American Pharmacists Association
For Every Pharmacist. For All of Pharmacy.

American Pharmacists Association
House of Delegates – March 22-25, 2024

To be completed by the Office of the Secretary of the House of Delegates

Item No.: **2**
Date received: **1/22/24**
Time received: **6:54pm ET**

NEW BUSINESS
(To be submitted and introduced by Delegates only)

Introduced by: Matthew Lacroix, PharmD, MS, BCPS, FAPhA
(Name)

January 22
(Date)

Rhode Island Delegation
(Organization)

Subject: **Community Pharmacy Methadone Dispensing for Opioid Use Disorder**

Motion: Adopt the following policy statements as written

1. APhA supports changes in laws, regulations, and policies to permit DEA-registered and trained opioid treatment program clinicians and other providers the ability to prescribe methadone for opioid use disorder and offer referrals to addiction specialist physicians according to patient need.

2. APhA supports changes in laws, regulations, and policies to permit community pharmacy dispensing of methadone for opioid use disorder and appropriate reimbursement for these services.

3. APhA supports partnerships and collaborations to increase patient access to opioid treatment programs (OTPs) and clinicians.

4. APhA advocates for interprofessional education on laws, regulations, and policies regarding office-based prescribing and community pharmacy dispensing of methadone in curricula, postgraduate training, and continuing professional development programs of all health professions.

Background:

More than 75% of more than 106,000 drug overdose deaths between August 2022 and August 2023 involved opioids.[1] The majority of these opioids were illegally produced high potency synthetic opioids, primarily fentanyl and fentanyl analogs. There are six million people in the US living with opioid use disorder (OUD) and would benefit from medication treatment; only one in five people receive treatment for their disease.[2,3] When accessible, methadone is an highly effective medication treatment for (OUD) which decreases all-cause

mortality in OUD patients by more than 50%; It is listed as an "essential medication" by the World Health Organization.[4,5] However, for half a century, federal regulations have made methadone for OUD treatment only available within opioid treatment programs (OTPs) also known as methadone maintenance or treatment programs.[6] Unlike the medical system, only OTP-based providers can prescribe methadone, patients are required to go every day for a dose, often restricted to early mornings only, and must stay in treatment for years before gaining approval for "take-home" regimens.[6] State and federal guidelines place additional onerous restrictions on patients, requiring counseling visits and observed urine samples.

Although there are ~1,700 OTPs in the US, 80% of counties and the entire state of Wyoming lack even one.[7] Although the number of OTPs in the U.S. increased by ~40% over the past decade, fatal and nonfatal overdoses have increased nearly annually in most of the US. The median drive time one-way to an OTP in rural areas is disproportionately longer as compared to urban areas, and significantly longer than traveling to community pharmacies located in the same urban and rural areas. [8–10]

While board-certified addiction medicine specialists are the ideal prescribers for methadone, there are fewer than 5,000 addiction medicine and psychiatry specialists in active practice. These are relatively small numbers to the nearly 1,000,000 physicians, 385,000 nurse practitioners, and 168,000 physician assistants and 60,000 community pharmacies available nationwide.[11–14] With adequate pre- and post-graduate training, these providers can safely prescribe methadone for OUD, greatly expanding access to this life-saving therapy.

