LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

MODEL PHARMACIST COLLABORATION FOR MEDICATION FOR OPIOID USE DISORDER ACT

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MODEL PHARMACIST COLLABORATION FOR MEDICATION FOR OPIOID USE DISORDER TREATMENT ACT

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SECTION I. TITLE.

This Act may be cited as the "Model Pharmacist Collaboration for Medication for Opioid Use Disorder Act," "Model Act," or "the Act."

Commentary

As with any chronic medical condition, evolving science and evidence inform the best approach to providing treatment for opioid use disorder. The best practices surrounding opioid use disorder continue to evolve, as does the language used to describe it. The Model Act uses the term "medication for opioid use disorder." Other common terms for this type of treatment are "medication-assisted treatment," "medication-based treatment," or "medication for addiction treatment."

The Act's drafters prefer "medication for opioid use disorder," which aligns with the evidence that opioid use disorder is a chronic disorder for which medications are a first-line treatment that are often an integral part of a person's long-term treatment plan, rather than complementary or temporary aids on the path to recovery.[1]

SECTION II. LEGISLATIVE FINDINGS AND PURPOSE.

(a) Legislative findings.—The [Legislature][2] finds that:

(1) The United States and the state of [insert name of state] are in the midst of the worst crisis of opioid-related harm in history;[3]

(2) In 2022, an estimated 3 million Americans had opioid use disorder, a chronic brain condition that comes about because of the effects of long term opioid use on the brain structure and function.[4] Opioid use disorder is a life-threatening condition associated with a 20-fold greater risk of early death due to overdose, infectious disease, trauma, and suicide.[5] More than one million individuals have died from a drug overdose since 1999, increasingly due to the presence of illicitly manufactured fentanyl and other potent synthetic opioids and stimulants in the illicit drug supply

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[1] ALAN I. LESHNER & MICHELLE MANCHER, EDS., MEDICATIONS FOR OPIOID USE DISORDER SAVE LIVES, NAT'L ACAD. PRESS 2 (2019), [hereinafter "MEDICATIONS FOR OPIOID USE DISORDER SAVE LIVES"].

[2] This Act contains certain bracketed words and phrases. Brackets indicate instances where state lawmakers may need to insert state-specific terminology or facts.

[3] *See Understanding the Epidemic*, CTRS. DISEASE CONTROL & PREVENTION (Aug. 8, 2023), https://www.cdc.gov/opioids/basics/epidemic.html.

[4] Mohammadreza Azadfard, Martin R. Huecker & James M. Leaming. *Opioid addiction*, in STATPEARLS (2022), https://www.ncbi.nlm.nih.gov/books/NBK448203/.

[5] MEDICATIONS FOR OPIOID USE DISORDER SAVE LIVES, *supra* note 1, at 1.

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market.[6] [Insert state-specific numbers, if desired.] Opioid overdose is now the leading cause of accidental death in the United States, with more people dying from an accidental overdose than a car crash;[7]

(3) Medication for opioid use disorder is the gold standard of medical care. Methadone, buprenorphine (commonly known by brand names such as Suboxone, Subutex, Zubsolv, and Sublocade), and extended-release naltrexone (commonly known by the brand name Vivitrol), are evidence-based, safe and highly effective medications that are already approved by the U.S. Food and Drug Administration (FDA) to treat opioid use disorder. By alleviating withdrawal symptoms, reducing opioid cravings, and decreasing the response to future drug use, these medications make people with opioid use disorder less likely to return to drug use and risk a fatal overdose;[8]

(4) Medication for opioid use disorder is the only evidence-based effective treatment that reduces the risk of death from overdose, dramatically reducing deaths from all causes by as much as 50 percent. [9] Few, if any, other medications have such a profound effect on mortality rates;

(5) Because opioid use disorder is caused by changes in brain circuitry, treatment with medication can restore healthy brain function and improve the quality of life for people with opioid use disorder and their families.[10] When given an appropriate dose, patients are not impaired psychologically, physically or emotionally and can safely engage in productive behaviors. Patients who receive medication stay in treatment longer, have better long-term treatment outcomes, and improved social

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[6] *Drug Overdose Deaths*, CTRS. DISEASE CONTROL & PREVENTION (Aug. 22, 2023), https://www.cdc.gov/drugoverdose/deaths/.

[7] *Preventable Deaths*, NSC INJURY FACTS, https://injuryfacts.nsc.org/all-injuries/preventable-death-overview/odds-of-dying/data-details/ (last visited April 11, 2024).

[8] MEDICATIONS FOR OPIOID USE DISORDER SAVE LIVES, *supra* note 1, at 2. Only methadone and buprenorphine alleviate withdrawal symptoms, but all three medications decrease cravings and block the euphoric effects of taking other opioids. *Id*.

[9] Marc R. Larochelle, Dana Bernson & Thomas Land et al., *Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association with Mortality*, 7 ANNALS INTERNAL MED. 137, 140 (2018); Luis Sordo, Gregoria Barrio & Maria Bravo et al., *Mortality Risk During and After Opioid Substitution Treatment: Systematic Review and Meta-analysis of Cohort Studies*, 357 BMJ j1550 at 12 (2017); Matthias Pierce, Sheila M. Bird & Matthew Hickman et al., *Impact of Treatment for Opioid Dependence on Fatal Drug-related Poisoning: A National Cohort Study in England*, 111 ADDICTION 298, 302 (2015).

[10] James Bell & John Strang, *Medication Treatment of Opioid Use Disorder*, 87 BIOLOGICAL PSYCHIATRY 82, 83 (2019); John Strang, Nora D. Volkow & Louisa Degenhardt et al., *Opioid Use Disorder*, NATURE REVS. DISEASE PRIMERS 7 (2020).

functioning. They are also less likely to inject drugs,[11] contract and transmit infectious diseases,[12] and engage in criminal behavior;[13]

(6) Strong evidence also indicates that medication for opioid use disorder is cost-effective compared to no treatment, with lifetime cost savings of $25,000 to $105,000 per patient including savings in health care and criminal legal costs;[14]

(7) Despite its effectiveness, only 11 percent of individuals with opioid use disorder receive medication for opioid use disorder.[15] Stigma and discrimination against people with opioid use disorder, misunderstandings about how medication for opioid use disorder work, a lack of opioid treatment programs,[16] a shortage of practitioners who prescribe medication for opioid use disorder,[17] and the overall shortage of primary care and addiction treatment practitioners, particularly in rural areas,[18] are key barriers to care;

(8) Community pharmacies can greatly expand access to medication for opioid use disorder by transforming them into low-barrier points for access for treatment. The U.S. has over 60,000 community pharmacies, and 90 percent of Americans live within five miles of a pharmacy;[19]

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[11] JENNIFER J. CARROLL, ALICE ASHER, VIKRAM KRISHNASAMY & DEBORAH DOWELL, LINKING PEOPLE WITH OPIOID USE DISORDER TO MEDICATION TREATMENT: A TECHNICAL PACKAGE OF POLICY, PROGRAMS, AND PRACTICES 7 (2022).

[12] MEDICATIONS FOR OPIOID USE DISORDER SAVE LIVES, *supra* note 1, at 5.

[13] John C. Ball & Allen Ross, *Reduction of Crime Through Methadone Maintenance Treatment, in* THE EFFECTIVENESS OF METHADONE MAINTENANCE TREATMENT 195, 195 (1991); Elizabeth A. Evans, Donna Wilson & Peter D. Friedmann, *Recidivism and Mortality After In-jail Buprenorphine Treatment for Opioid Use Disorder*, 231 DRUG & ALCOHOL DEPENDENCE, Feb. 1, 2022, at 3 (2022).

[14] *See* Michael Fairley, Keith Humphreys & Vilija R. Joyce et al., *Cost-effectiveness of Treatments for Opioid Use Disorder*, 78 JAMA PSYCHIATRY 767, 772–73 (2021).

[15] Nora Volkow, *Making Addiction Treatment More Realistic and Pragmatic: The Perfect Should Not be the Enemy of the Good*, NAT'L INST. ON DRUG ABUSE (Jan. 4, 2022), https://nida.nih.gov/about-nida/noras-blog/2022/01/making-addiction-treatment-more-realistic-pragmatic-perfect-should-not-be-enemy-good.

[16] Tanvi Rao, et al. *Exploring Urban-rural Disparities in Accessing Treatment for Opioid Use Disorder*, AMERICAN INSTITUTES FOR RESEARCH (Nov. 2021), https://www.air.org/resource/equity-focus/exploring-urban-rural-disparities-accessing-treatment-opioid-use-disorder.

