Dispensing Methadone for Opioid Use Disorder Under the 72 Hour Rule

Guide for Hospital Emergency Departments and Inpatient Units

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ScalaNW

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Introduction

This guide outlines legal, clinical, and operational procedures for emergency department and inpatient hospital care teams to dispense methadone to patients with opioid use disorder (OUD) under the 72-Hour Rule (21 CFR § 1306.07(b)). It is intended for use by clinicians, pharmacists, care coordinators, and hospital administrators.

Disclaimer: Hospitals should consult with their legal counsel and compliance teams before implementation. This guide is designed for Washington State hospitals and is informed by federal and state regulations; it is intended to support, not replace, institutional policy and legal review.

Key Terms

Administer: Give a dose of medication to a patient for immediate use.

Dispense: Provide medication in a container for a patient to take away for later self-administration.

Prescribe: Issue a prescription for the patient to obtain from a pharmacy.

Order: Refers to a medication ordered (not prescribed) to an inpatient or ED pharmacy by a provider for the purpose of direct administration or dispensing to the patient.

OUD: Opioid Use Disorder

OTP: Opioid Treatment Program; OTPs are federally certified programs authorized to dispense methadone (and other opioid agonist medications) for OUD treatment.

DEA: Drug Enforcement Administration

PMP: Prescription Monitoring Program

Regulatory Framework

The 72-Hour Rule (21 CFR § 1306.07(b)) allows emergency department and inpatient hospital pharmacies to dispense up to a 72-hour supply of methadone to patients with OUD to bridge them to an Opioid Treatment Program (OTP). Key provisions:

- **Linkage to care is required.** Hospitals must connect patients to follow up care for OUD treatment. This can be a scheduled appointment or, more commonly, a walk-in visit within 72 hours. Only OTPs can provide ongoing OUD treatment with methadone.
- **Maximum supply:** 3 days (72 hours). There are no limits on daily dose amount or frequency.
- **Extension:** Not permitted.
- **Frequency:** Once per encounter. The 72-hour rule may be used again for the same patient only if it is for a new episode of care.

The existing DEA registration for the hospital is sufficient to order and administer methadone and utilize the utilize the 72-hour rule. No additional license or OTP certification is required. Required registration and compliance elements are consistent with standard controlled substances regulations and include:

- **DEA registration:** Hospital registration (Schedules II-V); ordering provider registration for Schedule II substances.
- **Inventory compliance:** Ordering/receiving: DEA Form 222 or Controlled Substance Ordering System; locked storage with limited access; perpetual inventory or regular audits.
- **Recordkeeping compliance:** Records maintained for a minimum of 2 years and readily retrievable for inspection.

Refer to 21 CFR § 1306 for the complete federal rules and regulations governing controlled substance prescribing.

Patient Scenarios

Consider dispensing methadone under the 72-hour rule in the following scenarios:

- A patient initiates methadone while in the ED/during hospitalization and will be discharged when a next-day OTP intake is not available.
- A patient is already enrolled in an OTP and is discharged when a next-day OTP visit for their next dose is not possible (e.g., weekend closures)

Special considerations: Transfers to Skilled Nursing Facilities

In Washington State, SNFs cannot refuse to accept a patient because they are taking methadone. A SNF that refuses to accept a patient because they take methadone should be reported to the Department of Social and Health services, here: Report Concerns Involving Vulnerable Adults | DSHS.

Patients being discharged to a SNF or other subacute rehabilitation setting require additional care coordination to ensure methadone continuity. These patients cannot independently present to an OTP for intake after discharge, and most SNFs are not currently dispensing methadone. The OTP can coordinate with the SNF to dispense the medication on an ongoing basis (e.g., SNF staff pick up doses from the OTP, the OTP delivers medication to the SNF, or the patient is transported to the OTP).

Key considerations:

- Some OTPs in WA currently admit patients remotely via audio visual telemedicine while patients are still hospitalized. All OTPs are legally allowed to do so under state and federal law, but a hospital partner may need to specifically suggest this possibility when care transitions are planned with an OTP partner.
- The OTP can provide methadone doses for the SNF staff to administer or dispense to the patient.
- The OTP and SNF must have a confirmed plan for medication delivery or pickup before the patient transfers.
- Discharge planners must communicate with both the OTP and the SNF to coordinate care. The OTP must be informed when the patient is discharged.

