Model Protocol Using Pharmacists on the Care Team to Expand Access to Treatment of Opioid Use Disorder

Executive Summary

Congress recently eliminated the X-waiver, a federal barrier to pharmacists prescribing medications for opioid use disorder (MOUD). States can now use pharmacists to improve access to MOUD. This model protocol was developed to help health care providers and boards of pharmacy utilize pharmacists to expand access to MOUDs and help curb the opioid crisis in their communities.

1. Purpose: To formally identify the function that pharmacists, licensed in [insert state], may perform in providing drug therapy management to patients with opioid use disorder (OUD).

2. Authority: [Insert reference to state pharmacy practice act]

3. Pharmacist registration and training
   - A pharmacist authorized to issue an order to initiate or adjust a medication assisted treatment that is a controlled substance shall register with the federal Drug Enforcement Administration and complete the training required by Section 303 of the Controlled Substances Act (21 U.S.C. 823), as well as any future education needed to maintain registration.

4. Referral criteria:
   - Patients with a known or suspected opioid use disorder are referred by a provider, patient care team member, or
   - By patient self-referral.

5. Prior to undertaking drug therapy management authorized under this protocol, the pharmacist shall:
   - Conduct an interview and physical assessment of the patient for signs and symptoms of opioid use and opioid use disorder sequalae.
   - Review the patient's medical records and perform medication reconciliation, if available.
   - Order and interpret any laboratory tests necessary to support patient assessment.
   - Query the state prescription drug monitoring program (PDMP) to obtain controlled substance prescription history.

6. The pharmacist may perform the following authorized functions in accordance with this protocol and the standards of care for the treatment of opioid use disorder:
   - Drug Therapy Management
     - Initiate, modify, discontinue, and administer formulations of buprenorphine, naltrexone, or other medications FDA approved for treatment of opioid use disorder.
     - Initiate, modify, discontinue, and administer naloxone or other medications FDA approved for overdose prevention.
     - Initiate, modify, discontinue, and administer medications for the treatment of opioid induced side effects.
     - Initiate, modify, discontinue, and administer medications for the treatment of opioid withdrawal symptoms including but not limited to alpha-2 agonists, antiemetics, antihistamines, anticonvulsants, antidiarrheal agents, analgesics, and sedative hypnotics.
     - Initiate, modify, discontinue, and administer medications for the purpose of opioid tapering.
   - Develop a treatment plan for opioid use disorder including referral to medical services, case management, psychosocial services, substance use counseling, and residential treatment as indicated.
     - For patients who self-refer to the pharmacist for treatment, the pharmacist will have direct communication with a collaborating physician to review the treatment plan by a method and frequency determined by the physician.

7. Documentation and Reporting
   - The pharmacist's assessment, clinical findings, and plan of care will be documented in a health record mutually accessible by the referring provider, collaborating physician, and/or primary care provider. If a mutually accessible health record is not available documentation will be shared via facsimile or other secured communication platform.
   - Pharmacists shall report prescribing and dispensing of any controlled substance or any other required medications to the state prescription drug monitoring program, as required by state law.

Note: This language was adapted from the California Board of Pharmacy's State Protocol (https://www.pharmacy.ca.gov/licensees/collaborative_practice.pdf).

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