

Objectives

- To understand the impact of telehealth policies in the prescribing of controlled substances
- To understand the differences between Digital Mental Health Startups and Telepsychiatry
- To understand the evidence behind ketamine and psychedelic treatment for psychiatric disorders
- To understand the FDA warning on compounded ketamine products for the treatment of psychiatric disorders

Telehealth

Types of changes	Pre-Pandemic	Post-Pandemic
Who ...can participate?	Only certain licensed providers can perform telehealth Patients and providers must have a preexisting relationship prior to engaging in telehealth care	Any type of clinician can bill for Medicare services No preexisting relationship is required
Where ... is it allowed? Which facilities and physical locations?	Telehealth must be done at specific sites (designated rural areas, specific types of medical facilities) Physicians must be physically located at their place of practice for all telehealth visits Patient and physician must be in the same state	Telehealth can be conducted from any site including the patients' home Physicians may conduct telehealth from home Telehealth can be provided to a patient in a different state (state specific restrictions apply)
What ...does it look like? What can be prescribed?	Must be audio-visual Only approved technology platforms	Audio-visual or audio-only Expanded approved platforms, including facetime, zoom, and skype
How ...does reimbursement look?	Medicare coinsurance and deductibles apply to telehealth visits Reimbursements for telehealth services is lower than for in-person services	Providers may waive cost-sharing for telehealth paid for by federal programs All telehealth visits, including audio-only, will be reimbursed as if it was conducted in person

Table 1 DEA and Center for Medicare Services (CMS) Policy changes in response to the COVID-19 pandemic. Adapted from Shaver 2022 and DEA.org¹