Identify this scenario early and develop a coordination plan well in advance of discharge. General questions and concerns about SNF transfers for patients taking methadone can be directed to the Washington State Opioid Treatment Authority office via Lauren Kula: lauren.kula@hca.wa.gov

Workflows

The following workflows apply to methadone dispensation from both inpatient and ED settings. Care teams should coordinate to ensure that all steps are completed.

Provider Workflow

For clinical guidance on initiating or continuing methadone in the ED or inpatient, see Resources.

Step 1: Identify Treatment Plan

- Determine treatment plan.
  - For methadone continuation
    - Verify dose with OTP and continue throughout treatment.
    - OTPs provide 24/7 dose verification via phone. See the Washington State Opioid Treatment Program Guide for contact information.
    - If unable to immediately verify dose, follow initiation protocol until verified.
  - For methadone initiation
    - Methadone is highly effective for withdrawal; offer regardless of intent to continue after discharge.
    - Prior to discharge, use shared decision-making with patient regarding MOUD options for ongoing treatment.
  - For complete clinical guidance, see Resources.
- Review PMP for controlled substance history and address any concerns (e.g., recent fills, multiple prescribers).
- Coordinate with nurse/care coordinator to confirm date of OTP visit (appointment or walk-in availability) to determine need for dispensed doses.

Step 2: Assess Patient Eligibility

- Assess patient ability to safely store and self-administer methadone.
  - **Caution:** When a patient is initiating methadone, carefully consider the safety of discharging them with high doses for multiple days. The fewer doses needed to bridge to care, the better. Careful patient education is critical (see step 5).
- All criteria met **(required):**
  - Patient has moderate-to-severe opioid use disorder (OUD).
  - Patient desires linkage to OTP for ongoing care.
  - Patient is medically stable for discharge.
  - Patient able to safely self-administer medication.
  - Patient able to securely store medication.

Step 3: Enter Medication Order

- Transmit methadone order to inpatient pharmacy.
  - Dose and frequency (once daily or divided)
  - Quantity: number of doses needed to bridge to OTP (maximum 3-day supply)
- Document medical necessity for dispensing methadone to the patient under the 72-Hour Rule.
- Enter naloxone dispensing order or otherwise ensure the patient will be discharged with naloxone.
  - In Washington State, emergency departments are required to dispense naloxone to patients with OUD or those otherwise at risk of opioid overdose, in compliance with SB5195.

Step 4: Coordinate Dispensing

- Retrieve the dispensed medication from the inpatient pharmacy and deliver it to the patient or appoint a delegate with appropriate licensure to do this. Appropriate delegates include midlevel providers and registered nurses.
  - Ordering provider/delegate may accompany patient to the inpatient pharmacy window , OR
  - Medication may be delivered by the provider/delegate to the patient bedside at discharge.

Step 5: Patient Education

- Provide or delegate patient education, including:
  - Dosing Instructions
    - Take exact dose once daily (or divided twice daily if ordered); same time each day
    - Do NOT double doses if missed
  - Safe Storage
    - Store secure/locked (preferably in lockbox, locking bag, or locking prescription bottle) and out of reach of children
    - Do NOT share medication (risk of fatal overdose)
  - Overdose Prevention and Response
    - Overdose risk factors: taking more than prescribed, mixing with other CNS depressants (avoid alcohol, benzodiazepines, other opioids or substances that make you sleepy)
    - Signs of overdose: unresponsiveness; slowed, abnormal, or no breathing, blue/grey lips or fingernails
    - How to respond if you witness an overdose: give naloxone and rescue breaths, call 911

Nurse Workflow

For clinical guidance on initiating/continuing methadone in acute care settings, see Resources.

Step 1: Coordinate Linkage to Care

Care coordination tasks may be delegated to an appropriate role (e.g., care coordinator, peer, social worker), when available.