[17] Ryan K. McBain, Andrew Dick, Mark Sorbero & Bradley D. Stein, *Growth and Distribution of Buprenorphine-waivered Providers in the United States, 2007-2017*, 172 ANNALS INTERNAL MED. 504, 506 (2020).

[18] C. Holly A. Andrilla, Cynthia Coulthard & Eric H. Larson, *Barriers Rural Physicians Face Prescribing Buprenorphine for Opioid Use Disorder*, 15 ANNALS FAMILY MED. 359, 359 (2017); Kevin P. Conway, Dalia Khoury & Rainer Hilscher et al., *Rural and Urban Differences in Undersupply of Buprenorphine Provider Availability in the United States, 2018*, 17 ADDICTION SCI. & PRAC., no. 5, at 2 (2022).

[19] Lucas A. Berenbrok, Shangbin Tang & Nico Gabriel et al., Access to Community Pharmacies: A Nationwide Geographic Information Systems Cross-section Analysis, 62 J. AM. PHARMACISTS ASS'N 1816, 1818 (2022).

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(9) Pharmacists are at the front line of providing harm reduction services, offering access to naloxone to reverse opioid overdose, selling nonprescription syringes to prevent the spread of infectious diseases, and fentanyl test strips to identify fentanyl in drug supplies;[20]

(10) The COVID-19 pandemic highlighted how pharmacists can dramatically expand access to public health and primary care services by increasing and sustaining community-based, cost-effective access to medication, vaccines, and testing when authorized by their state-defined scope of practice, standing orders, or collaborative practice agreements. From February 2020 through September 2022, pharmacists administered over half of all COVID-19 vaccines in the United States, helped avert one million deaths, and reduced $450 billion in excess healthcare costs associated with the pandemic;[21] and

(11) Evidence shows that pharmacists performing collaborative drug therapy management with physicians and other prescribers, via collaborative practice agreements, can increase access to medication for opioid use disorder, improve treatment quality, reduce costs, and help patients remain in treatment.[22]

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[20] CARROLL et al., *supra* note 11, at 18.

[21] John D. Grabenstein, *Essential Services: Quantifying the Contributions of America's Pharmacists in COVID-19 Clinical Interventions*, 62 J. AM. PHARMACISTS ASS'N 1929, 1929–30 (2022).

[22] Traci C. Green, Rachel. Serafinski & Seth A. Clark et al., *Physician-Delegated Unobserved Induction with Buprenorphine in Pharmacies*, 388 NEW ENG. J. MED. 185, 185–86 (2023); Haley Pals & Jeffrey Bratberg, *Improving Access to Care Via Psychiatric Clinical Pharmacist Practitioner Collaborative Management of Buprenorphine for Opioid Use Disorder*, 62 J. AM. PHARMACISTS ASS'N 1422, 1425 (2022); Li-Tzy Wu, William S. John & Udi E Ghitza et al., *Buprenorphine Physician–pharmacist Collaboration in the Management of Patients with Opioid Use Disorder: Results from a Multisite Study of the National Drug Abuse Treatment Clinical Trials Network*, 116 ADDICTION 1805, 1808 (2021); Lindsay M. Mailloux, Matthew T. Haas, Janel M. Larew & Beth M. DeJongh, *Development and Implementation of a Physician-pharmacist Collaborative Practice Model for Provision and Management of Buprenorphine/Naloxone,* 11 MENTAL HEALTH CLINICIAN 35, 38 (2021); Bethany A. DiPaula & Elizabeth Menachery, *Physician-pharmacist Collaborative Care Model for Buprenorphine-maintained Opioid-dependent Patients* 55 J. AMER. PHARMACISTS ASS'N 187, 189 (2015).

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(b) Purpose.—It is the intent of the [Legislature] through this Act to:

(1) Save the lives and improve the health and quality of life of individuals who have an opioid use disorder by expanding access to and availability of medication for opioid use disorder within [state];

(2) Increase the health care workforce providing medication for opioid use disorder by authorizing pharmacists (1) to prescribe medications for opioid use disorder for treatment and refer patients for longer-term treatment pursuant to a statewide protocol and (2) to prescribe, initiate, monitor, and adjust longer-term treatment pursuant to collaborative practice agreements for collaborative drug therapy management;

(3) Require [insert state-specific Medicaid terminology] and private health insurance coverage for pharmacists' comprehensive patient care and medication management services provided as part of a standing protocol or drug therapy management collaborative practice for medication for opioid use disorder; and

(4) Establish a grant program to incentivize and sustain interprofessional collaborations that include pharmacists through educational programs, statewide initiatives, community programs, and pilot programs developed pursuant to this Act.

Commentary[23]

This Model Act provides state legislators with an evidence-based framework to increase access to medication for opioid use disorder by authorizing pharmacists to prescribe, initiate, dispense, administer, and monitor these medications pursuant to a statewide standing protocol and collaborative practice agreements for collaborative drug therapy management. Community pharmacists offer low-barrier access to patients. Experts believe that pharmacists are chronically underutilized in the U.S. health care delivery system given their level of education, training, and visibility in the community.[24] Moreover, pharmacists are consistently rated one of the nation's

[23] The commentary in this Model Act serves two primary purposes. The first purpose is to provide the reader with background information about the genesis of language in the Act. To the extent that the model language is based on already proposed legislation or a particular document, the commentary notes this. The second purpose is to provide an explanation about why the Act contains particular provisions and the rationale behind these decisions, along with a discussion of issues (occasionally controversial) with which policymakers must grapple when state-specific legislation is introduced, negotiated, and amended.

[24] S. Giberson, S. Yoder & M.P. Lee, Improving Patient and Health System Outcomes Through Advanced Pharmacy Practice: A Report to the U.S. Surgeon General, U.S. Pub. Health Serv. 10 (2011) ("Maximizing the roles and scope of pharmacists to deliver a variety of patient-centered primary care and public health, in collaboration with physicians, is a proven and existing paradigm of care that can be efficiently implemented.").

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most trusted type of health care providers.[25] This Model Act offers an approach to increasing the health care workforce offering medication for opioid use disorder, particularly in underserved areas such as rural counties and traditionally underserved communities.

Opioid misuse has taken a terrible toll in terms of lives lost and harm caused to individuals and society. But opioid use disorder is a chronic, treatable condition,[26] and medication for opioid use disorder is the gold standard for treatment.[27] This does not mean that recovery from opioid use disorder occurs only through medication. Some individuals are able to stop misusing opioids on their own, while others recover through support groups or specialty treatment with or without medication. But many individuals need medication for opioid use disorder to help with recovery, just as many individuals require prescription medication to manage high blood pressure or diabetes.[28]

As of April 2024, the FDA has approved three drugs for medication for opioid use disorder: (1) methadone; (2) buprenorphine (known by the brand names Suboxone, Subutex, Zubsolv, and Sublocade); and (3) extended-release naltrexone (commonly known by the trade name Vivitrol). All three medications alleviate opioid cravings, and it is standard of care for many patients to receive them on a long-term basis. Buprenorphine and methadone also reduce withdrawal symptoms and are administered to people going through withdrawal to reduce discomfort and discourage further opioid use that often leads to overdose. Individuals receiving methadone and buprenorphine have a 50 percent lower risk of dying than those without treatment or those treated solely through counseling or 12-step programs that do not offer medication.[29] Naltrexone does not relieve withdrawal symptoms and therefore should only be administered to people to prevent relapse after they have abstained from use of opioids, generally after seven to 10 days.[30] Unlike methadone and buprenorphine, naltrexone has not been associated with a reduction of overdose death risk.[31]

Unfortunately, stigma and discrimination against people with opioid use disorder, driven by deeply ingrained moral, social, professional, and legal norms, create barriers to effective treatment with medication. For example, stereotypes about perceived moral failings or dangerousness of people with opioid use disorder remain a barrier to appropriate care and treatment. Stigma disinclines people to seek treatment, makes providers hesitant to offer it, and

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[25] Megan Brenen and Jeffrey M. Jones, *Ethics Rating of Nearly All Professions Down in U.S.*, GALLUP (Jan. 22, 2024), https://news.gallup.com/poll/608903/ethics-ratings-nearly-professions-down.aspx.

[26] *Treatment Improvement Protocol (TIP) 63: Medications for Opioid Use Disorder*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. at ES-1 (2021) [hereinafter "SAMHSA TIP 63"].

[27] MEDICATIONS FOR OPIOID USE DISORDER SAVE LIVES, *supra* note 1, at 4.

