MACS
Maryland Addiction Consultation Service

METHADONE "3-DAY" DISPENSING RULE
FACT SHEET

What is the "3-day" Dispensing Rule?

- In 2023, a "3-day rule" exception to the Narcotic Addict Treatment Act of 1974 (NATA; Title 21 C.F.R.§ 1306.07) was published.
- The updated 2023 exception allows practitioners to **dispense** (instead of merely administer) up to a 3-day supply all at once for the purpose of initiating maintenance or detoxification treatment while referral to treatment is coordinated. No renewals or extensions of the 3-day period are permitted for the same episode.
- The most common settings that utilize the 3-day dispensing rule include hospitals (admitted patients or those on observation), the emergency department and jails.

Clinical Recommendations

- **Eligibility and Verification of Methadone Dose**
  - Patient Eligibility: Those who are presenting with opioid overdose, opioid withdrawal, or opioid use disorder and require linkage to methadone treatment. This includes patients who are temporarily unable to receive methadone from their current OTP (e.g., weekend closure of OTP).
  - Facility/Provider Eligibility: Those who have proper DEA approval to administer/dispense controlled substances ***and*** access to a pharmacy that has methadone stocked
- **Standardization**
  - Develop written protocols that clearly define: a) Eligible clinical settings (e.g., ED, inpatient units, observation units); b) Eligible clinicians; c) Approved dosing ranges and maximum duration; d) Required documentation and pharmacy workflows
  - Educate participating providers on the 3-day role and *administering vs. dispensing vs. prescribing*
- **Methadone Dose Selection**
  - Patients Not Already in an OTP: Start methadone 30 mg by mouth daily and arrange for follow-up with an OTP
  - Patients Already in an OTP: If possible, confirm methadone dose information, last known dose taken, and patient status should be confirmed for patients already receiving methadone at an OTP. The Maryland Department of Health provides a regularly updated list of OTP after-hours contact information if needed here (scroll to the bottom of the page). If dose information cannot be confirmed, start methadone 30 mg by mouth daily and arrange for follow-up with an OTP.

Continued on Page 2

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Clinical Recommendations — Continued

- **Pharmacy Coordination and Oversight**
  - Coordinate with on-site or affiliated pharmacy services to ensure compliance with federal and state regulations
  - Provide in unit-dose or clearly labeled take-home packaging with clear written and verbal instructions
  - The dispensing of the controlled substance should be documented and witnessed by the pharmacy.
- **Methadone Dispensing**
  - Provider will retrieve the methadone from the pharmacy and dispense it to the patient
  - Medication should be paired with harm reduction measures (naloxone and overdose education).
- **Documentation and Monitoring**
  - Clinical documentation should explicitly state that dispensing is occurring under 21 CFR §1306.07(b) to relieve acute withdrawal while arranging a treatment referral.
  - Ensure that the patient is set up with an appointment at their OTP for continuation of methadone. If possible, track successful OTP linkages.
- **Special Considerations**
  - Methadone Safety Monitoring:
    - Monitor for signs of respiratory distress and sedation
    - Consider ordering an electrocardiography (EKG) if patient has any other medical indications for an EKG, such as cardiac issues or QTc-prolonging medications
  - Pain Management:
    - If the patient is on methadone for OUD and has uncontrolled pain on non-opioid multimodal therapies, the patient may receive their verified methadone OTP dose and short-acting opioids if clinically appropriate.

When to Contact MACS

- Clarity on whether the 3-day rule is appropriate for your patient or your treatment facility
- Guidance on methadone dose selection and patient-specific considerations
- Interest in learning more about health systems that are implementing the 3-day rule and have established procedures
- Support in coordinating with pharmacies to secure methadone
- General questions and support when working with patients with substance use disorders and chronic pain

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