- Schedule and document OTP appointment or confirm walk-in availability within 72 hours of discharge.
  - Number of bridge doses will be determined by timing of appointment/walk-in availability.
- Document and provide patient with date, time, and location for OTP visit (appointment or walk-in) to occur within 72 hours of discharge.
- If possible, obtain an ROI to coordinate with the receiving OTP and send the discharge summary, including information on doses administered and bridge doses dispensed.
- Address barriers to care linkage.
  - Help the patient plan around competing responsibilities (e.g., childcare, work).
  - Provide transportation resources if needed (e.g., bus passes, ride vouchers, Medicaid transportation).
  - Inform the patient that they will need to prove their identity at the OTP. If they have one, they should bring a government-issued photo ID.
    - OTPs are required to verify identity but are not mandated to verify it with specific documentation (WAC 246-341-1000).
    - Some OTPs require a government-issued photo ID. Others will accept alternative forms of identity verification such as a hospital ID bracelet or a photo on file in the Central Registry or an EHR (e.g., from a previous admission at another OTP admission, a hospital EHR).
    - If the patient does not have a government-issued photo ID, call the OTP to determine whether and what type of alternative documentation they will accept.
  - If the patient has private insurance, they should bring their insurance card.
  - Reassure patients that they will be seen at the OTP regardless of ongoing substance use.
  - There is typically insufficient time in an ED encounter to achieve a therapeutic dose of methadone. Reassure patients discharged with a sub-therapeutic dose that the OTP will work with them to increase the dose to manage symptoms.

Step 2: Coordinate Dispensing

- Notify provider of date/time of planned OTP visit.
- Confirm methadone ordered by provider.
- Notify pharmacy that patient is ready for discharge and provider/delegate will retrieve dispensed methadone for the patient.
- If directed by the ordering provider to be the delegate, retrieve the dispensed medication from the inpatient pharmacy and deliver it to the patient. (E.g., accompany patient to the inpatient pharmacy window or deliver bedside at discharge).
- Ensure naloxone is ordered for dispensing or otherwise ensure the patient is discharged with naloxone.
  - In Washington State, emergency departments are required to dispense naloxone to patients with OUD or those otherwise at risk of opioid overdose, in compliance with SB5195.

Step 3: Provide Discharge Instructions

- Provide and review discharge instructions with the patient.
- Ensure the patient is aware of the date, time, and location for OTP visit (appointment or walk-in).
- Perform and document patient education, including:
  - Dosing Instructions
    - Take exact dose once daily (or divided twice daily if ordered); same time each day
    - Do NOT double doses if missed
  - Safe Storage
    - Store secure/locked (preferably in lockbox, locking bag, or locking prescription bottle) and out of reach of children
    - Do NOT share medication (risk of fatal overdose)
  - Overdose Prevention and Response
    - Overdose risk factors: taking more than prescribed, mixing with other CNS depressants (avoid alcohol, benzodiazepines, other opioids or substances that make you sleepy)
    - Signs of overdose: unresponsiveness; slowed, abnormal, or no breathing, blue/grey lips or fingernails (lack of oxygen)
    - How to respond if you witness an overdose: give naloxone and rescue breaths, call 911

Pharmacist Workflow

Step 1: Complete Pre-Dispense Review

Upon receiving an order to dispense methadone under the 72-Hour Rule:

- Verify regulatory authority to dispense methadone.
  - Hospital DEA registration
  - Ordering provider has active DEA registration for Schedule II substances
- Confirm patient eligibility documented.
  - Diagnosis of moderate-to-severe OUD
  - Able to safely self-administer and store medication
  - OTP visit to occur within 72 hours
- Confirm clinically appropriate.
  - Appropriate dose and quantity (see clinical guidance in Resources)
  - No contraindications (allergy, respiratory depression, QTc >500ms)
- Review and document PMP findings.

Step 2: Prepare Medication

- Prepare methadone per order.
- Label per Schedule II requirements and state law.
  - Patient name and DOB
  - Drug name, strength, quantity
  - Ordering provider name
  - Date dispensed
  - Pharmacy information
  - Directions for use
  - Required warnings/auxiliary labels
- Label for patient safety.
  - Meet outpatient labelling standards
  - Separately label each dose to ensure clarity of dosing instructions
- Prepare naloxone.
- Final pharmacist verification of prepared medications.