[28] SAMHSA TIP 63, *supra* note 26, at ES-2.

[29] MEDICATIONS FOR OPIOID USE DISORDER SAVE LIVES, *supra* note 1, at 117.

[30] Methadone and buprenorphine are opioid agonists that activate specific receptors in a person's brain. Naltrexone is an opioid antagonist, a drug that blocks opioids by attaching to the opioid receptors without activating them. MEDICATIONS FOR OPIOID USE DISORDER SAVE LIVES, *supra* note 1, at 19.

[31] LaRochelle, *supra* note 9. *See also* Elizabeth M. Ajazi, Nabarun Dasgupta & Stephen W. Marshall et al., *Revisiting the X:BOT Naltrexone Clinical Trial Using a Comprehensive Survival Analysis*, 16 J. ADDICTION MED. 440, 443 (2022).

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encourages friends and family to advocate for less effective abstinence-based approaches to recovery.[32]

While increasing segments of the public acknowledge that opioid use disorder is a chronic medical condition, the use of medication to treat it is nonetheless perceived by many as simply substituting one addiction with another. This false belief results from a misunderstanding of the difference between addiction and dependence. According to the National Institute on Drug Abuse, addiction is compulsive drug use despite negative consequences; dependence is needing a substance to function without withdrawal.[33] Addiction is, by definition, harmful. Dependence is not harmful when it reduces the risk of death and improves health and functioning, which is what occurs during medication treatment. Many people develop a dependence on medications when used effectively. These include insulin for diabetes and medications for conditions such as hypertension, seizure disorders, and depression.

Many people may not know that medication for opioid use disorder is the safest and most effective option for opioid use disorder treatment. The effectiveness of medication for opioid disorder is supported by a robust body of rigorous scientific evidence. This is acknowledged by myriad government agencies and professional organizations, including the National Institute of Health, Health and Human Services, and the Substance Abuse and Mental Health Services Administration (SAMHSA).[34] Patients with opioid use disorder receiving outpatient medication treatment are more likely to stay in treatment and have significantly better outcomes than those treated without medication.[35] Randomized clinical trials, the benchmark for demonstrating

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[32] MEDICATIONS FOR OPIOID USE DISORDER SAVE LIVES, *supra* note 1, at 110; Sophie Bryan & Marcelo H. Fernández-Viña, *Stigma Around Opioid Use Disorder Presents Challenges to Treatment*, PEWTRUSTS.ORG (May 4, 2022), https://www.pewtrusts.org/en/research-and-analysis/articles/2022/05/04/panel-discussion-stigma-around-opioid-use-disorder-presents-challenges-to-treatment.

[33] Charles P. O'Brien, Nora Volkow, *What's in a Word? Addiction Versus Dependence in DSM-V*, 163 AM. J. PSYCHIATRY 764 (2006).

[34] SAMHSA TIP 63, *supra* note 25, at ES-2.

[35] Joshua D. Lee, Peter D. Friedmann, Timothy W. Kinlock & Edward V. Nunes, *Extended-release Naltrexone to Prevent Opioid Relapse in Criminal Justice Offenders*, 374 NEW ENG. J. MED. 1232, 1236 (2016) (illustrating that naltrexone use was associated with longer periods of abstinence than among those receiving usual, non-pharmacological treatment); Suzanne Nielsen, Briony Larance & Louisa Degenhardt et al., *Opioid Agonist Treatment for Pharmaceutical Opioid Dependent People*, COCHRANE DATABASE SYST. REV., Issue 9, 2022, at 2 ("[M]aintenance treatment with buprenorphine appears more effective than non-opioid treatments."); Richard P. Mattick, Courtney Breen, Jo Kimber & Marina Davoli, *Buprenorphine Maintenance Versus Placebo or Methadone Maintenance for Opioid Dependence*, COCHRANE DATABASE SYST. REV., Issue 2, 2014, at 2–4 ("[B]uprenorphine at high doses (16 mg) can reduce illicit opioid use effectively compared with placebo, and buprenorphine at any dose studied retains people in treatment better than placebo."); David A. Fiellin, Richard S. Schottenfeld & Christpher J. Cutter et al., *Primary Care-based Buprenorphine Taper vs Maintenance Therapy for Prescription Opioid Dependence: A Randomized Clinical Trial*, 174 JAMA INTERNAL MED. 1947, 1951 (2014) (illustrating that buprenorphine taper was associated with a higher chance of recurrence than unchanged buprenorphine treatment); Richard P. Mattick, Courtney Breen, Jo Kimber & Marina Davoli, *Methadone Maintenance Therapy Versus No Opioid Replacement Therapy for Opioid Dependence*, COCHRANE DATABASE SYST. REV., Issue 3, 2009, at 2 ("Methadone maintenance treatment can keep people who are dependent on heroin in treatment programs and reduce their use of heroin."); Sandra D. Comer, Maria A. Sullivan & Elmer Yu et al., *Injectable, Sustained-release*

efficacy in clinical treatment, show that medication is more effective in reducing illicit opioid use than treatment without medication.[36] Individuals receiving methadone or buprenorphine medication for opioid use disorder have a lower chance of experiencing a fatal or non-fatal overdose than those without treatment or those being treated solely through counseling or 12-step programs that do not offer medication.[37] Medication for opioid use disorder also reduces criminal behavior and recidivism.[38]

Because methadone and buprenorphine are controlled substances, federal laws control who can prescribe them and how. Practitioners can prescribe most controlled substances if they have state authority to prescribe and are registered with the Drug Enforcement Administration (DEA). However, methadone and buprenorphine have been more tightly restricted. Methadone for opioid use disorder can only be administered or dispensed to an individual at a federally certified and accredited opioid treatment program (OTP), commonly known as a "methadone clinic."[39]

Under federal law, buprenorphine for opioid treatment can be prescribed in any practice setting. However, before January 2023, buprenorphine could only be prescribed by state-authorized practitioners, meaning physicians and certain midlevel providers like advance practice nurses and physician assistants, but not pharmacists. Authorized practitioners had to file a special notice of intent with SAMHSA, receive an "X-waiver," and comply with additional regulatory requirements, including limits on the number of patients they could treat with

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Naltrexone for the Treatment of Opioid Dependence: A Randomized, Placebo-controlled Trial, 63 ARCHIVES GEN. PSYCHIATRY 210, 212 (2006) (explaining that individuals receiving naltrexone stayed in treatment longer than those without pharmacological treatment); Karen L. Sees, Kevin L. Deucchi & Carmen Masson et al., *Methadone Maintenance vs 180-day Psychosocially Enriched Detoxification for Treatment of Opioid Dependence: A Randomized Controlled Trial*, 283 JAMA 1303, 1309 (2000) (showing that maintained methadone treatment led to lower recurrence and greater treatment retention than methadone tapering).

[36] Mattick et al., *Buprenorphine Maintenance, supra* note 35; Evgeny Krupitsky, Edward V. Nunes & Walter Ling et al., *Injectable Extended-Release Naltrexone for Opioid Dependence: A Double-blind, Placebo-controlled Multicentre Randomised Trial*, 377 LANCET 1506, 1511 (2011) (reporting that naltrexone use "nearly double[d] the median length of retention in treatment"); Lee et al., *Naltrexone to Prevent Opioid Relapse*, *supra* note 35; Mattick et al., *Methadone Maintenance Therapy*, *supra* note 35.

[37] Louisa Degenhardt, Deborah Randall & Wayne Hall et al., *Mortality Among Clients of a State-wide Opioid Pharmacotherapy Program over 20 years: Risk Factors and Lives Saved*, 105 DRUG & ALCOHOL DEPENDENCE 9 (2009) ("At the population level, the [medication for addiction] treatment program averted an additional 1,111 deaths during the study period."); Amy Gibson, Louisa Degenhardt & Richard P. Mattick et al., *Exposure to Opioid Maintenance Treatment Reduces Long-term Mortality*, 103 ADDICTION 462, 466 (2008) (finding that MAT, "regardless of whether this was methadone or buprenorphine, increased long-term survival"); Robert P. Schwartz, Jan Gryczynski & Kevin E. O'Grady et al., *Opioid Agonist Treatments and Heroin Overdose Deaths in Baltimore, Maryland, 1995–2009*, 103 AM. J. PUBLIC HEALTH 917, 923 (2013) ("The association between the increase in the number of buprenorphine patients and the decrease in heroin-related overdose deaths in Baltimore was statistically significant and strong."); Marc Auriacombe, Mélina Fatséas & Jacques Dubertnet et al., *French Field Experience with Buprenorphine*, 13 AM. J. ADDICTIONS S17, S24–S25 (2004) (discussing the correlation between increased use of MAT and decreased opioid-related mortality); WORLD HEALTH ORGANIZATION, GUIDELINES FOR THE PSYCHOSOCIALLY ASSISTED PHARMACOLOGICAL TREATMENT OF OPIOID DEPENDENCE 26 (2009) ("[T]he mortality rate in methadone treatment is approximately one third the rate out of treatment.").

