



# Public Policy Statement on the Role of Pharmacists in Medications for Addiction Treatment

## Introduction

Well over two million Americans have died from an alcohol-related cause or drug-related overdose since 2000, exposing at least forty times as many Americans to devastating personal loss.<sup>1–9</sup> Medication, specifically indicated and prescribed for addiction, is fundamental to effective treatment.<sup>10</sup> While utilization rates remain low,<sup>11,12</sup> addiction medications are cost effective, reduce harmful substance use and related morbidity and mortality, improve health outcomes, and enhance quality of life.<sup>13–21</sup>

Pharmacists help to ensure the safe and effective use of addiction medications, such as buprenorphine, the most commonly used medication for the treatment opioid use disorder (OUD) that can be prescribed or dispensed in clinicians' offices.<sup>22</sup> Despite buprenorphine's distinct mechanism of action,<sup>23</sup> safety, effectiveness, and lower risk classification than full opioid agonists under the Controlled Substances Act (CSA), some pharmacies still associate significant risk with ordering and dispensing buprenorphine, possibly conflating harms associated with diversion of medications like oxycodone and alprazolam with buprenorphine's diversion risks.<sup>22,24</sup> Notably, the use of diverted buprenorphine is largely associated with unmet treatment needs.<sup>25</sup> Nationally, buprenorphine comprised an estimated 1% of drugs identified in all reports submitted to federal, state, and local forensic laboratories from law enforcement operations in 2022.<sup>25–27</sup>

Challenges to accessing buprenorphine at pharmacies are not always well-understood or clearly identified, nor have they been addressed sufficiently. Relatedly, settlement terms of large lawsuits involving pharmaceutical manufacturers, wholesale distributors, and retail chain pharmacies likely intensified pharmacies' risk concerns.<sup>28,29</sup> These terms have not been revisited or amended by state attorneys general to ensure adequate pharmacy access to medications for OUD (MOUD) or overdose reversal, specifically.

Pharmacies are crucial to accessing and improving the utilization of medications for addiction treatment, however. Pharmacies are highly accessible nearly everywhere; there are over 61,000 community pharmacies employing over 140,000 pharmacists in the U.S.<sup>30–32</sup> Congress recognized the importance of pharmacies in improving long-term health outcomes when including medication therapy management programs<sup>33</sup> in Medicare's 2003 outpatient prescription drug benefit,<sup>34</sup> and all states have enacted policies allowing "collaborative pharmacy practice"<sup>\*</sup> enabling pharmacists

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\* Model language from the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* ("Model Act/Rules") of the National Association of Boards of Pharmacy defines "**collaborative pharmacy practice**" as "that practice of pharmacy whereby one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners under protocol and in collaboration with practitioner(s) to provide patient care services to achieve optimal medication use and desired patient outcomes."

to provide “*direct patient care services*”<sup>35</sup> under certain conditions.<sup>36,37</sup> Simultaneously, however, states highly regulate the practice of pharmacy resulting in such sheer variability across states that discerning the best public policy practices among states is a challenge.<sup>36,38–41</sup> Furthermore, while elimination of the federal Drug Enforcement Administration (DEA) ‘X-waiver’ has had minimal demonstrated impact on buprenorphine utilization rates thus far,<sup>42</sup> it is an important opportunity for states to remove barriers to forms of collaborative pharmacy practice for the treatment of OUD.<sup>43,44</sup>

Notwithstanding collaborative pharmacy practice opportunities, states usually prevent pharmacists from making patient diagnoses or performing differential diagnoses through scope of practice limitations,<sup>38,39,45–47</sup> considering training variability, a pharmacist’s corresponding responsibility in DEA regulations, and risks associated with misdiagnosis. Finally, there are significant barriers to implementation and scalability that limit the effectiveness of direct patient care services delivered in community pharmacies.<sup>34,48–50</sup>

## Background

### Challenges at Pharmacies to Accessing Addiction Medications

While challenges to accessing buccal/sublingual buprenorphine at pharmacies have been a focal point for policymakers, less attention has been paid to specific challenges to accessing buprenorphine monoprodukt tablets, long-acting injectable (LAI) buprenorphine, and LAI naltrexone, the latter indicated for OUD and alcohol use disorder (AUD). Finally, long standing federal regulations prohibit pharmacies from dispensing methadone when prescribed for the treatment of OUD rather than for pain.<sup>51</sup>

