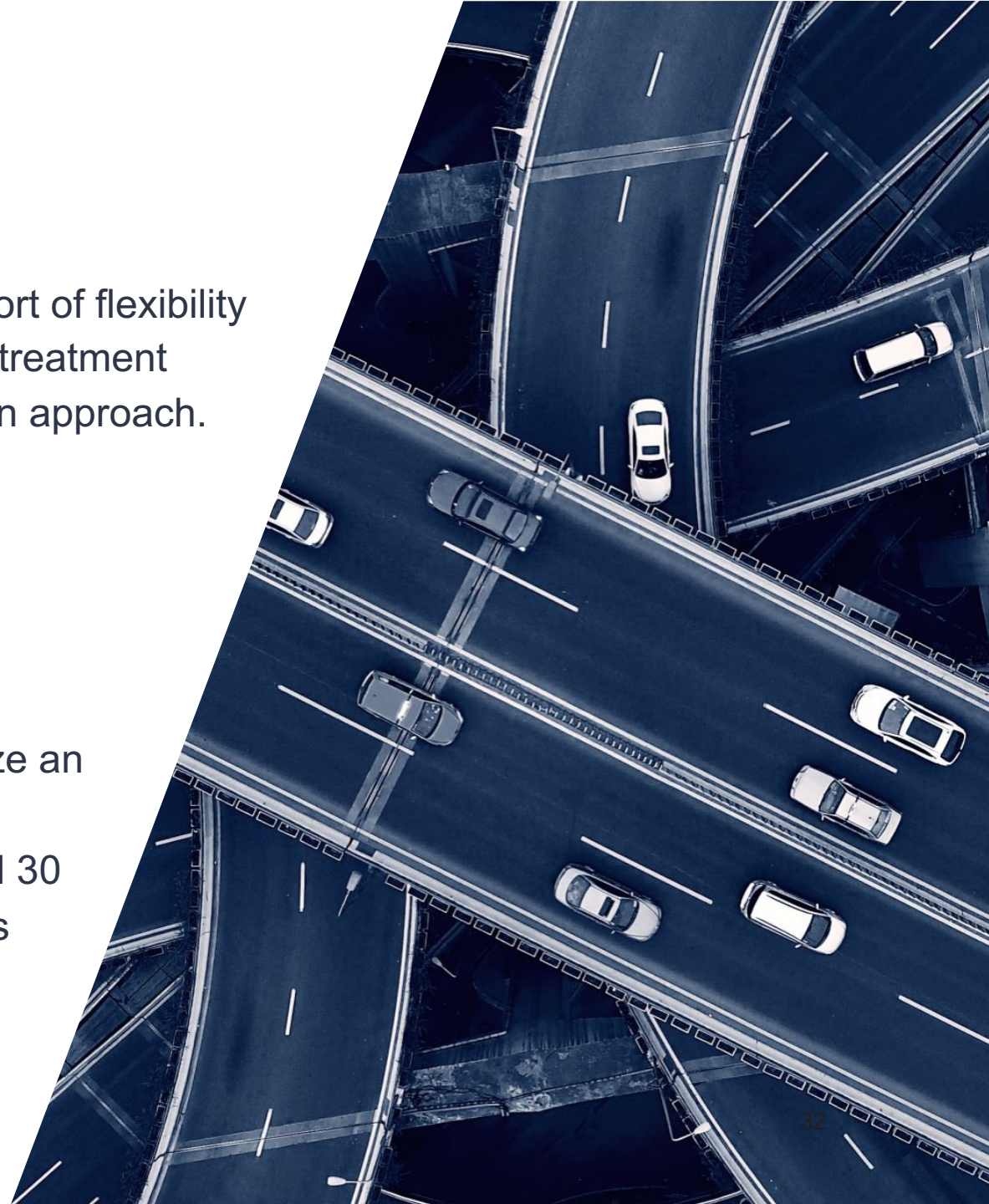
State Licensure Considerations

Interstate Services Post-Pandemic

During pandemic: Nearly every state provided *some* sort of flexibility regarding licensure requirements to facilitate telehealth treatment during the pandemic, but no two states were the same in approach.

National Trends post-pandemic:

- States are introducing telehealth licensure paths, but progress is slow. Rules vary for physicians and non-physician practitioners.
    - In California, proposed legislation would authorize an LMFT, CSW, or CPC licensed in another state to provide services in CA for a period not to exceed 30 consecutive days in cal year in certain conditions
- Adoption of interstate licensure compact laws



Don’t forget…

Other California legal requirements and issues for telebehavioral health practice (not exhaustive)

- Obtaining and documenting **patient consent**
- **Verification** of patient identity during initial clinical encounter
- Medical record **documentation** to support claim
- Data **privacy & security** of platform (HIPAA, Part 2, CMIA, LPS)
- **Credentialing/privileging** and accreditation requirements for practitioners on your medical staff
- Telehealth **equipment maintenance** and upkeep
- Compliance of arrangements with federal (if applicable) and/or state **fraud and abuse** laws, including anti-kickback and self-referral laws
- **Scope of practice** issues
- Review of private payor contracts – confirm/negotiate **coverage/payment** of telehealth services covered

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Questions?

Alicia Macklin, JD, MPH

Phone: 310.551.8161

Email: amacklin@hooperlundy.com

Andrea Frey, JD, MPH

Phone: 415.874.8507

Email: afrey@hooperlundy.com

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