Community pharmacists stocked and dispensed methadone for pain management *and* OUD prior to the regulations, but currently can only dispense methadone for treatment of pain.[15–17] During the COVID-19 pandemic, take-home doses of methadone for up to 28 days were permitted for any stable patient temporarily from OTPs after federal and some state laws were relaxed.[18] Reported overdose deaths with methadone identified declined from 4.5% in January 2019 to 3.2% in August 2021, which was the time frame during which take-home doses were allowed.[19,20] This demonstrates how better access to methadone for OUD is safe, and Substance Abuse and Mental Health Services Administration (SAMHSA) has proposed guidance that would permanently permit 28 day take-homes for anyone 31+ days in treatment.[21] The Board of Directors of the American Society for Addiction Medicine (ASAM) approved the following statement "SAMHSA and Drug Enforcement Administration (DEA) regulations should allow pharmacy dispensing and/or administration of methadone that has been prescribed for patients who meet certain criteria by a legally authorized prescriber of controlled medications who is affiliated with an OTP, is an addiction specialist physician, or is a physician who has met specific qualifications." In 2023, the federal Modernizing Opioid Treatment Access Act (MOTAA) was introduced to permit addiction physicians specialists to prescribe methadone which can be dispensed from community pharmacies.[22] In a study where community pharmacy dispensing of methadone for OUD was permitted, participants reported strong satisfaction, and attendance rate to pharmacies was perfect.[23,24] The National Institute for Drug Abuse (NIDA) Clinical Trials Network (CTN) has funded a trial of physician prescribed and community pharmacy dispensed methadone (CTN-131).[25]

Increasing collaboration between providers would improve access to OUD treatment and give patients a better chance for sustaining recovery, whether they want to and are able to go to an OTP or whether they seek care at a community pharmacy. There is approximately one OTP for every thirty two pharmacies in the country, with many areas having no local OTPs.[26] OTPs typically have dispensing hours from 5am to 12pm, varying between facilities, which may limit adherence to treatment. Fortunately, community pharmacies are open for broader ranges of time, allowing easier access for attendance for dosing administration. Ultimately, patients should maintain the choice of treatment setting when pharmacies can dispense methadone for OUD.

In Canada, Australia, the United Kingdom (UK), and in western Europe, community pharmacies have provided methadone access for decades.[27] In Australia, pharmacists are considered clinicians who may supervise dosing administration once they have received orientation, training, and support to provide their services.[28] The majority of prescriptions for methadone are written by general practitioners, and over 70% of prescriptions are dispensed by community pharmacists.[29] In Canada, pharmacists are able to dispense methadone with a valid written order or prescription so long as they complete their training of the Narcotic Control Regulations. Once healthcare providers in Canada complete all trainings required in their province, they may prescribe methadone that can be dispensed in retail or community pharmacies.[30]

Pharmacists feel that lack of training is a barrier to their ability in dispensing methadone for OUD including inadequate baseline knowledge from post-graduate education and limited available training courses.[31] If training were to be more readily accessible, pharmacists would be more likely to participate and feel more adequately prepared for methadone dispensing for OUD. Student pharmacists were less likely to perceive stigma associated with OUD than pharmacists who are currently practicing, and they did desire more participation in patient care managing OUD. Student pharmacists would like to receive exposure to therapeutic knowledge and lived experience of OUD and methadone treatment, more so than what is currently implemented into their curriculum.[32] Providing continuing education to providers is an efficient and frequently used method for providers to stay current with treatments for patients. Modules for clinician education and training for methadone have been developed and will increase confidence for providing medication treatment for OUD with methadone. Implementation and provider engagement to these services is key to improving OUD treatment in order to decrease opioid overdose mortality.

We are grateful for the assistance of Cassie Capezza, University of Rhode Island PharmD '24 for initial drafts of the statements, background writing, and research.

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Current APhA Policy & Bylaws:

2003, 1972 Methadone Used as Analgesic and Antitussive

APhA encourages developers of methadone programs to place pharmacists in charge of their drug distribution and control systems.
(JAPhA. NS12:308; June 1972) (JAPhA. NS43(5)(suppl 1):S58; September/October 2003) (Reviewed 2006) (Reviewed 2011) (Reviewed 2016)