Step 3: Dispense and Counsel

- Confirm patient name and date of birth.
- Dispense medication to:
  - Ordering provider, OR
  - Ordering provider-appointed delegate. Legally, a delegate must have one of the following credentials: MD, PA, APRN, RN.
- Document name and credentials of recipient.
- Ensure controlled substance log signed by recipient.
- Counsel patient on dosing instructions, safe storage, opioid overdose prevention and response (see Patient Counseling under Tools and Templates).
- If possible, provide a locking bag or locking bottle for safe medication storage.

Step 5: Communicate with OTP

When the patient presents for follow-up, the OTP should call the pharmacy to confirm the provided methadone doses.

- Inform of last several doses of methadone administered (amount and date/time).
- Inform of doses dispensed for bridge supply.
- Document date/time of call, OTP staff member name/title, information provided.

Tools & Templates

EHR Documentation

Dispensing Order

Methadone _____ mg PO

Frequency: ☐ Once daily ☐ Divided BID

Quantity: _____ doses (maximum 3-day supply)

Indication: Opioid use disorder, F11

Comment: Bridge to OTP under 72-Hour Rule (21 CFR § 1306.07(b))

Ordering Provider Signature: _____ Date: _____

Visit Note Discharge Summary

Methadone [dose] mg x [number] days dispensed on [date], [time]

OTP follow up: [OTP Name], [date]

Overdose prevention education completed, naloxone [provided/ordered/declined]

Dispensed to: [This provider / Delegated practitioner (name/credentials)] and delivered to patient.

Patient counseled on dosing instructions, safe storage, overdose prevention and response, and follow up plan and demonstrates understanding.

Controlled substance log

Medication order pick-up receipt

Pharmacy: _____

Contact: _____

Patient

Patient name: _____

Patient ID: _____

Medication Order

Ordering provider: _____ DEA #:_____

Medication: _____

Concentration: _____

Dose:_____ Quantity: _____

Directions: _____

Dispensing Information

Date: _____ Time: _____

Dispensing pharmacist: _____

Signature: _____

Receiver name & credentials: _____

Signature: _____

Patient Counseling

Patient Counseling Quick Reference

Cover all points. Use teach-back method to confirm understanding.

- Dosing Instructions
  - Take exact dose once daily (or divided twice daily if ordered); same time each day
  - Do NOT double doses if missed
- Safe Storage
  - Store secure/locked, out of reach of children
  - Do NOT share medication (risk of fatal overdose)
- Overdose Prevention and Response
  - Overdose risk factors: taking more than prescribed, mixing with other CNS depressants (avoid alcohol, benzodiazepines, other opioids or substances that make you sleepy)
  - Signs of overdose: unresponsiveness; slowed, abnormal, or no breathing, blue/grey lips or fingernails (lack of oxygen)
  - How to respond if you witness an overdose: give naloxone and rescue breaths, call 911

Implementation

Implementing methadone dispensing under the 72-Hour Rule builds on existing controlled substance infrastructure, allowing quick start up. The following guidance walks through a simple phased approach, followed by resources to help address questions or concerns that may arise.

Implementation Phases

Timelines will vary based on institutional size and EHR complexity.

Phase 1: Preparation (4-8 weeks)

- Designate an implementation lead.
- Identify clinical and pharmacy champions. Involving pharmacy leadership early is critical to success.
- Review existing controlled substance policies (methadone follows the same procedures as other Schedule II medications).
- Consult with legal counsel and risk management. To prepare, see Regulatory Framework under Introduction and Legal and Risk Management Concerns below).
- Identify local OTPs for care coordination, see Washington State Opioid Treatment Program Guide.
- Begin methadone procurement through existing Schedule II processes.

Phase 2: Workflow Adaptation and Education (4-8 weeks)

- Collaborate with champions to adapt provided workflows and templates as needed.
- Assess electronic health record capabilities and make modifications as needed, including:
  - Add a methadone dispensing order and ensure that it is readily distinguishable from an inpatient order for administration. E.g., "methadone CONCENTRATED solution (TAKE HOME SUPPLY)."
  - Develop a pathway for dispensation orders to be automatically reported to the PMP. If automated reporting is not possible, integrate real time dispensation order reporting processes into workflows.
- Engage local OTP(s) to confirm referral processes and inform of intent to use the 72-Hour Rule to bridge patients to care.
- Educate relevant teams (providers, nurses, pharmacy, care navigators, peers, social work, risk management) on the 72-Hour Rule and workflows.
- Confirm billing codes and processes for dispensed methadone with hospital billing and compliance teams. See Billing below.
- Establish a method for tracking dispensed methadone for quality improvement.