August 2023 Top 5 Telehealth Diagnoses

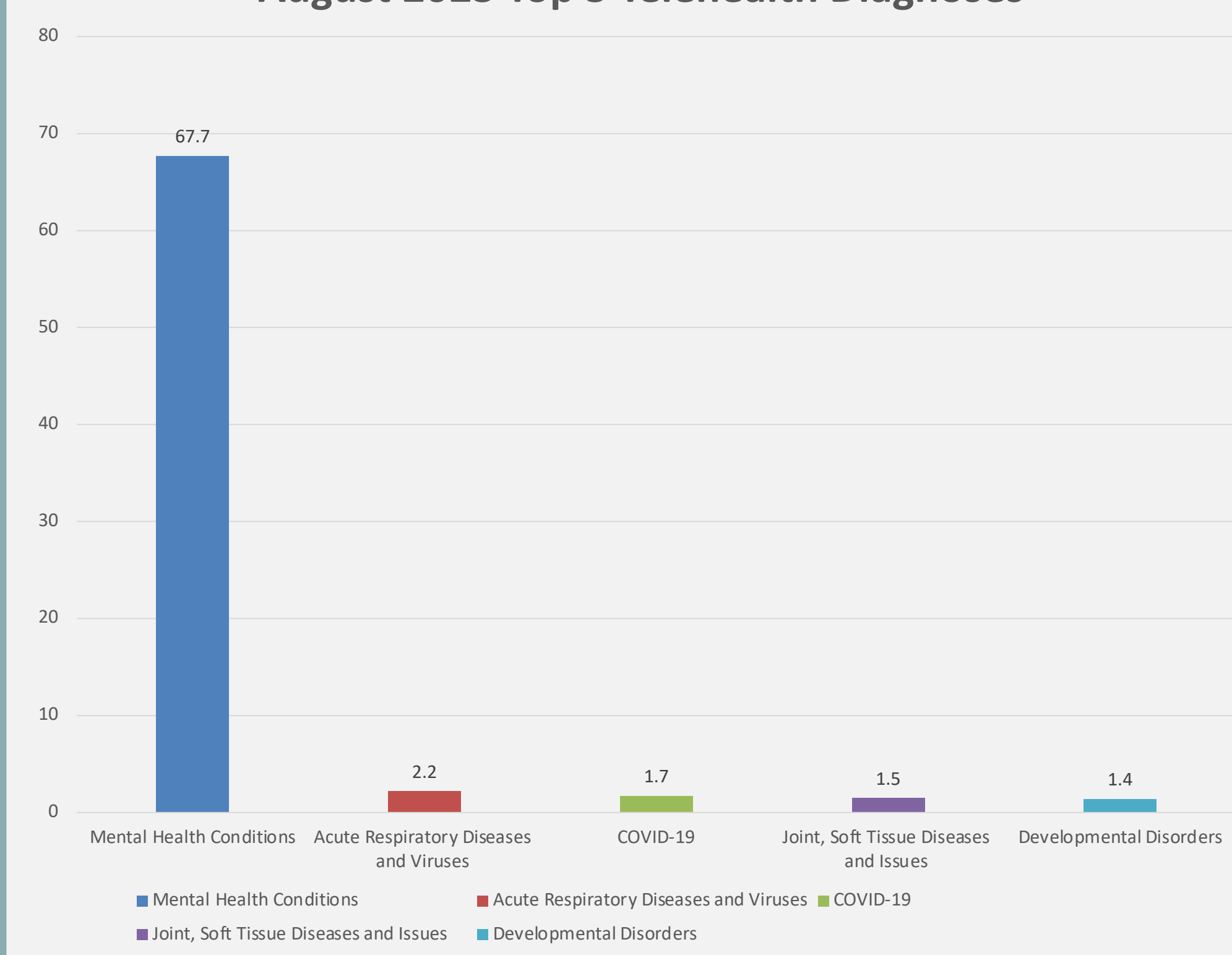
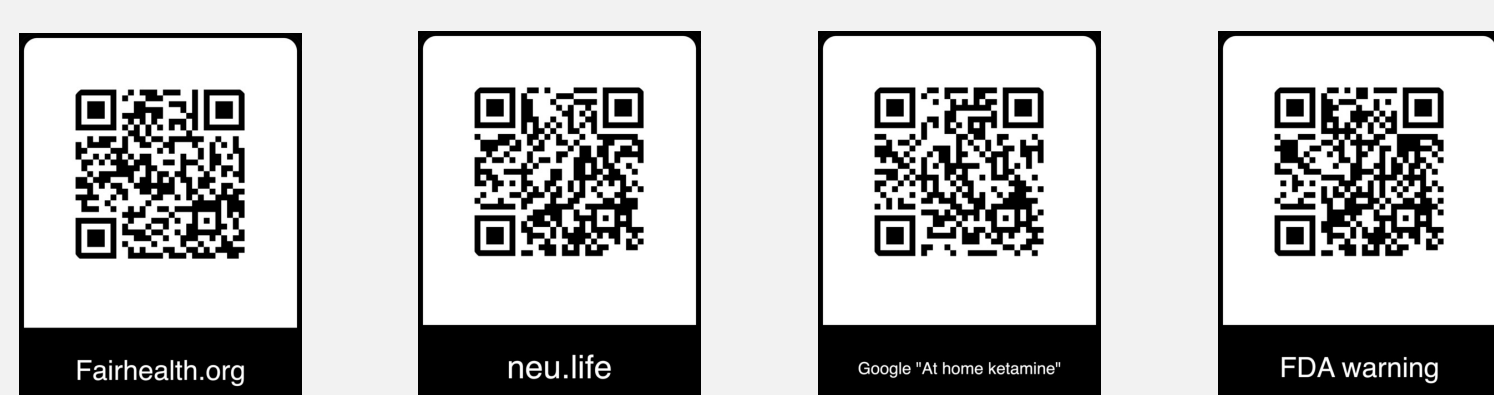


Chart 1: FairHealth Inc Monthly Telehealth Regional Tracker for the United States August 2023 demonstrates the top 5 most common billing diagnoses used by telehealth providers²



Case

40-year-old man with past psychiatric history of Major Depressive Disorder, Generalized Anxiety Disorder, Opioid Use disorder (in remission), history of hallucinogen and stimulant use and past medical history of hypertension and HIV...