[38] Ball & Ross, *supra* note 13; Evans et al., *supra* note 13.

[39] 42 C.F.R. § 8.12(h).

buprenorphine for opioid use disorder. The Mainstreaming Addiction Act, which was signed into law December 29, 2022 removed the X-waiver requirement.[40]

Unfortunately, there is a long-standing shortage of U.S. practitioners who prescribe buprenorphine, particularly primary care practitioners. When the X-waiver requirement was in place, less than 10 percent of U.S. primary care providers were authorized to prescribe buprenorphine.[41] As a result, nearly 20 million people lived in counties without a practitioner allowed to prescribe buprenorphine.[42] With the Mainstreaming Addiction Act eliminating the X-waiver requirement, experts hope that more practitioners will prescribe buprenorphine to those patients who need it.[43] However, many parts of the country, particularly rural communities, suffer from an overall shortage of primary care practitioners and addiction treatment specialists.[44] This shortage is particularly acute in rural areas.[45]

Removal of the X-waiver requirement means that states can now authorize pharmacists to prescribe buprenorphine for treatment of opioid use disorder, either through independent prescriptive authority, statewide protocols, or collaborative practice agreements. Ten states already authorize pharmacists to prescribe all controlled substances, including buprenorphine for opioid use disorder, through independent practice or collaborative practice agreements.[46]

This Model Act provides state law authority for pharmacists to become low-barrier providers of medication for opioid use disorder by authorizing pharmacists to prescribe medication for opioid use disorder pursuant to a statewide protocol and to prescribe, initiate, monitor, and adjust longer-term medication treatment pursuant to drug therapy management collaborative practice agreements. As of April 2024, federal law would restrict community pharmacist prescribing to buprenorphine and extended-release naltrexone as methadone for

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[40] *See* Consolidated Appropriations Act of 2023, Pub. L. No. 117-328, § 1262 (2023). *See also Removal of DATA Waiver (X-Waiver) Requirement*, SAMHSA.GOV (Jan. 25, 2023), https://www.samhsa.gov/medications-substance-use-disorders/removal-data-waiver-requirement ("All practitioners who have a current DEA registration that includes Schedule III authority, may now prescribe buprenorphine for Opioid Use Disorder in their practice if permitted by applicable state law and SAMHSA encourages them to do so.").
[41] McBain et al., *supra* note 17, at 505 (2020).
[42] C. Holly, A. Andrilla, Tessa E. Moore, Davis G. Patterson & Eric H. Larson, *Geographic Distribution of Providers with a DEA Waiver to Prescribe Buprenorphine for the Treatment of Opioid Use Disorder: A 5-Year Update*, 35 J. RURAL HEALTH 108, 109 (2019).
[43] However, some states have laws that restrict prescribing of buprenorphine which will continue to create barriers to care. Barbara Andraka-Christou, Adam J. Gordon & Kathryn Bouskill et al., *Toward a Typology of Office-based Buprenorphine Treatment Laws: Themes from a Review of State Laws*, 16 J. ADDICTION MED. 192, 206 (2022).
[44] Andrilla et al., *supra* note 18; Conway et al., *supra* note 18; IHS MARKIT LTD., *supra* note 17.
[45] Peter Jaret, *Attracting the Next Generation of Physicians to Rural Medicine*, AM. ASS'N MED. COLL. (Feb. 3, 2020), https://www.aamc.org/news-insights/attracting-next-generation-physicians-rural-medicine. Jamey J. Lister, Addie Weaver & Jennifer D. Ellis et al., *A Systematic Review of Rural-specific Barriers to Medication Treatment for Opioid Use Disorder in the United States*, 46 AM. J. DRUG & ALCOHOL ABUSE 273, 274 (2020).
[46] *See* DIVERSION CONTROL DIV., MID-LEVEL PRACTITIONERS AUTHORIZATION BY STATE, U.S. DEP'T JUST. DRUG ENFORCEMENT ADMIN., https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf.

opioid use disorder can only be administered or dispensed at federally certified and accredited opioid treatment programs (OTP), commonly known as "methadone clinics."[47]

SECTION III. DEFINITIONS.

[States may already have definitions in place for some or all of the following listed terms. In such case, states are free to use the existing definitions in place of those listed below.]

For purposes of this Act, unless the context clearly indicates otherwise, the words and phrases listed below have the meaning given them in this section:[48]

(a) Collaborative drug therapy management.—"Collaborative drug therapy management" means one or more pharmacists working within the context of a protocol described in a collaborative practice agreement to assume professional responsibility for performing patient assessments, counseling, and referrals; ordering laboratory tests; administering drugs; and selecting, initiating, monitoring, continuing, and adjusting drug regimens;[49]

(b) Collaborative practice agreement.—"Collaborative practice agreement" means a written agreement between one or more pharmacists or pharmacies and one or more practitioners or health care entities in which the collaborating practitioners authorize pharmacists to provide specified patient care services;

(c) Medication for opioid use disorder.—"Medication for opioid use disorder" means the use of medications approved by the United States Food and Drug Administration to treat opioid use disorder;[50]

(d) Opioid.—"Opioid" means natural, synthetic, or semi-synthetic chemicals that interact with opioid receptors on nerve cells in the body and brain. This class of drugs includes heroin, synthetic opioids such as fentanyl, and opioid analgesics, such as oxycodone, hydrocodone, codeine, and opiates like morphine;[51]

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[47] 42 C.F.R. §8.12(h).

[48] Where a definition is based on, adapted from, or directly pulled from, language from an enacted statute, proposed legislation, or other research material, the footnote referenced at the end of the definition provides that source.

[49] BEST PRACTICES FOR HEART DISEASE & STROKE: A GUIDE TO EFFECTIVE APPROACHES AND STRATEGIES, CTRS. DISEASE CONTROL & PREVENTION 83 (2022).

[50] Best practices surrounding and concerning treatment substance use are evolving, as is the language to describe it. Thus, while the Model Act uses the term "medication for opioid use disorder" there are other terms for this type of treatment including "medication-assisted treatment, "medication-based treatment," or "medications for addiction treatment."

[51] *Opioids: Commonly Used Terms*, CTRS. DISEASE CONTROL & PREVENTION (Jan. 6, 2021), https://www.cdc.gov/opioids/basics/terms.html.

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(e) Opioid use disorder.—"Opioid use disorder" means a pattern of opioid use leading to clinically significant impairment or distress, as manifested by symptoms identified in the most recent publication of the Diagnostic and Statistical Manual of Mental Disorders of the American Psychological Association or its successor;[52]

(f) Pharmacist.—"Pharmacist" means an individual licensed, registered, certified, or otherwise authorized by [state] law to practice pharmacy;

(g) Practitioner.—"Practitioner" means an individual licensed, registered, certified, or otherwise authorized by [state] to prescribe medication for opioid use disorder; and

(h) Statewide protocol – "Statewide protocol" means a protocol issued by a state board or agency that authorizes pharmacists to prescribe a medication or category of medications under the protocol.[53]

Commentary

The definition of medication for opioid use disorder aligns with the evidence that opioid use disorder is a chronic disorder for which medications are a first-line treatment.[54] Research shows that counseling should not be required for medication treatment and requiring counseling can often a barrier to care.[55] Counseling and behavior therapies should be available and accessible to all patients who want it.

Collaborative practice agreements create a formal, reciprocal practice relationship between a pharmacist and practitioner. The agreement specifies what functions are delegated to the pharmacist by the collaborating practitioner, in addition to the pharmacist's typical scope of practice.[56] The definition in the Model Act is one used by the CDC and many state laws,[57] although terminology varies among states. For example, the National Association of Boards of Pharmacy Model State Pharmacy Act uses the term "collaborative pharmacy practice

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[52] MODEL ACCESS TO MEDICATION FOR ADDICTION TREATMENT IN CORRECTIONAL SETTINGS ACT, LEGIS. ANALYSIS & PUB. POL'Y ASS'N (LAPPA) 7–8 (Oct. 2020), http://legislativeanalysis.org/wp-content/uploads/2021/03/Model-Access-to-Medication-for-Addiction-Treatment-in-Correctional-Settings-Act-1.pdf.