#### *Nonfulfillment of the Core Function to Dispense*

In defining pharmacy practice, states traditionally include the core function to dispense lawful prescriptions but not necessarily a *duty* to so dispense.<sup>45,47,52</sup> Washington, New Jersey, and California have enacted “*duty to dispense*” clauses;<sup>52–55</sup> New Jersey’s law maintains pharmacy practice sites must properly dispense lawful prescriptions without undue delay.<sup>56</sup> The inconsistent availability of buprenorphine for pharmacists to dispense lawful prescriptions promptly suggests certain factors are contributing to some pharmacists’ nonfulfillment of the core function to dispense, including misinterpretation of buprenorphine’s associated risks and addiction stigma.<sup>22,24,26,57–67</sup> Indeed, pharmacy organizations are establishing consensus-based guidelines for pharmacy access to buprenorphine.<sup>68</sup> Factors resulting in nonfulfillment of the core function to dispense could be addressed by programs that facilitate the dispensing of opioid agonist medications lawfully prescribed for OUD, such as those providing financial incentives to retail pharmacies.<sup>22,69</sup>

#### *Ambiguity Related to Pharmacists’ Corresponding Responsibility*

Another determining factor contributing to access challenges at pharmacies is pharmacists’ application of, and attempts to resolve, red flags applied to buprenorphine prescribed for OUD under DEA policy, which is largely imposed on DEA-registered pharmacies and pharmacists through adjudication.<sup>70</sup> Under DEA regulations, pharmacists have “*corresponding responsibility*” with prescribing practitioners for the proper prescribing and dispensing of controlled substances.<sup>71</sup> To be “*effective*,” controlled medication prescriptions must be “*issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his [sic] professional practice.*”<sup>71</sup> “*Knowingly filling*” a purported prescription for a controlled substance that was not so issued is subject to penalties.<sup>71,72</sup> While the DEA recommends best practices for identifying out of

scope prescriptions in The DEA's Pharmacists' Manual,<sup>73</sup> pharmacies must generally glean red flags from the DEA's regular enforcement actions. These enforcement actions – for certain controlled medication dispensing practices when red flags suggestive of diversion were not resolved prior to dispensing – revoke pharmacies' DEA registrations.<sup>70,74</sup> Red flags commonly cited in such actions include pattern prescribing, patients traveling far distances, cocktail/drug combination or cash payment for prescription medication, therapeutic duplication, and doctor shopping.<sup>72</sup> State boards of pharmacy may also levy fines, place on probation, suspend, or revoke licenses for not preventing diversion effectively.<sup>75</sup>

### Other Legal Compliance Concerns

DEA-registered manufacturers and distributors must report “*suspicious orders*” including unusual sizes, patterns, or frequencies of orders of controlled substances to the DEA and relevant division offices, which may be done through the DEA's centralized database, the *Suspicious Orders Report System* (SORS) required by 2018 federal legislation.<sup>76,77</sup> In 2023, the DEA clarified that neither the DEA, nor the CSA as amended in 2018, regulates the volume of controlled substances with quantitative thresholds that limit registrants' ordering or dispensing, but rather requires registrants to design and operate a system to identify *suspicious orders*, which may involve the use of self-set purchasing thresholds.<sup>78</sup>

Settlement agreements among states attorneys general, including with Walmart, Walgreens, and CVS,<sup>79,80</sup> and Cardinal Health, AmeriSourceBergen, and McKesson, the latter three denoted “Injunctive Relief Distributors” under an agreement effective July 2021, likely exacerbated legal compliance concerns, especially within retail chain pharmacies. The agreement with Injunctive Relief Distributors requires them to implement systems applying specific metrics for identifying “*Red Flags*,”<sup>28</sup> using specific dispensing datasets that are provided by their retail pharmacy customers to (1) review the total number and dosage units of dispensed prescription medications, (2) evaluate sales of controlled substances to cash-paying patients, (3) review the top prescribers of certain “*highly diverted*” controlled substances, and (4) consider the extent to which a pharmacy serves out-of-area patients.<sup>81</sup> Under Injunctive Relief Distributors' settlement agreement terms, “*highly diverted*” substances can include buprenorphine.<sup>28†</sup>