2019, 2016 Substance Use Disorder

1. **APhA supports legislative, regulatory, and private sector efforts that include pharmacists' input and that will balance patient/consumers' need for access to medications for legitimate medical purposes with the need to prevent the diversion, misuse, and abuse of medications.**
2. **APhA supports consumer sales limits of nonprescription drug products, such as methamphetamine precursors, that may be illegally converted into drugs for illicit use.**
3. **APhA encourages education of all personnel involved in the distribution chain of nonprescription products so they understand the potential for certain products, such as methamphetamine precursors, to be illegally converted into drugs for illicit use. APhA supports comprehensive substance use disorder education, prevention, treatment, and recovery programs.**
4. **APhA supports public and private initiatives to fund treatment and prevention of substance use disorders.**
5. **APhA supports stringent enforcement of criminal laws against individuals who engage in drug trafficking.**

(JAPhA. 56(4):369; July/August 2016) (JAPhA. 59(4):e28; July/August 2019) (Reviewed 2022)

2023 2016 Medication for Substance Use Disorders Medication-Assisted Treatment

APhA supports expanding access to medications indicated for opioid use disorders (MOUDs) and other substance use disorders, including but not limited to pharmacist-administered injection services for treatment and maintenance of substance use disorders that are based on a valid prescription.
(JAPhA, Volume 63, Issue 4, 1265 – 1281)

2020 Increasing Access to and Advocacy for Medications for Opioid Use Disorder- (MOUD)

1. APhA supports the use of evidence-based medicine as first-line treatment for opioid use disorder for patients, including healthcare professionals in and out of the workplace, for as long as needed to treat their disease.
2. APhA encourages pharmacies to maintain an inventory of medications used in treatment of opioid use disorder (MOUD), to ensure access for patients.
3. APhA encourages pharmacists and payers to ensure patients have equitable access to, and coverage for, at least one medication from each class of medications used in the treatment of opioid use disorder.
(JAPhA. 62(4):942; July 2022)

2023 Pharmacy Shortage Areas

1. APhA recognizes geographic proximity and transportation to pharmacies as key determinants in equitable access to medications, vaccines, and patient care services.
2. APhA calls for laws, regulations, and policies that reduce pharmacy shortage areas and ensure equitable access to essential services.
3. APhA supports the development of financial incentives to establish physical pharmacy locations in pharmacy shortage areas and to prevent the closure of pharmacies in underserved areas.
(JAPhA, Volume 63, Issue 4, 1265 – 1281)

2023 Access to Essential Medicines

APhA advocates regulation, policies and legislation that recognize access to quality and affordable essential medicines as a fundamental human right.
(JAPhA, Volume 63, Issue 4, 1265 – 1281)

2004, 1975 Other Health Care Professional Organizations

APhA supports continuing joint action with other health care and professional organizations.

2023 Uncompensated Care Mandates in Pharmacy

1. APhA calls for commensurate compensation for the provision of compulsory or mandated pharmacy services that include all products, supplies, labor, expertise, and administrative fees based on transparent economic analyses of existing and future services.
(JAPhA, Volume 63, Issue 4, 1265 – 1281)

2023 Workplace Conditions

1. APhA calls for employers to provide fair, realistic, and equitable workplace conditions for pharmacy personnel that promote a safe, healthy, and sustainable working environment.
2. APhA urges all entities that impact pharmacy personnel workplace conditions to adopt the Pharmacists Fundamental Responsibilities and Rights.
3. APhA urges employers to develop and empower pharmacy personnel to use flexible practice management models based on available staffing, expertise, and resources that balance workloads to minimize distractions.
4. APhA advocates for employers to provide workplace onboarding and training for pharmacy personnel to optimize employee performance and satisfaction.
5. APhA encourages pharmacy personnel, starting with leaders, to model and facilitate individualized healthy working behaviors that improve well-being and to encourage and empower colleagues to do the same.
6. APhA opposes the sole use of productivity and fiscal measures for employee performance evaluations.
7. APhA calls for employers and employees to collaborate in the development and use of behavioral performance competencies in performance evaluations.
(JAPhA, Volume 63, Issue 4, 1265 – 1281)