[53] *Scope of Practice*, AM. PHARMACISTS ASS'N, https://pharmacist.com/Practice/Practice-Resources/Scope-of-Practice; *see also* Alex J. Adams & Krystalyn K. Weaver, *The Continuum of Pharmacist Prescriptive Authority*, 5 ANNALS PHARMACOTHERAPY, 778, 780 (2016).

[54] MEDICATIONS FOR OPIOID USE DISORDER SAVE LIVES, *supra* note 1, at 2.

[55] *See generally* Laura Amato, Silvia Minozzi, Marina Davoli & Simona Vecchi, *Psychosocial Combined with Agonist Maintenance Treatments Versus Agonist Maintenance Treatments Alone for Treatment of Opioid Dependence,* COCHRANE DATABASE SYST. REV., Issue 10, 2011; Dennis McCarty, Brian Chan & Christina Bougatsos et al., *Interim Methadone – Effective but Underutilized: A Scoping Review*, 225 DRUG & ALCOHOL DEPENDENCE, August 2021, at 4 (2021).

[56] ADVANCING TEAM-BASED CARE THROUGH COLLABORATIVE PRACTICE AGREEMENTS, CTRS. DISEASE CONTROL & PREVENTION (2017), at 9 [hereinafter "ADVANCING TEAM-BASED CARE"].

[57] *See, e.g.,* FLA. STAT. ANN. § 465.1865 (West 2024); MASS. GEN. LAWS ch. 112 § 24B1/2 (West 2024).

agreement."[58] North Carolina's statute simply refers to an "agreement."[59] Other commonly used terms for a collaborative practice agreement are "collaborative care agreement" and "consult agreement,"[60] The Act's drafters use the term collaborative practice agreement because it is most frequently used by public health officials, like the CDC.

While most state laws limit the collaborating practitioner to a physician, a growing number of states allow for collaborative practice agreements between pharmacists and nurse practitioners or physician assistants. This Model Act uses the more inclusive term "practitioner," although the drafters realize that a particular federal or state law may limit eligible practitioners to physicians or that state legislators may prefer to use the term "physician."

The definition of collaborative drug therapy management comes from the CDC. Similar definitions appear in state laws, although they tend to be less descriptive of the pharmacy services authorized than the CDC.[61] The Act's drafters thought the CDC's detailed definition would be most helpful to law makers considering adopting this Model Act. State law frequently uses the shorter term "drug therapy management" to describe these services, but the Act's language reinforces that pharmacist services are provided as part of a collaborative practice agreement.

The commentary to Section V below describes how collaborative drug therapy management can be used to provide medication for opioid use disorder.

SECTION IV. AUTHORIZING STATEWIDE PROTOCOL FOR PHARMACISTS TO PRESCRIBE MEDICATION FOR OPIOID USE DISORDER.

(a) In general.—

(1) Within sixty (60) days of the effective date of this Act, the [board of pharmacy in consultation with the department of public health or other appropriate department] shall issue a statewide protocol for pharmacists to prescribe medication for opioid use disorder.

(2) Pharmacists prescribing medication for opioid use disorder pursuant to the statewide protocol authorized by this section shall be eligible for and must obtain a registration from the state of [name of state or appropriate bureau] and the United

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[58] MODEL STATE PHARMACY ACT AND MODEL RULES OF THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY, NAT'L ASS'N BOARDS OF PHARMACY 11 (Aug. 2022).
[59] N.C. GEN. STAT. §90-18(3a) (West 2024)
[60] ADVANCING TEAM-BASED CARE, *supra* note 55.
[61] *See* ME. STAT. tit. 32 §13702 (West 2024); NEV. REV. STAT. §639.0051 (West 2024); MASS. GEN. LAWS ch. 112 §24B1/2 (West 2024).

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States Drug Enforcement Administration to prescribe medications for opioid use disorder classified as controlled substances.

(3) Notwithstanding any other provision of law, pharmacists are permitted to prescribe medications for opioid use disorder in accordance with the protocol authorized by this section.

(b) Requirements.—The statewide protocol shall:

(1) Identify circumstances under which community pharmacists may prescribe medication for opioid use disorder;

(2) Identify standards and processes by which community pharmacists shall refer patients for whom they prescribe medication for opioid use disorder to treatment programs offering medication for opioid use disorder;

(3) Provide that community pharmacists shall use their professional judgment to assess the clinical appropriateness of the patient's request and the length of treatment appropriate to assure that patients transition to longer-term treatment and are not abruptly terminated from medication for opioid disorder putting them at increased risk of overdose or suicide; and

(4) Comply with federal requirements for prescribing controlled substances and medication for opioid use disorder, including, but not limited to, 21 U.S.C. 812, 21 U.S.C. 823, and 21 U.S.C. 829.

(c) Supply.—Licensed pharmacies and pharmacy departments shall maintain on the premises at all times a sufficient supply of medication for opioid use disorder in accordance with the usual needs of the community.

Commentary

Under present federal law, this section would allow community pharmacists to prescribe buprenorphine and naltrexone for opioid use disorder pursuant to a statewide protocol, but not methadone. Buprenorphine and naltrexone may be prescribed in any practice setting, including community pharmacies. Methadone for opioid use disorder may only be administered and dispensed for treatment of opioid use disorder at a federally accredited and certified opioid treatment program (OTP), commonly referred to as "methadone clinics." The statewide protocol language in this section is intentionally broad, encompassing all types of medications for opioid treatment, recognizing that the FDA may approve additional drugs and that federal restrictions for prescribing methadone for opioid use disorder may change.

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Buprenorphine alleviates withdrawal symptoms and reduces opioid cravings and can be life saving for those going through opioid withdrawal. Due to the unique properties of buprenorphine, it is safer than all other prescription opioids in the U.S.[62] Some leaders have raised concerns that buprenorphine might be diverted, that is, shared or sold with others, as prescription pain relievers once were. However, research indicates that that most people who share their prescription buprenorphine do so to help others manage their withdrawal symptoms or continue treatment when care is not available or interrupted. Recent studies indicate that sharing buprenorphine is associated with a decrease in opioid overdose deaths.[63] Two states, Vermont and Rhode Island, have already decriminalized the possession of non-prescribed buprenorphine, which may prompt other states to follow suit.[64] Expanding access to buprenorphine treatment is likely to reduce diversion.

However, walk-in and same day appointments for physician and other practitioner prescribed buprenorphine treatment are rare. Typical wait times can be two to three weeks.[65] Many smaller towns and rural areas have no health care providers who offer buprenorphine treatment for opioid use disorder.[66] Doctors' offices and clinics are typically closed during the evenings and on weekends. Community pharmacists can offer same day and walk-in services. They are open weekends and evenings. Almost everyone lives within five miles of a community pharmacy.[67]

The statewide protocol authorized by this section will allow community pharmacists to prescribe buprenorphine quickly to help relieve withdrawal symptoms and protect against the risk of overdose without having to delay care until the patient can be seen by a physician or other practitioner with prescriptive authority.[68] Buprenorphine is a Schedule III controlled substance that may only be prescribed by a practitioner authorized by state law and registered with the DEA to prescribe Schedule III drugs. This section creates state law authorization for community

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[62] Suhani Dalal, Ahish Chitneni & Amnon A. Berger et al., *Buprenorphine for Chronic Pain: A Safer Alternative to Traditional Opioids*, 9 HEALTH PSYCHOLOGY RSCH., no. 1, 2021, at 2. Overdose deaths involving only buprenorphine are almost unheard of. Daniel M. Strickland & George Gale, *Buprenorphine and Drug Overdose Deaths*, 5 ANNALS CLINICAL TOXICOLOGY, no. 1, 2022, at 1–2.

[63] CTR. BEHAVIORAL HEALTH & J., BURPRENORPHINE DIVERSION IN THE TREATMENT OF OPIOID USE DISORDER, WAYNE STATE UNIV. (Jun. 2020), https://behaviorhealthjustice.wayne.edu/ote/diversion_brief_7_20.pdf.

[64] John C. Messinger, Anand Chukka, and J. Wesley Boyd, *The Case for Decriminalizing the Street Sale of Buprenorphine*, STAT (Mar. 22, 2023), https://www.statnews.com/2022/03/22/case-for-decriminalizing-buprenorphine-street-sale.

