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To Save Lives, ASAM Calls for Policies to Ensure Pharmacists Can Dispense Medications for Addiction Treatment Without Undue Delay, While Urging Caution in Allowing Pharmacists the Ability to Prescribe

ASAM recommends the federal government exempt controlled medications that have been approved for the treatment of substance use disorder (SUD) (only) from "suspicious order" reporting requirements, among other actions

Rockville, MD – Today, the American Society of Addiction Medicine (ASAM) released its <u>Public</u> <u>Policy Statement on the Role of Pharmacists in Medications for Addiction Treatment,</u> addressing key challenges in pharmacy practice that contribute to <u>low utilization rates</u> of medications that are specifically indicated and prescribed for the treatment of substance use disorder (SUD). Cost-effective addiction medications are critical because they reduce harmful substance use and related morbidity and mortality, improve health outcomes, and enhance quality of life. Ultimately, medications are essential to effective treatment of people with addiction, but current policies make access to them unnecessarily difficult for many patients.

Pharmacists Must Dispense Medications for Addiction Treatment Without Undue Delay

Pharmacists help ensure the safe and effective use of medications, such as buprenorphine, the medication most often prescribed in the U.S. for treating opioid use disorder (OUD). However, because some pharmacies still associate significant risk with ordering and dispensing buprenorphine for OUD – possibly conflating harms associated with diversion of medications like oxycodone – some pharmacists are not fulfilling their core function of dispensing lawful prescriptions. Factors also undermining pharmacists' core function to dispense include (1) ambiguity related to pharmacists' responsibilities under Drug Enforcement Administration (DEA) regulations, (2) federal requirements to report "suspicious orders" of controlled substances, and (3) terms of opioid settlement agreements.

Patients' limited pharmacy access to addiction medications like buprenorphine costs lives, and is major reason for the underutilization of medication for addiction treatment for one of America's most vulnerable populations. ASAM strongly recommends states enact policies to

help ensure pharmacies dispense FDA-approved addiction medications without undue delay, and dramatically lower more Americans risk of dying, including by drug overdose.

"Well over two million Americans have died from an alcohol-related cause or drug-related overdose since 2000, exposing many millions more to devastating, personal loss," said Dr. Brian Hurley, MD, MBA, President of ASAM. "Policymakers should focus on advancing policies to ensure that pharmacists can fulfill their core function to dispense lawful prescriptions for addiction medications. Future efforts to improve access to and utilization of addiction medications – particularly buprenorphine and methadone for use in OUD treatment - involving clinical pharmacists should not come at the expense of protecting pharmacy access to addiction medication treatment."

A top recommendation in the statement is that Congress amend federal law to exempt controlled medications FDA-approved for the treatment of SUD (only) from federal suspicious order reporting requirements, and further, in the absence of Congressional action, the Department of Justice/Drug Enforcement Administration clarify that no action will be taken against any party for excluding such medications in suspicious order reporting – paving the way for such medications' removal from any related algorithms, threshold limits, or automated checks by manufacturers, distributors, and pharmacies.

ASAM Urges Caution in Allowing Pharmacists the Ability to Prescribe Medications

In its statement, ASAM also describes state efforts to expand pharmacists' role in medications for addiction treatment using patient-specific collaborative practice agreements, state-based protocols, and advanced practice licenses. These state policies often aim to leverage the accessibility of the nation's 61,000 community pharmacies and 140,000 community pharmacists, however, policies that allow pharmacists to prescribe medications may not always be appropriate, considering variability in training and risks associated with misdiagnosis.

As policymakers consider new methods to address the addiction crisis, they must use caution. According to the statement, "States [should] develop programs to promote best practices in, and incentivize appropriately qualified, licensed physicians and pharmacists to engage in, patient-specific collaborative practice agreements for addiction medications, including reimbursement for pharmacists' services, provided that" the arrangements adhere to certain guardrails, including requiring physicians first diagnose patients with SUD.

ASAM Recommendations

To help increase utilization rates of medications in addiction treatment, ASAM recommends a range of actions including:

- (1) States establishing pharmacy practice sites' and/or pharmacists' duty to dispense lawful prescriptions for addiction medications without undue delay; pharmacies align corporate policies and store protocols accordingly.
- (2) State attorneys general amending opioid settlement agreements to ensure adequate access to medications for OUD and overdose reversal and remove provisions hindering access to controlled medication formulations approved for the treatment of SUD (only).

- (3) The federal government exempting controlled medication formulations approved for the treatment of SUD (only) from federal suspicious order reporting requirements.
- (4) Federal and state authorities (including but not limited to those regulating licensed healthcare professionals or overseeing state prescription drug monitoring programs), public and private payers (and their drug utilization boards and committees), and medical and pharmacy organizations conduct binding review processes to update and synchronize any "red flag" or "suspicious order" policies to the extent under their control, and, as fundamental to these processes, any red flag policies should be removed that:
 - Inappropriately or unreasonably limit geographic distance between patient and prescriber or patient and pharmacy, especially considering increased utilization of telemedicine.
 - b. Limit patients to payment through insurance coverage.
 - c. Suspect dose increases for an individual patient.
 - d. Suspect and/or distinguish between buprenorphine and other buprenorphine/naloxone combination products that are approved by the FDA to treat OUD.
 - e. Suspect patients receiving prescriptions from multiple providers from the same medical practice.
 - f. Require patients to provide a diagnostic code on their prescription.
 - g. Require prescribers' verbal confirmation of prescription or practice details by telephone only.

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About the American Society of Addiction Medicine

The American Society of Addiction Medicine (ASAM), founded in 1954, is a professional medical society representing over 7,000 physicians, clinicians, and associated professionals in the field of addiction medicine. ASAM is dedicated to increasing access and improving the quality of addiction treatment, educating physicians and the public, supporting research and prevention and promoting the appropriate role of physicians in the care of patients with addiction. For more information, visit www.ASAM.org.