Initial exam

- Found down, unresponsive to stimuli, diaphoretic, and surrounded by bilious emesis.
- Significant fluctuations in alertness with intermittent severe agitation
- Did not respond to naloxone administration

Initial Labs

- Notable for Cr 1.27, Lactate 2.1, otherwise WNL
- Urine Toxicology: + Amphetamines, + Oxycodone,
- Serum Tox: negative for acetaminophen, ethanol, salicylate, tricyclic
- CT Head/Abdomen/Pelvis: Unremarkable

Interventions

- Administered lorazepam 2mg IV in response to severe agitation threatening the safety of patient and staff
- Patient became somnolent with a Glasgow Coma Scale of 6
- Intubated and transferred to ICU

ICU Course

- Physical exam: Intubated, hypothermic, had mild clonus and diffuse red blanching rash on extremities and face
- Poison control recommended labs and EKG checks every 4 hours
- 8 hours after intubation, patient self extubated and psychiatry was consulted

Psychiatric Evaluation

- Waxing and waning mental status, inattentive, consistent denial of intentional toxic ingestion
- Collateral revealed history of toxic ingestions and text messages that suggested intentional suicide attempt in the setting of intoxication and interpersonal conflict
- Patient had combined alcoholic beverages, GBL/GHB, and Biktarvy
- Prescription Monitoring Program revealed series of ketamine prescriptions not disclosed by patient
- Patient was referred for inpatient level of psychiatric care

Prescriptions

Total: 18 | Private Pay: 5

Filled	Drug	QTY	Days	Prescriber	Dispenser	PMP
01/18/2023	Ketamine HCl Powder	1,411,919,951	3			MA
01/16/2023	Ketamine HCl Powder	0,235,200,001	2			MA
01/06/2023	gabapentin 300 Mg Capsule	30	30			MA
01/03/2023	Ketamine HCl Powder	0,459,190,978	2			MA
01/03/2023	Ketamine HCl Powder	0,114,029,994	1			MA
11/29/2022	Ketamine HCl Powder	0,229,400,008	1			MA
11/29/2022	Ketamine HCl Powder					

Figure 1: Massachusetts Prescription Drug Monitoring Program (PDMP) data depicting controlled substance dispensations including variable ketamine powder prescriptions

At - Home Experience

- The patient disclosed that he used an app, called "nue.life" he completed a series of questionnaires to obtain "ketamine experiences" but was never formally evaluated by a prescriber either by audio or video call
- He received his compounded ketamine powder in the mail and had access to "experience playlists", meditations, and an instruction sheet
- He did not know the name the prescriber or how to contact them
- He was home alone when he suffered severe nausea and diaphoresis during his second "experience", was unable to call for help
- Efforts to obtain collateral from family medicine nurse practitioner who was listed as the prescriber were unsuccessful

Ketamine

- Ketamine has been found to be an effective treatment for unipolar depression, acute suicidality, and is most known for its rapid reduction in symptoms
- Exact mechanism of action is unknown, antidepressant effects thought to be related to opioid receptor and NMDA antagonism³
- American Psychiatric Association published a "Consensus Statement on the use of Ketamine in the Treatment of Mood Disorders"⁴ that has guidelines and suggestions for:
 - Patient Selection (strict inclusion criteria and contraindications)
 - Clinician Training and Experience
 - Treatment Setting
 - Mode of Medication Delivery
 - Follow-ups and Assessment
 - Safety Measures
 - Continuation of Treatment
- IV Ketamine treatments (well studied, not FDA- approved) and intranasal ketamine treatments (FDA-approved) are administered in a monitored setting under the care of Psychiatrists and Anesthesiologists
- Route matters for bioavailability
 - IV(100%)>>> intranasal (70%) > oral (26%)⁵
- Safety Concerns with ketamine products:
 - abuse, dissociation, sedation
 - respiratory depression and blood pressure increases
 - lower urinary tract and bladder symptoms

Clinical Considerations

- Diagnostically, pattern of risky behaviors, interpersonal conflict, and toxic ingestions in the setting of perceived abandonment suggest personality contributions that call into question indication for ketamine
- Per the APA Guidelines, due to his active substance use and history of prior ketamine abuse, ketamine therapy is contraindicated
- Patient has a history of hypertension making clinical monitoring during ketamine administration even more important