The presence of patients at pharmacies who have an undefined distance to their prescriber, pay in cash, or use medication ‘slang,’ can cause some pharmacists not to dispense buprenorphine, and further, it can cause some pharmacists to require patients/prescribers to provide diagnostic codes on prescriptions, prescribers to confirm via telephone the patient's medication dose or quantity, or the prescribers' location and specialty, or finally, for some pharmacists to state counterfactually that the pharmacy simply does not stock buprenorphine.<sup>24</sup> Although the DEA advised registered distributors in March 2024 to reexamine self-set thresholds to ensure timely patient access to buprenorphine,<sup>82</sup> buprenorphine dispensing challenges persist.<sup>83</sup>

### Unique Challenges Related to Certain Addiction Medication Formulations

Buprenorphine is available alone (“BUP”) or in combination with naloxone (“BNX”), the latter intended to prevent misuse.<sup>84,85</sup> Practice guidelines and payers' restrictions discourage the prescription of BUP for OUD treatment unless a clinical exception applies.<sup>86</sup> However, the addition of naloxone to buprenorphine may not add any real misuse deterrent utility,<sup>85,87</sup> indicating the use of BUP outside those narrow clinical exceptions is also appropriate at the prescribers' professional discretion. After an initiation period with buccal/sublingual BNX or BUP,

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† Other Injunctive Relief Distributor settlement agreement “*Red Flags*” are 1) ordering ratios of a) highly diverted controlled substances to non-controlled substances, b) highly diverted controlled substances (base codes or drug families) to non-controlled substances, 2) excessive ordering growth of controlled substances, and 3) unusual formulation ordering.

buprenorphine is available in a monthly or weekly LAI formulation (“Sublocade” or “Brixadi”)<sup>88</sup> that eliminates daily dosing; however, both LAI medications are costly,<sup>89</sup> their coverage made contingent on payers’ utilization management policies,<sup>90,91</sup> and both are subject to a federally-required restricted distribution system (Risk Evaluation and Mitigation Strategy or “REMS”)<sup>92,93</sup> intended to prevent their direct dispensing to patients and potential self-administration.<sup>94</sup> Thus, REMS limits the ability to order and dispense Sublocade and Brixadi to only *certified* health care settings and pharmacies, with procedures and processes in place that include prohibiting the distribution, transfer, loan, or sale of Sublocade and Brixadi.<sup>94</sup>

The prevalence of AUD exceeds that of OUD, and utilization rates of AUD-indicated medication are low, about 8 percent in 2019.<sup>21</sup> The opioid antagonist medication naltrexone in LAI formulation is indicated and prescribed for both AUD and OUD. Factors driving underutilization of LAI naltrexone for either AUD or OUD, such as its expense, are of concern, as it has superior rates of adherence and retention compared to oral naltrexone.<sup>95,96</sup>

### Policies Elevating Pharmacists’ Role in Medications for Addiction Treatment

Advanced practice pharmacy rose out of a desire to meet societal needs for advancing patient care beyond preparing and dispensing medication.<sup>97</sup> Today, many states authorize pharmacists under certain conditions to initiate and administer vaccines, naloxone, emergency contraceptives, HIV PrEP and PEP, and more.<sup>40,98–101</sup> Furthermore, states are incorporating models for collaborative pharmacy practice care, which include (1) prescriber-pharmacist collaborative practice agreements (CPAs) (that may be patient- or population-specific, or statewide);<sup>102,103‡</sup> (2) statewide standing orders<sup>§</sup> or state-based protocols,<sup>\*\*</sup> and (3) independent, ‘tiered’ pharmacist licensing for advanced practice;<sup>41,105</sup> only in specific cases do these models pertain to addiction medication. California, Idaho, Massachusetts, Montana, New Mexico, North Carolina, Ohio, Tennessee, Utah, and Washington recognize DEA-registered, licensed pharmacists as mid-level practitioners, with various authorities to initiate, administer, procure, or dispense controlled substances.<sup>106</sup>