[65] Martha Bebinger, *Study Taps Pharmacies as Addiction Treatment Option During Opioid Crisis*, WBUR (Jan. 11, 2023), https://www.wbur.org/news/2023/01/11/pharmacies-opioid-addiction-treatment-study; Elizabeth Brico, *Let's End Dangerous Wait Times for Accessing Opioid Use Disorder Meds*, FILTER (Jan. 8, 2020), https://filtermag.org/dangerous-wait-methadone-buprenorphine.

[66] Hannah M. Gregory, Veronica M. Hill & Robert W. Parker, *Implications of Increased Access to Buprenorphine for Medical Providers in Rural Areas: A Review of the Literature and Future Directions*, 13 CUREUS, no. 11, Nov. 2021, at 2; Yih-Ing Hser & Larissa J. Mooney, *Integrating Telemedicine for Medication Treatment for Opioid Use Disorder in Rural Primary Care: Beyond the COVID Pandemic*, 37 J. RURAL HEALTH 246, 246 (2020).

[67] Berenbrok et al., *supra* note 19.

[68] The federal Ryan Haight Act regulates the use of telehealth for all controlled substances prescribing, including methadone and buprenorphine when used for opioid use disorder. 21 U.S.C. § 829.

pharmacists to prescribe buprenorphine and to obtain a limited state and DEA controlled substance registration for that purpose.

Extended-release naltrexone reduces opioid cravings but does not relieve withdrawal symptoms. It should only be administered to people to prevent recurrence after they have abstained from opioids. The statewide protocol authorized by this section will allow pharmacists to initiate extended-release naltrexone for people who have gone through opioid withdrawal, are concerned about returning to drug use, and would prefer to start naltrexone after a discussion of the relative benefits and risks of naltrexone as compared to buprenorphine. Naltrexone, because it is not a controlled substance, can be prescribed by any licensed health care provider who is authorized to prescribe it under state law. The standing order provides such prescriptive authority.

Statewide protocols and statewide standing orders for pharmacy services have become a successful vehicle for increasing quick and easy access across a wide range of medication services. At least 33 states have standing orders authorizing pharmacists to dispense naloxone, a medication that treats and reverses opioid overdose.[69] All states and the District of Columbia have standing orders authorizing pharmacists to administer influenza vaccines without a patient-specific prescription, and 48 states and DC have standing orders allowing pharmacists to administer COVID-19 vaccines.[70] At least 18 states have standing orders or statewide protocols that allow pharmacists to dispense hormonal contraceptives.[71]

California already authorizes pharmacists to prescribe medication for opioid use disorder pursuant to a state protocol, to the extent authorized by federal law.[72] Missouri has a state law authorizing a statewide standing order for pharmacists to administer naltrexone.[73] Wisconsin's pharmacy practice laws authorize pharmacists to administer medications via injection, and some pharmacists in the state use that authority to provide patients with naltrexone.[74] In January 2024, Nevada authorized pharmacists to prescribe and dispense medication for opioid use disorder.[75]

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[69] *See* OPIOID ANTAGONIST ACCESS: SUMMARY OF STATE LAWS, LEGIS. ANALYSIS & PUB. POL'Y ASS'N (LAPPA) 8 (Oct. 2023), https://legislativeanalysis.org/opioid-antagonist-access-summary-of-state-laws/.
[70] PHARMACIST ADMINISTERED VACCINES, AM. PHARMACISTS ASS'N (Aug. 2022), https://naspa.us/wp-content/uploads/2021/01/Pharmacist-Immunization-Authority-December-2022.pdf.
[71] Kristen Engelen, *Statewide Pharmacist Protocols for Hormonal Contraceptives Help Reduce Patient Access Barriers*, RXLIVE (Nov. 12, 2021), https://rxlive.com/blog/statewide-pharmacist-protocols-for-hormonal-contraceptives-help-reduce-patient-access-barriers/.
[72] CAL. BUS. & PROF. § 4052(a)(14) (West 2024). California uses the term "medication-assisted treatment." *Id.*
[73] MO. ANN. STAT. § 195.206 (West 2024).
[74] WIS. STAT. ANN. § 450.035 (West 2024); see also James H. Ford II, Aaron Gilson, and David A. Mott, *Systematic Analysis of the Service Process and the Legislative and Regulatory Environment for a Pharmacist-Provided Naltrexone Injection Service in Wisconsin*, 7 PHARMACY 59 (June 2019), https://doi.org/10.3390/pharmacy7020059.
[75] NEV. REV. STAT. ANN. § 639.28079 (West 2024).

SECTION V. AUTHORIZING COLLABORATIVE PRACTICE FOR PHARMACISTS TO MANAGE MEDICATION FOR OPIOID USE DISORDER.

(a) In general.—Notwithstanding any other provision of law, pharmacists and pharmacies and practitioners and related health care entities may enter into a collaborative practice agreement that permits the pharmacist to provide collaborative drug therapy management services for medication for opioid use disorder, including prescribing, administering, and dispensing medications for opioid use disorder, and initiating, monitoring, and adjusting such medications, including tapering and discontinuation.

(b) Federal requirements.— Any collaborative practice agreement for drug therapy management pursuant to this section shall comply with federal requirements for prescribing controlled substances and medication for opioid use disorder, including, but not limited to, 21 U.S.C. 812, 21 U.S.C. 823, and 21 U.S.C. 829.

(c) Pharmacist training and scope of practice.—

(1) The services delegated to the pharmacist must be within the collaborating practitioner's scope of practice; and

(2) Prior to providing collaborative drug therapy management services for medication for opioid use disorder services under a collaborative practice agreement, a pharmacist must complete the training specified in the Medication Access and Training Expansion Act, 21 U.S.C. 823, and any other training specified in the collaborative practice agreement to increase pharmacists' knowledge, comfort, and willingness to prescribe, initiate, stabilize, maintain, and monitor patients to whom they also dispense medication for opioid use disorder.[76]

(d) Location of services.—Services provided pursuant to collaborative drug therapy management agreements for medication for opioid use disorder under this section may be provided at any location in this state including but not limited to community pharmacies, both affiliated and unaffiliated with hospital systems, hospitals, correctional facilities, office-based ambulatory care settings, opioid treatment programs, or other health care and community settings.

[76] Scott A. Davis, Robyn Dryer & William Zule et al., *A Content Review of Buprenorphine Training Programs for Pharmacists*, 6 EXPORATORY RSCH. CLINICAL & SOC. PHARMACY, no. 100154, June 2022, at 1–2.

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(e) Scope of agreements.—Collaborative drug therapy management agreements for medication for opioid use disorder may be between a single pharmacist or multiple pharmacists and a single practitioner or multiple practitioners or among entities, like pharmacies and health systems. Such agreements may apply to a single patient, multiple patients, or patient populations as specified in the agreement.

(f) Record of agreements.—The collaborating pharmacist and practitioner must maintain a signed copy of the collaborative drug therapy management agreement on file at their respective practice locations and must make such agreement available to the [state board of medicine, state board of nursing (as applicable) and state board of pharmacy] upon request.

(g) Rules and regulations.—The [state board of medicine, state board of nursing, and state board of pharmacy] shall adopt rules to implement this section.

Commentary

This section specifies that state law authorizes collaborative practice agreements so that pharmacists can be integral members of the patient care team and provide collaborative drug therapy management services for medication for opioid use disorder. Collaborative drug therapy management involves developing a collaborative practice agreement between one or more practitioners or health care entities and one or more pharmacists or pharmacies. The collaborative practice agreement in this section allows qualified pharmacists working within the context of a defined protocol to:

- perform patient assessments, counseling, and referrals;
- order, perform, and review laboratory tests;
- prescribe, dispense, and administer medications for opioid use disorder; and
- select, initiate, monitor, continue, adjust, and follow-up drug regimens.[77]

Robust data show that pharmacists working pursuant to collaborative drug therapy management practice agreements with physicians and other practitioners increase access to treatment, improve treatment quality, and improve medication adherence by providing drug therapy management services for a variety of chronic, long-term conditions including diabetes, hypertension,[78] and opioid use disorder.[79]

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[77] *See* ADVANCING TEAM-BASED CARE, *supra* note 56.
[78] *Id.*; Margie E. Snyder, Tara R. Earl & Siobhan Gilchrist et al., *Collaborative Drug Therapy Management: Case Studies of Three Community-based Models of Care*, 12 PREVENTING CHRONIC DISEASE, no. E39, Mar. 2015, at 5.
[79] *See* Pals & Bratberg, *supra* note 22; Wu et al., *supra* note 22; Mailloux et al., *supra* note 22; DiPaula & Menachery, *supra* note 22.

