

TO: Maryland Hospital Association

FROM: Behavioral Health Administration

RE: Circumstances in which buprenorphine-containing products can be prescribed or and/or dispensed in an Emergency Department.

DATE: June 6, 2017

The Maryland Hospital Association (MHA) has inquired about the circumstances in which buprenorphine-containing medications can be prescribed and/or dispensed in an Emergency Department.

There are several regulatory entities that govern the delivery of buprenorphine under different circumstances.

Typical Buprenorphine Prescribing in an Outpatient Setting:

The DATA 2000 law and related amendments in the 2016 CARA statute allows physicians, Nurse Practitioners (NPs), and Physicians Assistants (PAs) with prescriptive authority and who meet specific criteria to prescribe buprenorphine for patients with opioid use disorder.

The specific criteria are as follows:

1. Physicians need to complete a minimum of 8 hours of training provided or approved by one of 5 certifying entities (ASAM, AAAP, APA, AOAAM, AMA)
2. NPs/PAs need to complete a minimum of 24 hours of training provided or approved by one of 5 certifying entities (ASAM, AAAP, APA, AOAAM, AMA)
3. After completing the required training, submit a one-page, intent-to-prescribe form to SAMHSA/DEA.
4. Within 45 days, SAMHSA/DEA issues an updated DEA certificate with an “X” number that needs to be included on all buprenorphine related prescriptions written by the practitioner for the treatment of opioid use disorder.
5. In the first year of prescribing, MDs/NPs/PAs may not prescribe to more than 30 patients at a time. A patient is considered to remain on a prescriber’s roster for the duration of the prescription.
6. After a year of prescribing up to 30 patients, the practitioner may submit a request to SAMHSA/DEA to prescribe up to 100 patients at a time.
7. After a year of prescribing up to 100 patients, only MDs may submit a request to SAMHSA/DEA to prescribe up to 275 patients at a time. Additional requirements in this circumstance include additional credentialing or practicing in a “qualified practice setting”.

Physicians, NPs, and PAs who provide care in ED settings can obtain free waiver training and prescribe buprenorphine for patients they see with opioid use disorder, at least up to 100 patients without any additional requirements.

Buprenorphine Dispensing in an Outpatient Setting:

Under the Narcotic Addiction Treatment Act of 1974, all practitioners who use full opioid agonist medications to treat opioid use disorder must hold a separate DEA registration and follow regulations and rules, including accreditation requirements, set forth by SAMHSA and the DEA.

The entities that hold these registrations are known as Opioid Treatment Programs (OTPs). Currently, methadone is the only full opioid agonist medication approved for this indication and this setting. Buprenorphine, a partial opioid agonist, is also approved for dispensing through an OTP. This does not require a waiver through DATA 2000 but in an OTP, buprenorphine must be dispensed, cannot be prescribed, and all the rules and regulations that apply to methadone delivery then also apply to the provision of buprenorphine.

EDs typically would not hold separate registration and accreditation as an OTP.

Dispensing Buprenorphine in an Acute Hospital Setting:

No limitations exist on physicians or other authorized hospital staff to order and dispense buprenorphine to hospitalized patients requiring treatment of opioid use disorder (either maintenance or withdrawal management) when this is secondary to other medical and/or surgical conditions. In this circumstance, the opioid use disorder is incidental to the primary medical and/or surgical condition so treatment is considered a way of avoiding complicating the main health problem.

While this is important for EDs to understand, it does not have direct bearing on ED workflows.

Dispensing Buprenorphine in an Outpatient Setting in Medical Emergencies:

The majority of buprenorphine prescribing done in the U.S. occurs by waived prescribers (ie those with the “X”). Buprenorphine dispensing is also becoming more common in OTPs across Maryland.

There is one exception to the separate registration or waiver requirement for buprenorphine delivery in outpatient settings. This exception, known as the “three-day rule” in CFR 21 (Part 1306.07(b)), allows a practitioner who is not in an OTP or waived under DATA 2000, to administer (but not prescribe) an opioid agonist medication to a patient for the “purpose of relieving acute withdrawal symptoms” as long as:

- Not more than one day’s medication is administered or given to a patient at one time
- Treatment does not exceed 72 hours
- The 72-hour period cannot be renewed or extended

The intent of this regulatory exception is to offer an opportunity to provide relief from acute opioid withdrawal and allow time to arrange for referral and engagement into ongoing care. SAMHSA emphasizes that “this provision was established to augment, not to circumvent,” the separate registration/waiver requirement.

This may be an option for EDs that are working on increasing their waived prescriber pool.