2023 Enforcing Anti Discrimination in the Dispensing of Medicines

APhA affirms that discrimination and stigma should not impact a patient's ability to obtain medications.
(JAPhA, Volume 63, Issue 4, 1265 – 1281)

2019 Referral System for the Pharmacy Profession

1. APhA supports referrals of patients to pharmacists, among pharmacists, or between pharmacists and other health care providers to promote optimal patient outcomes.
2. APhA supports referrals to and by pharmacists that ensure timely patient access to quality services and promote patient freedom of choice.
3. APhA advocates for pharmacists' engagement in referral systems that are aligned with those of other health care providers and facilitate collaboration and information sharing to ensure continuity of care.
4. APhA supports attribution and equitable payment to pharmacists providing patient care services as a result of a referral.
5. APhA promotes the pharmacist's professional responsibility to uphold ethical and legal standards of care in referral practices.
6. APhA reaffirms its support of development, adoption, and use of policies and procedures by pharmacists to manage potential conflicts of interest in practice, including in referral systems.

(JAPhA. 59(4):e16; July/August 2019) (Reviewed 2022)

2018 Pharmacists Electronic Referral Tracking

1. APhA supports the development of electronic systems that enhance and simplify the ability of pharmacists in all practice settings to receive, send, and track referrals among all members of the health care team, including other pharmacists, irrespective of the health care system, model, or network in which the patient participates.
2. APhA supports the interoperability and integration of referral tracking systems with electronic health records so patients can receive the benefit of optimally coordinated care from all members of the health care team.

(JAPhA. 58(4):356; July/August 2018) (Reviewed 2020)

2012 Controlled Substances Regulation and Patient Care

1. APhA encourages the Drug Enforcement Administration (DEA) and other regulatory agencies to recognize pharmacists as partners that are committed to ensuring that patients in legitimate need of controlled substances are able to receive the medications.
2. APhA supports efforts to modernize and harmonize state and federal controlled substance laws.
3. APhA urges DEA and other regulatory agencies to balance patient care and regulatory issues when developing, interpreting, and enforcing laws and regulations.
4. APhA encourages DEA and other regulatory agencies to recognize the changes occurring in health care delivery and to establish a transparent and inclusive process for the timely updating of laws and regulations.
5. APhA encourages the U.S. Department of Justice to collaborate with professional organizations to identify and reduce (a) the burdens on health care providers, (b) the cost of health care delivery, and (c) the barriers to patient care in the establishment and enforcement of controlled substance laws.

(JAPhA. NS52(4):457; July/August 2012) (Reviewed 2015)

2019 Patient-Centered Care of People Who Inject Non-Medically Sanctioned Psychotropic or Psychoactive Substances

1. APhA encourages state legislatures and boards of pharmacy to revise laws and regulations to support the patient-centered care of people who inject non-medically sanctioned psychotropic or psychoactive substances.
2. To reduce the consequences of stigma associated with injection drug use, APhA supports the expansion of interprofessional harm reduction education in the curriculum of schools and colleges of pharmacy, postgraduate training, and continuing professional development programs.
3. APhA encourages pharmacists to initiate, sustain, and integrate evidence-based harm reduction principles and programs into their practice to optimize the health of people who inject non-medically sanctioned psychotropic or psychoactive substances.

4. APhA supports pharmacists' roles to provide and promote consistent, unrestricted, and immediate access to evidence-based, mortality- and morbidity-reducing interventions to enhance the health of people who inject nonmedically sanctioned psychotropic or psychoactive substances and their communities, including sterile syringes, needles, and other safe injection equipment, syringe disposal, fentanyl test strips, immunizations, condoms, wound care supplies, pre- and post-exposure prophylaxis medications for human immunodeficiency virus (HIV), point-of-care testing for HIV and hepatitis C virus (HCV), opioid overdose reversal medications, and medications for opioid use disorder.
5. APhA urges pharmacists to refer people who inject non-medically sanctioned psychotropic or psychoactive substances to specialists in mental health, infectious diseases, and addiction treatment; to housing, vocational, harm reduction, and recovery support services; and to overdose prevention sites and syringe service programs.
(JAPhA. 59(4):e17; July/August 2019) (Reviewed 2021) (Reviewed 2022)