Mental Health Startups

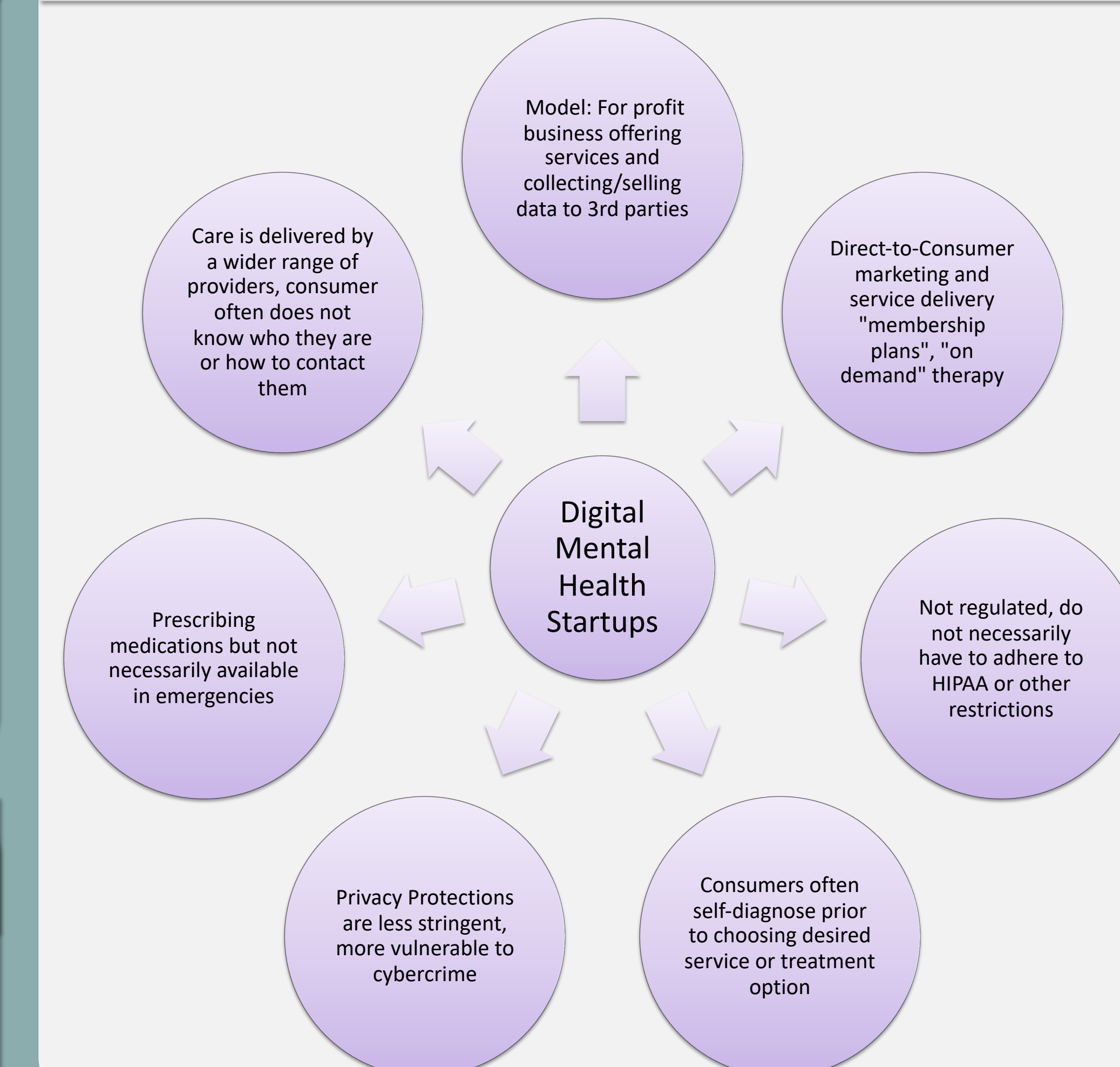


Figure 2: Adapted from Achtyes 2023 "Telepsychiatry in the Era of Digital Mental Health"⁶

Conclusions

This case highlights the impact that reduced regulations surrounding controlled-substance prescribing has had on at home mental health services, including ketamine and other psychedelic therapies

- Concerns with at-home ketamine services such as these include:
- Eligibility criteria that is not in line with the American Psychiatric Association Guidelines
 - Reduced efficacy given low bioavailability of oral formulations and scarcity of data on the safety profile
 - Lack of medical supervision during medication administration and minimal contact with prescribing provider
 - Minimal training in psychiatric diagnoses and clinical management of psychiatric illnesses for prescribing providers

This case specifically involves ketamine but these considerations surrounding safety, indication, efficacy also apply to other web-based mental health treatments including other psychedelics

Given the nature of these online services, patients may forget to disclose prescriptions they are receiving from Digital Mental Health Startups thus psychiatrists should always carefully review prescription drug monitoring information for controlled substances

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