Phase 3: Pilot and Rollout (1-3 weeks)

- Verify methadone inventory is secured prior to rollout.
- Consider a pilot with a small group of providers before full rollout.
- Announce rollout in clinical staff meetings and huddles.
- Offer and provide support to troubleshoot initial cases.

Phase 4: Quality Improvement (Ongoing)

- Track number of patients offered/dispensed methadone.
- Hold debriefs with case reviews to address challenges and celebrate successes.
- If possible, maintain regular communication with OTP(s) to improve care coordination.
- Refine workflows based on real-world experience.

Billing

For Medicaid clients, HCA has established HCPCS codes for dispensed buprenorphine (J0571-J0575) and methadone (S0109) that may be used to bill for facility stock medications dispensed to the patient. These codes are not setting-specific and apply to both ED and inpatient settings. These should be billed as a separate line item with one of the following HCPCS codes and the National Drug Code (NDC) of the product distributed:

1. J0571 - Buprenorphine, oral, 1 mg
2. J0572 - Buprenorphine/naloxone, oral, less than or equal to 3 mg Buprenorphine
3. J0573 - Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 6 mg Buprenorphine
4. J0574 - Buprenorphine/naloxone, oral, greater than 6 mg, but less than or equal to 10 mg Buprenorphine
5. J0575 - Buprenorphine/naloxone, oral, greater than 10 mg Buprenorphine
6. S0109 - Methadone, oral, 5 mg

Codes should be billed for the total units dispensed, up to a 3-day supply.

For ED encounters in which MOUD is initiated, hospitals can bill HCPCS add-on code G2213 (Initiation of medication for the treatment of opioid use disorder in the emergency department setting, including assessment, referral to ongoing care, and arranging access to supportive services), in addition to the primary ED E/M code (99282-99285).

For current code details, rates, and billing requirements, refer to the HCA provider billing guides and fee schedules.

Addressing Concerns and Barriers

Legal and Risk Management Concerns

Hospitals nationwide use the 72-Hour Rule safely and legally. Existing controlled substance infrastructure provides sufficient regulatory compliance for this practice.

- The 72-Hour Rule (21 CFR § 1306.07(b)), as amended by 88 Fed. Reg. 53377 (Aug. 8, 2023) (FR Doc. 2023-16892), explicitly authorizes hospital practitioners to dispense, not just administer, up to a three-day supply of opioid agonists for OUD without additional registration as an OTP.
- This is standard medical care, not experimental practice. Appropriate medical treatment (i.e., providing methadone for OUD) reduces liability risk compared to failing to treat OUD or opioid withdrawal, which may result in self-directed discharge, worsening of other medical conditions, or use of unregulated opioids resulting in overdose.
- Hospitals already discharge patients with medications that carry risks (insulin, anticoagulants, opioids for pain) using standard precautions. Risk mitigation through standard procedures includes:
  - Documented informed consent and patient education and counseling
  - Clear written and verbal dosing instructions
  - Unit-dose packaging when possible
  - Naloxone provided with overdose prevention education
- Washington State Opioid Treatment Authority (WA SOTA)
  - The WA SOTA is designated by the state to govern the treatment with MOUD in OTPs (42 CFR § 8.2).
  - The WA SOTA encourages the use of 21 CFR § 1306.07(b) by hospitals and emergency departments.
  - WA SOTA contact information: Jessica Blose, Jessica.blose@hca.wa.gov, 360-643-7850

Clinician Hesitancy

- Clinical champion(s) should mentor hesitant colleagues.
- Methadone is standard medical care for opioid use disorder, a treatable health condition. Providing MOUD reduces the risk of patient-directed discharge, allowing patients to complete necessary medical care and reducing re-admission.
- Methadone has decades of safety data. When dosed appropriately, the benefits of methadone substantially outweigh the risks.
- Clinicians do not need to be addiction specialists; providers without expertise can follow ScalaNW protocols for guidance, and the University of Washington Psychiatry Consult Line (PCL) is available 24/7 for consultation at 877-927-7924.