2020 Community-Based Pharmacists as Providers of Care

1. APhA advocates for the identification of medical conditions that may be safely and effectively treated by community-based pharmacists.
2. APhA encourages the training and education of pharmacists and student pharmacists regarding identification, treatment, monitoring, documentation, follow-up, and referral for medical conditions treated by community-based pharmacists
3. APhA advocates for laws and regulations that allow pharmacists to identify and manage medical conditions treated by community-based pharmacists.
4. APhA advocates for appropriate remuneration for the assessment and treatment of medical conditions treated by community-based pharmacists from government and private payers to ensure sustainability and access for patients.
5. APhA supports research to examine the outcomes of services that focus on medical conditions treated by community-based pharmacists.
(JAPhA. 60(5):e10; September/October 2020)

2013 Ensuring Access to Pharmacists' Services

1. Pharmacists are health care providers who must be recognized and compensated by payers for their professional services.
2. APhA actively supports the adoption of standardized processes for the provision, documentation, and claims submission of pharmacists' services.
3. APhA supports pharmacists' ability to bill payers and be compensated for their services consistent with the processes of other health care providers.
4. APhA supports recognition by payers that compensable pharmacist services range from generalized to focused activities intended to improve health outcomes based on individual patient needs.
5. APhA advocates for the development and implementation of a standardized process for verification of pharmacists' credentials as a means to foster compensation for pharmacist services and reduce administrative redundancy.
6. APhA advocates for pharmacists' access and contribution to clinical and claims data to support treatment, payment, and health care operations.
7. APhA actively supports the integration of pharmacists' service level and outcome data with other health care provider and claims data.
(JAPhA. 53(4):365; July/August 2013) (Reviewed 2018) (Reviewed 2019) (Reviewed 2021)

2005, 1977 Government-Financed Reimbursement

1. APhA supports only those government-operated or -financed, third-party prescription programs which ensures that participating pharmacists receive individualized, equitable compensation for professional services and reimbursement for products provided under the program.
2. APhA regards equitable compensation under any government-operated or -financed, third party prescription programs as requiring payments equivalent to a participating pharmacist's prevailing charges to the self-paying

public for comparable services and products, plus additional, documented, direct and indirect costs which are generated by participation in the program.

3. APhA supports those government-operated or -financed, third-party prescription programs which base compensation for professional services on professional fees and reimbursement for products provided on actual cost, with the provision of a specific exception to this policy in those instances when equity in professional compensation cannot otherwise be attained.

(JAPhA. NS17:452; July 1977) (JAPhA. NS45(5):558; September/October 2005) (Reviewed 2009) (Reviewed 2011) (Reviewed 2012) (Reviewed 2017) (Reviewed 2021) (Reviewed 2022)

1987 Compensation for Cognitive Services

1. APhA recognizes that pharmacists provide to patients cognitive services (i.e., services requiring professional judgment) that may or may not be related to the dispensing or sale of a product.

2. APhA supports compensation of pharmacists for providing cognitive services (i.e., services requiring professional judgment) that may or may not be related to the dispensing or sale of a product.

(Am Pharm. NS27(6):422; June 1987) (Reviewed 2005) (Reviewed 2009) (Reviewed 2011) (Reviewed 2013) (Reviewed 2018)

****Phone numbers will only be used by the New Business Review Committee in case there are questions for the delegate who submitted the New Business Item content.**

New Business Items are due to the Speaker of the House by **January 22, 2024** (60 days prior to the start of the first House session). Consideration of urgent items can be presented with a suspension of the House Rules at the session where New Business will be acted upon. Please submit New Business Items to the Speaker of the House via email at hod@aphanet.org.