#### Accreditation, Education, Credentialing, and Privileging for Advanced Practice Pharmacy Roles

In a final rule in 2012, the Centers for Medicare and Medicaid Services (CMS) modified the definition of “*medical staff*” to include non-physician practitioners, allowing for credentialed and privileged advanced practice pharmacists to practice within health systems ‘at the top of their license’ in accordance with state laws and institutional bylaws for medical staff.<sup>107,108</sup> However, the credentialing and privileging process for advanced practice pharmacists lacks standardization and is far less common than for physicians, physician assistants, and nurse practitioners.<sup>109–113</sup> Although accreditation of pharmacy practice education has advanced significantly, including for the Doctor of Pharmacy (PharmD), pharmacists gain the core competencies to provide clinical

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‡ **Collaborative practice agreements (CPAs)** create formal relationships between, and delegate functions from, one or more prescribers (physicians and other licensed clinicians with prescriptive authority), to qualified pharmacists, to engage in collaborative drug therapy management. CPAs define the conditions that permit (or do not permit) pharmacists to assume responsibility for performing certain duties, including 1) patient assessments; 2) ordering medication-related laboratory tests; 3) administering medications; and 4) initiating, modifying, or discontinuing medication regimens for patients (or patient populations).<sup>104</sup>

§ **Statewide standing orders** are authorizations issued by a single prescriber allowing all pharmacists in a state to dispense medication(s) directly to a patient in certain scenarios. Typically, the person who issued the agreement is indicated on the prescriptions as the prescriber.<sup>103</sup>

\*\* **State-based protocols** provide the framework specifying the conditions under which qualified pharmacists are authorized to initiate or manage a specified medication or category of medications and usually do not permit, allow, or require pharmacists to make a diagnosis. Such protocols are issued by an authorized state body, often boards of pharmacy, pursuant to relevant state laws and regulations.

services in advanced practice roles through accredited residency/fellowship programs (or equivalent post-licensure experience) and board certification in one or more of the fifteen specialties of the Board of Pharmacy Specialties (BPS).<sup>35,37,111,114,115</sup>

While some states credential pharmacists with practice-based certificates, board certification by the BPS in a relevant specialty, such as the Board Certified Psychiatric Pharmacist (BCPP),<sup>116</sup> is considered the gold standard credential to qualify pharmacists for advanced practice.<sup>117</sup> Institutional privileging, which formally recognizes pharmacists' nonphysician provider status and expanded scope of practice, requires the navigation of intersecting state scope of practice laws and institutional bylaws, privileging varies with state boards' documentation requirements for CPAs, and it further varies with CPAs that, in turn, contain a varying degree of required scrutiny of documentation.<sup>108</sup> For CPAs, state boards generally require a fee and verification of pharmacists' licensure and credentials (as defined by the state) and can include committee or administrative review processes of pharmacists' intended scope of practice.<sup>108</sup> Finally, the Joint Commission has privileging requirements for accreditation; to practice at institutions, pharmacists are subject to the focused professional practice evaluation (FPPE) and ongoing professional practice evaluation (OPPE).<sup>118</sup>

### *Collaborative Pharmacy Practice in General*

Innovative collaborative pharmacy practice models offer an exciting opportunity to improve access to essential health care services for vulnerable patient populations, and the Veterans Health Administration (VHA) demonstrates this promise. At VHA facilities, all pharmacists are designated *clinical pharmacists*, with a subset designated *clinical pharmacy specialists* with facility-level agreements for advanced practice roles.<sup>119–122</sup> The VHA's collaborative pharmacy practice success is attributed to its foundational credentialing and privileging process,<sup>118</sup> and has improved access to and care itself for veterans with addiction.<sup>123–130</sup> Outside the VHA, many studies show that pharmacist-provided patient care services through forms of collaborative pharmacy practice benefit patient outcomes for certain chronic conditions, such as diabetes, depression, and hypertension.<sup>131–135</sup>