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In a study conducted in 2022 in Rhode Island, a collaborative practice agreement authorized 21 community pharmacists at six pharmacies to offer walk-in and same-day appointments for patients to begin treatment with buprenorphine or naltrexone for opioid use disorder, with all patients opting for buprenorphine. During the first pharmacy visit, the pharmacist screened each patient, using checklists to assess patients' histories and withdrawal symptoms. The pharmacist then confirmed a buprenorphine regimen with a collaborating physician with an X-waiver to prescribe buprenorphine before initiating and adjusting the treatment plan. Pharmacists initiated buprenorphine treatment for more than half the patients enrolled in the study, equivalent to treatment rates in other settings, thereby making no wait, low-threshold opioid use disorder treatment available for the first time in Rhode Island and reducing burdens on physicians and others. Once a patient reached a stable dose, the project randomly assigned patients to receive pharmacy-based follow-up care or to be seen by a buprenorphine waivered practitioner or an opioid treatment program. After one month, almost 90 percent of patients receiving pharmacy-based care remained in treatment compared with only 17 percent of those receiving care from a physician with an X-waiver certified to prescribe buprenorphine or opioid treatment center. The collaboration showed that community pharmacies are a safe and effective way to expand opioid use disorder treatment. [80]

In an earlier 2021 North Carolina study, a collaborative drug therapy management agreement provided that a physician with an X-waiver to prescribe buprenorphine for medication for opioid use disorder would screen and prescribe buprenorphine, and then transfer patient care to a community pharmacist for six months. During monthly pharmacy visits, the pharmacist conducted a thorough patient assessment, checked the state's prescription drug monitoring program, and provided patient education and counseling as outlined in the protocol. Both the physician and pharmacist reviewed the patient assessment prior to releasing the monthly prescription. This collaboration successfully kept patients in treatment, saved physician time, and benefited patients. Patients reported that using a community pharmacy, as opposed to traditional physician office-based care, for their monthly assessment was "very or extremely useful and convenient" and community pharmacies were "ideal settings for treatment." The physicians and community pharmacists who participated in the study expressed similarly positive reports that physician-pharmacist collaboration provided better quality care than the usual office-based physician-only treatment.[81]

Both these studies were conducted when federal law restricted prescribing of buprenorphine for opioid use disorder to physicians and certain midlevel providers excluding pharmacists, who held a federal X-waiver.[82] Now that the Mainstreaming Addiction Act has eliminated the X-waiver requirement, state authorization for pharmacists to prescribe buprenorphine via independent practice, statewide standing protocols, or collaborative practice agreements allows pharmacists to register with the DEA and obtain authorization to prescribe

[80] Green et al., *supra* note 22; Bebinger, *supra* note 65.
[81] Wu et al., *supra* note 22.
[82] *See supra* text accompanying note 40 (explaining the federal X-waiver requirement and its repeal).

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buprenorphine for opioid use disorder.[83] This section will permit collaborative practice agreements that allow pharmacists to prescribe medications for opioid use disorder. It also authorizes collaborative practice agreements that allow pharmacists to initiate, monitor, modify, and adjust such medications when prescribed by another practitioner.

Forty-seven states authorize pharmacy collaborative practice agreements for at least some collaborative drug therapy management services.[84] However, the scope of statutory authorization varies significantly from state to state. Some statutes specifically authorize collaborative practice agreements for drug therapy management services but limit such collaborations to an exclusive or illustrative list of conditions which typically do not include medication for opioid use disorder.[85] Some state laws allow pharmacists to perform some of the functions of collaborative drug therapy management, but not others, with a number of states prohibiting collaborative practice agreements to initiate medication.[86] Other state laws limit the pharmacists who may enter into collaborative agreements by specifying additional credentials or training beyond those required for licensure.[87] Still other state statutes limit the practitioners with prescriptive authority who may enter into collaborative agreements.[88] Several states prohibit collaborative practice agreements for controlled substances. A few limit their use to inpatient settings.[89]

This Model Act provides that practitioners and pharmacists may enter into collaborative practice agreements for the full range of drug therapy medication services for opioid use disorder, including prescribing medication for opioid use disorder as long as the services delegated to the pharmacist are within the collaborating practitioner's scope of practice. Some state lawmakers may prefer more restrictive authorization for collaborative practice agreements for collaborative drug therapy management and, the Model Act's authorization for pharmacist collaborative practice for medication for opioid use disorder can be made subject to restrictions that already exist in state law, including additional training or educational requirements.

However, the collaborative practice authorized by this section is intentionally broad. As recommended by the National Governors Association's Center on Best Practices and by a workgroup within the National Alliance of State Pharmacy Associations, the Act authorizes broad collaborative practice provisions that allow specific provider functions to be determined at

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[83] *See* SAMHSA.GOV*, supra* note 40 ("All practitioners who have a current DEA registration that includes Schedule III authority, may now prescribe buprenorphine for Opioid Use Disorder in their practice is permitted by applicable state law and SAMHSA encourages them to do so.").
[84] *Survey of Pharmacy Law*, NAT'L ASS'N BOARDS PHARMACY 142, 150–56 (2021).
[85] *See e.g.,* FLA. STAT. § 465.1865 (West 2024) (regarding collaborative pharmacy practice for chronic health conditions).
[86] ADVANCING TEAM-BASED CARE, *supra* note 56, at Appendix A, Table 2.
[87] *See id.*, Appendix A, at Table 1 and Table 3.
[88] *See id.,* Appendix A, at Table 1.
[89] *See id*., Appendix A, at Table 1 and Table 2.

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the provider level.[90] The intent is to allow pharmacists, practitioners, and their professional boards the flexibility to develop collaborative practice agreements that comport with the evolving science of clinical practice and professional standards.

Subsection (b) makes clear that collaborative practice agreements for collaborative drug therapy management services for medication for opioid use disorder must comply with federal law requirements for prescribing controlled substances, medication for opioid use disorder, and the use of telehealth. The language referencing federal law allows state collaborative practice agreements to evolve as federal law changes, something that occurred several times in the last decade, including as the result of waivers issued as part of the COVID-19 Public Health Emergency. Similarly, the Model Act references federal law restrictions rather than having state law restate those restrictions because federal law is evolving in light of experiences during the COVID-19 epidemic, and other scientific and clinical studies.[91]

Several excellent resources are available to help pharmacists and practitioners draft collaborative practice agreements including a resource guide from the Centers for Disease Control and Prevention.[92] The collaborative drug therapy managed practice agreement for medication for opioid use disorder used in the 2023 Rhode Island study is available from the New England Journal of Medicine.[93]

SECTION VI. INSURANCE COVERAGE.

(a) Medicaid.—In addition to the cost of the drug and a dispensing fee, and not withstanding any other law,[state Medicaid agency/name] shall reimburse for pharmacist comprehensive patient care and medication management services provided as part of a statewide protocol or collaborative drug therapy management for medication for opioid use disorder at least equivalent to reimbursement for similar services provided by other practitioners.

(b) Private insurance.—Every individual or group health insurance contract, plan, or policy that provides coverage for medication for opioid use disorder that is delivered, issued for

[90] *Pharmacist Collaborative Practice Agreements: Key Elements for Legislative and Regulatory Authority*, NAT'L ALL. STATE PHARMACY ASS'NS (2015), https://naspa.us/wp-content/uploads/2017/01/CPA-Workgroup-Report-FINAL.pdf; Frederick Isasi & Esther Krofah, *The Expanding Role of Pharmacists in a Transformed Health Care System*, NAT'L GOVERNORS ASS'N 12 (2015).
[91] In December 2022, SAMHSA issued draft regulations that would make permanent some of the flexibilities for opioid treatment programs to prescribe medication for opioid use disorder instituted during the COVID-19 Public Health Emergency. *See* Notice of Proposed Rulemaking: Medications for the Treatment of Opioid Use Disorder, 87 Fed. Reg. 77330 (Dec. 16, 2022).
[92] *Advancing Team-Based Care, supra* note 56.
[93] Green et al., *supra* note 22.

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delivery, amended, or renewed in this state on or after the effective date of this Act, shall reimburse for the cost of the drug, toxicology testing and interpretation, a dispensing fee, and pharmacist comprehensive patient care services including referral to specialty care provided as part of a standing order or collaborative drug therapy management for medication for opioid use disorder at least equivalent to reimbursement for similar services provided by other practitioners.

