PUBLICATION

Coronavirus: Relief for Behavioral Health Providers in Agency Waivers, Guidance

Authors: Michaela Dawn Poizner

March 20, 2020

As federal agencies scramble to provide regulatory relief from the fall-out of the coronavirus pandemic taking hold in the United States, several waivers and bulletins provide guidance specifically applicable to substance use disorder and mental health treatment providers.

Below is a round-up of the agency activity relevant to the behavioral health industry that we've seen so far.

Delivery of Medication-Assisted Treatment

SAMHSA Allowing Longer Doses of Take-home Medications

The Substance Abuse and Mental Health Services Administration (SAMHSA) released guidance on March 16, 2020 allowing states and individual providers to request exceptions to SAMHSA's limits on the amount of takehome medication that opioid treatment providers (OTPs) can dispense to a patient receiving treatment for opioid use disorder (OUD):

- In states <u>with</u> declared states of emergency:
 - States may request a blanket exemption for stable patients in an OTP to receive up to 28 days of take-home medication for OUD.
 - States may request a blanket exemption to allow dispensing of up to 14 days of take-home medication for OUD patients who are less stable, but who the OTP believes can safely handle that level of take-home medication.
- In states <u>without</u> declared states of emergency, individual OTPs can request a blanket exemption in accordance with the guidelines above. Exemption requests do not need to be submitted for individual patients.

SAMHSA cautions that OTPs and states should "use appropriate clinical judgment and existing procedures to identify stable patients" and reminds those seeking to dispense medications in accordance with the waivers above to ensure that sufficient medication is on hand and ordered to meet the increased demand.

Read SAMHSA's guidance on take-home medication dosage waivers.

DEA Allowing Delivery of Medication Assisted Treatment Drugs to Patients

On March 16, 2020, the Drug Enforcement Administration (DEA) granted a waiver request by SAMHSA from the requirements in 21 C.F.R. § 1301.74(i) during the public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020 to allow DEA-registered narcotic treatment programs (NTPs) to provide take-home medications to quarantined patients through alternative delivery methods under the NTP's established chain of custody protocol. Specifically, NTPs are permitted to make a "doorstep" delivery of take-home medications in an approved lock-box.

Additionally, the DEA waiver allows that an authorized NTP staff member, a law enforcement officer or National Guard personnel may deliver the medication. Absent the waiver, regulation required that medication be administered or dispensed to the patient by the licensed practitioner or by a registered nurse, licensed practical nurse or pharmacist under the direction of the licensed practitioner.

Read the DEA waiver on dispensing medication to NTP patients.

Use of Telemedicine for Substance Use Disorder and Mental Health Treatment Use of Telemedicine to Prescribe Controlled Substances for Medication Assisted Treatment

The DEA has released guidance confirming that prescriptions for controlled substances, including for medication assisted treatment, via telemedicine are not required to be predicated on an in-person medical evaluation, which is typically required by law, as long as:

- The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice;
- The telemedicine communications take place through an audio-visual, two-way interactive communication system; and
- The practitioner acts in accordance with applicable law.

The Ryan Haight Act of 2008 requires that a practitioner prescribing a controlled substance has conducted at least one in-person medical evaluation of the patient (21 U.S.C. § 829(e)), but the act provides an exception to this requirement where the Secretary of HHS has declared a public health emergency (21 U.S.C. § 802(54)(D)).

According to the DEA, as long as the provider satisfies the requirements in the three bullet points above, a practitioner may issue a prescription for a controlled substance using any method currently allowed by the DEA, regardless of whether the provider has evaluated the patient in person.

Read the DEA's guidance on prescribing controlled substances via telemedicine.

General Expansion of Ability to Treat Patients Via Telemedicine

On March 17, 2020, the Centers for Medicare & Medicaid Services (CMS) issued a variety of waivers related to the provision to telemedicine services, including:

- Eliminating restrictions on where patients can be located when receiving services (including in their homes);
- Expanding the list of practitioners permitted to provide telemedicine services;
- Granting flexibility in reducing or waiving cost-sharing for telemedicine visits; and
- Relaxing enforcement of security requirements under HIPAA for telemedicine platforms.

While these telemedicine waivers are not specifically applicable to behavioral health providers, increasing reliance on telemedicine for substance use disorder and mental health treatment mean these waivers may provide significant relief for behavioral health organizations seeking to maintain treatment for patients during a time of quarantine and social distancing.

Read CMS's fact sheet on the telemedicine waivers.

Read Baker Donelson's previous alert on the CMS telemedicine waivers, additional telemedicine guidance.

Disclosure of Alcohol and Substance Use Disorder Patient Information in Emergency

SAMHSA has released guidance reminding Part 2 programs treating alcohol and substance use disorder patients via telemedicine that written patient consent is not required for disclosure of patient-identifying information during a medical emergency (42 C.F.R. § 2.51; 42 U.S.C. § 290dd-2(b)(2)(A)). The Part 2 program, or another lawful holder of the alcohol or substance use disorder patient's records, may disclose the patient's records to medical personnel in the event of a medical emergency, even if the telemedicine treatment relationship prevents the provider from obtaining the patient's prior written consent to disclosure. Medical personnel receiving the patient's information may re-disclose the information for treatment purposes, as needed.

If a Part 2 program makes a disclosure pursuant to the medical emergency exception, the Part 2 program must appropriately document the disclosure in its records. SAMHSA concluded its guidance by emphasizing that "under the medical emergency exception, providers make their own determinations whether a bona fide medical emergency exists for purposes of providing needed treatment to patients."

Read SAMHSA's guidance regarding the application of Part 2 in a medical emergency.

Care for Psychiatric Inpatients in Acute Care Hospital Beds

CMS announced on March 13, 2020 that acute care hospitals with distinct part inpatient psychiatric units may relocate patients from the psychiatric unit to the acute care unit in the event of an emergency, while continuing to bill for inpatient psychiatric services. The blanket waiver, one of several that CMS has issued, is available to Medicare and Medicaid providers in all states during the President's declaration of a national emergency and the public health emergency declared by the Secretary of HHS.

The waiver is available where the hospital's acute care beds are appropriate for psychiatric patients and the staff and environment are conducive for safe care. CMS specified this means assessing the acute care bed and unit location to ensure psychiatric patients who are at risk of harming themselves or others can be safely cared for.

If a hospital transfers a psychiatric patient to an acute care bed, the patient's medical record must be annotated to indicate the patient is a psychiatric inpatient being cared for in an acute care bed because of capacity needs or other exigent circumstances.

Read all of the CMS Medicare and Medicaid waivers related to COVID-19.

For more information on how this issue may affect your business or related matters, please contact Michaela Poizner, or any member of Baker Donelson's Health Law Group. Also, for more information visit the Coronavirus (COVID-19): What You Need to Know information page on our website.