Rural and Low-Resourced Hospitals

- If the nearest OTP is distant, they may offer mobile methadone services, telehealth intakes, and/or transportation services that can make care linkage possible. Confirm feasibility during treatment planning.
- Consider buprenorphine when OTP care in unavailable, including 72-hour buprenorphine dispensation if pharmacy access is limted.
- The 72-hour bridge is especially valuable when follow-up requires significant travel or when OTPs lack capacity for next-day intakes.
- Start with a small inventory to minimize financial and storage burden.
- Utilize the University of Washington Psychiatry Consult Line (PCL) for case consult.

Frequently Asked Questions

1. **Won't this enable addiction?**

   No. Methadone is evidence-based medical care that reduces the risk of death by 50% or more. Withholding medications for opioid use disorder enables continued use of unregulated opioids.

2. **What if something goes wrong?**

   Appropriate medical care with documented informed consent and patient education is defensible. Not treating a known medical condition carries greater risk.

3. **What about pregnant patients?**

   Methadone is a first-line treatment for OUD in pregnancy. See Resources for clinical guidance.

4. **What if the patient is unhoused or lacks stable housing?**

   Homelessness is not a contraindication. Provide safe storage education and a lock bag/box, if possible. Extra care coordination support may be helpful.

5. **How do we handle patients who don't engage with an OTP and return for more methadone?**

   Extensions are not allowed under the 72-Hour Rule; however, if a patient returns to the hospital for a new care episode, a new 72-hour period may be initiated. If a patient did not engage with the OTP during the previous attempt, discuss and address barriers to engagement. Consider offering buprenorphine as a more flexible treatment option.

6. **If a patient missed their OTP dose, can I give it to them in the ED?**

   Yes. Methadone can be used as medically appropriate in the ED and inpatient hospital setting. For patient safety, verify the dose with the OTP prior to administration.

7. **Can buprenorphine also be dispensed?**

   Yes. The 72-hour rule applies to any "narcotic drug listed in any schedule" that is dispensed to a "narcotic dependent person for the purpose of maintenance or detoxification treatment" (21 CFR § 1306.07(b)). This guidance focuses on methadone because, unlike buprenorphine, it cannot be prescribed for OUD, it must be dispensed; however, it is allowable to dispense buprenorphine for the purpose of managing withdrawal or treating a substance use disorder.

Resources

Implementation

- Expanding Access to Methadone Treatment in Hospital Settings, SAMHSA
- DEA Pharmacist's Manual
- Washington State Opioid Treatment Programs
- Dispensing Methadone at Hospital Discharge: One Hospital's Approach to Implementing the "72-hour Rule" Change, Journal of Addiction Medicine
- Starts with One is an HCA-funded safe medication storage program that provides locking bags and locking medication bottles to pharmacies to use when dispensing controlled substances to patients.

Clinical Guidance

- Emergency Department Methadone Initiation
- Emergency Department Methadone Initiation in Pregnancy
- Inpatient Methadone Initiation
- Inpatient Methadone Initiation in Pregnancy
- Inpatient Methadone Continuation

Care Coordination

- Hospitals enrolled in ScalaNW can call the 24/7 appointment scheduling line and receive a confirmed date, time, and location for follow up appointment.
- The Washington State Opioid Treatment Program Guide contains all OTP locations and contact information.

References

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3. Alrawashdeh M, Rhee C, Klompas M, et al. Association of Early Opioid Withdrawal Treatment Strategy and Patient-Directed Discharge Among Hospitalized Patients with Opioid Use Disorder. J Gen Intern Med. 2023;38(10):2289-2297. doi:10.1007/s11606-023-08059-w
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5. Drug Enforcement Administration. Dispensing of Narcotic Drugs to Relieve Acute Withdrawal Symptoms of Opioid Use Disorder. Federal Register. 2023;88(151):53377-53378. FR Doc. 2023-16892.
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7. Singh-Tan S, Jakubowski A, Reicher ZH, et al. Impact of Medication for Opioid Use Disorder on Patient Directed Discharge Among Patients with Opioid Use Disorder. J Gen Intern Med. Published online January 23, 2026. doi:10.1007/s11606-026-10172-5

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