(c) Grant funded programs.—All grant funded programs offering or paying for medication for opioid use disorder shall reimburse for pharmacist comprehensive patient care services provided as part of a statewide protocol or collaborative drug therapy management for medication for opioid use disorder at least equivalent to reimbursement for similar services provided by other practitioners.

(d) Comprehensive patient care services.—Patient care services include counseling patients; monitoring medications; reviewing medical records; ordering lab tests; prescribing, dispensing, and administering medication for opioid use disorder; and referring to specialty care.

Commentary

All state Medicaid programs, Medicare, and some private insurance plans cover the cost of medicines and pharmacists' dispensing fees for medication for opioid use disorder. However, insurance coverage for these items does not necessarily mean that these services are free to patients. Some plans may have deductibles, copays, or prior authorization requirements. Such insurance costs can create significant barriers to treatment and, although outside the scope of this Act, the drafters encourage lawmakers to address these hurdles in separate legislation.

Even though Medicaid and some insurance cover the costs of medication for opioid use disorder and pharmacists' dispensing fees, sustainable fee structures are needed to support pharmacists' patient care services, including medication for opioid use disorder services delivered through statewide protocols and collaborative practice agreements for collaborative drug therapy management.[94] This section provides that Medicaid and private insurance policies must reimburse pharmacists for their time and expertise in counseling patients; monitoring medications; reviewing medical records; ordering lab tests; prescribing, dispensing, and administering medication for opioid use disorder; and referring for specialty care.

[94] CTRS. DISEASE CONTROL & PREVENTION, *supra* note 49.

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One source of grant funding for medication for opioid use disorder is the Substance Abuse Prevention and Treatment Block Grant administered by SAMHSA. State agencies may use this funding for substance use disorder treatment along with prevention activities.[95]

SECTION VII. FUNDING FOR EDUCATIONAL, COMMUNITY, AND PILOT PROGRAMS TO ENCOURAGE COMMUNITY PHARMACIST ENGAGEMENT AND COLLABORATION.

(a) Grant program.—There is established in the [department of health or other appropriate department(s)] a Community Pharmacy Medication for Opioid Use Disorder Access Grant Program (the "Grant Program") to fund educational programs, technical assistance, statewide initiatives, community programs, and pilot programs to incentivize community pharmacists to prescribe medications for opioid use disorder through a statewide protocol and collaborative practice agreements for collaborative drug therapy management pursuant to this Act.

(b) Guidelines and requirements.—The [department of health or other appropriate department(s)] shall:

(1) Adopt rules and regulations that set out guidelines and requirements to direct the distribution of funds from the Grant Program;

(2) Make funding available to support pharmacist prescribing of medications for opioid use disorder under a statewide protocol;

(3) Make funding available to support both new and existing collaborative practice agreements for pharmacist collaborative drug therapy management for medication for opioid use disorder programs in a broad spectrum of geographic regions within the state, including urban, suburban, and rural communities; and

(4) Ensure that all activities undertaken using grant funds are evidence-based and evidence-informed.

(c) Eligible activities.—The activities eligible for funding under this Section include, but are not limited to:

(1) Pilot collaborations between community pharmacists and practitioners using either or both standing orders or collaborative practice agreements for medication for

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[95] *Substance Abuse Prevention and Treatment Block Grant*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. (Apr. 24, 2023), https://www.samhsa.gov/grants/block-grants/subg.

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opioid use disorder that includes an evaluation component;

(2) Statewide, regional, or local conferences, continuing education programs, and networking opportunities for community pharmacists and collaborating practitioners;

(3) Development of websites containing resources to support standing protocol prescribing and collaborative practice for medication for opioid use disorder;

(4) Development of one or more helplines to connect pharmacists and practitioners with individuals who can provide information and support for collaborative practice for medication for opioid use disorder; and

(5) Media campaigns and peer and community outreach programs and workers to educate community members and people who use drugs about the availability of medication for opioid use disorder via community pharmacies.

(d) Federal funds.—The [state department of health or other appropriate department(s)] shall pursue federal funding, matching funds, grants, litigation proceeds, and foundation funding for the Community Pharmacy Medication for Opioid Use Disorder Access Grant Program.

(e) Additional sources. —The [department of health or other appropriate departments] may also receive such gifts, grants, and endowments for public or private sources as may be made from time to time, in trust or otherwise, for the use and benefit of the Grant Program and expand the same or any income derived from it according to the terms of the gifts, grants, or endowments.

Commentary

This section establishes a grant program to support education, outreach, and pilot programs to encourage community pharmacist collaboration in medication for opioid use disorder. Evidence-based means that activities funded under this section should be informed by findings of research. Evidence-informed means that activities should build off the empirical database of science and combine it with the lived experiences and wisdom of the community.

States should not need to appropriate additional state general revenue funds to support implementation of this Model Act. Research indicates that medication for opioid use disorder saves states money. According to the 2021 Substance Abuse and Mental Health Services Administration TIP 63: Medications for Opioid Use Disorders, research indicates that medication

for opioid use disorder is cost-effective and cost-beneficial.[96] Treatment with any of the three medications approved for treatment for opioid use disorder can lead to lower healthcare use and cost.[97] Extended use of methadone or buprenorphine treatment is often correlated with significantly lower rates of criminal activity. Individuals with opioid or other substance use disorders who engage in treatment are less likely to return to use and less likely to enter the criminal legal system.[98] Expanding access to medication for opioid use disorder is a cost-saving measure.

Beyond the prospect of cost savings, there are various avenues that states may pursue to fund increased provision of and access to medication for opioid use disorder. For example, the SAMHSA administers the formula-based Substance Abuse Prevention and Treatment Block Grant to provide funding to states, territories, and tribes. States, territories, and tribes may use this funding for substance use disorder treatment along with prevention activities.[99]

In addition, some states may be able to fund increased access to medication for opioid use disorder through opioid settlement funds. Opioid settlement funds are funds recovered by a state through litigation against the pharmaceutical industry, including pharmaceutical manufacturers or distributors.[100] For example, in Iowa, the state awarded $3.8 million to the University of Iowa Hospital to expand training for health professionals who want to prescribe medication for opioid use disorder.[101] Legislators and policymakers should consider allocating opioid settlement funds to cover costs associated with expanding access to medication for opioid use disorder within the state.

SECTION VIII. RULES AND REGULATIONS.

[Relevant state agencies and officials] shall promulgate such rules and regulations as are necessary to effectuate this Act within [insert time frame] of the date of enactment.

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[96] *See generally* SAMHSA TIP 63, *supra* note 26.
[97] *Id*.
[98] USE OF MEDICATION-ASSISTED TREATMENT FOR OPIOID USE DISORDER IN CRIMINAL JUSTICE SETTINGS, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. 3 (2019).
[99] SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., *supra* note 93.
[100] *Executive Summary*, NAT'L OPIOID SETTLEMENT, https://nationalopioidsettlement.com/executive-summary/.
[101] Natalie Krebs, *State Will Use Opioid Lawsuit Settlement Funds to Launch a New Addiction Treatment Program*, IOWA PUBLIC RADIO (Oct. 13, 2021, 4:44 P.M.), https://www.iowapublicradio.org/health/2021-10-13/state-will-use-opioid-lawsuit-settlement-funds-to-launch-new-addiction-treatment-program. ; Zach Fisher, *Iowa Attorney General Introduces New Tool to Fight Opioid Addiction*, WHO13 DES MOINES (Sept. 20, 2022), https://who13.com/news/iowa-attorney-general-introduces-new-tool-to-fight-opioid-addiction-in-iowa/.

SECTION IX. SEVERABILITY.

If any provision of this Act or application thereof to any individual or circumstance is held invalid, the remaining provisions of this Act shall not be affected nor diminished.

SECTION X. EFFECTIVE DATE.

This Act shall be effective on [specific date or reference to standard state method of determination of the effect].

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ABOUT THE LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

The Legislative Analysis and Public Policy Association (LAPPA) is a 501(c)(3) nonprofit organization whose mission is to conduct legal and legislative research and analysis and draft legislation on effective law and policy in the areas of public safety and health, substance use disorders, and the criminal justice system.

LAPPA produces cutting edge model laws and up-to-the-minute comparative analyses, publications, educational brochures, and other tools that can be used by national, state, and local criminal justice and substance use disorder practitioners who want the latest comprehensive information on law and policy. Examples of topics on which LAPPA has assisted stakeholders include naloxone laws, treatment in emergency settings, alternatives to incarceration for those with substance use disorders, medication for addiction treatment in correctional settings, and syringe services programs.

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