### *Physician-Pharmacist Collaborative Practice Models Improving Access to MOUD*

The elimination of the federal DEA 'X-waiver' is a significant opportunity for states to remove barriers to forms of collaborative pharmacy practice to treat OUD.<sup>42,43,136,137</sup> While the federal government continues to restrict dispensing of methadone to treat OUD to the nation's 2,000 opioid treatment programs (OTPs), numbering far fewer than 61,000 community pharmacies,<sup>138</sup> modernizing these federal restrictions can allow states a similar opportunity to realize important patient benefits.<sup>139</sup> Preliminary evidence supports patient-specific collaborative practice agreements for buprenorphine and methadone to treat OUD, in public health departments, independent and community or behavioral health chain retail pharmacies, and acute care settings.<sup>140–144</sup> Notably, in the studies discussed below, pharmacists provided critical patient care services construed broadly as co-management of SUD and medication monitoring, however, the requirements for pharmacists' education and training ranged widely, and physicians predominantly maintained responsibility for diagnosis and prescribing.<sup>140–144</sup> Although resources are needed to expand this evidence base, physician(s)-pharmacist(s) collaborative practice can safely optimize patient care, improve medication adherence through co-management of SUD and medication monitoring,<sup>145</sup> and save physicians' time by reducing workload burden,<sup>146</sup> helping to address persistent workforce shortages.<sup>146–150</sup>

In Maryland, a piloted physician–pharmacist buprenorphine/naloxone (BNX) long-term treatment model improved care and retention for health department patients.<sup>140</sup> In North Carolina, a

feasible and acceptable model under an operational care agreement among office-based BNX prescribers, and three community pharmacies, authorized pharmacists over six months to manage transferred stable patients' monthly prescription and long-term treatment visits; rates of adherence and retention rates were high, and no opioid-related safety events occurred.<sup>141</sup> In Rhode Island, a physician-delegated, pharmacist-facilitated initiation of BNX treatment for OUD model under a state-registered physician-pharmacist CPA<sup>151</sup> authorized specially-trained pharmacists to assess patients with OUD, determine medication regimens confirmed with X-waivered physicians, stabilize patients through initiating and adjusting treatment, and provide follow-up care to stabilized patients over one month; patients provided follow-up care from pharmacists had substantially higher rates of retention compared to those provided follow-up care from physicians.<sup>152</sup>

In Baltimore, under federal regulatory exemption, a CPA between an OTP and an independent retail pharmacy authorized OTP physicians to electronically prescribe methadone to stable patients and make dose adjustments. Pharmacists administered and dispensed methadone and provided follow-up care, including medication reconciliation and safety assessments, under the supervision of OTP physicians who kept federal/state records.<sup>142,143</sup> Patients' adherence and retention rates were 100 and 80 percent, respectively, at three months.<sup>142,143</sup> Additionally, the prescribing and pharmacy dispensing of methadone for OUD has been successfully implemented for decades in other parts of the world, including in Great Britain, Australia, and Canada.<sup>153</sup>

#### *Wide Variability in State-Based Protocols Improving Access to MOUD*

Facing persistent workforce shortages, states have also enacted state-based protocols, in contrast to private contract-based CPAs, to address challenges to accessing MOUD. In 2019, Massachusetts authorized trained pharmacists and pharmacy interns to administer LAI naltrexone, after the first dose, to persons 18 or older, provided it is prescribed by a licensed clinician.<sup>154</sup> The Nevada Board of Pharmacy recently promulgated a proposed regulation allowing separately-registered licensed pharmacists to make patient assessments for OUD (and for marriage and family therapists and clinical professional counselors may make such assessments as well), prescribe and dispense MOUD, and to be reimbursed for these services, without requiring specific education, training, or a CPA; however, it excludes administration of LAI medications.<sup>155</sup> In addition, the Colorado Governor recently signed a bill into law that requires the state Board of Pharmacy to develop statewide protocols<sup>156</sup> to provide for pharmacists to prescribe, dispense, and administer MOUD.<sup>157</sup>

#### *Limited Uptake of Tiered Licensure for Advance Practice Pharmacist Designations*

Outside of statewide protocols, some states have used advanced practice pharmacist designations ('tiered' licensure) that grant pharmacists provider status to improve access to health care in general. Four states have had meager uptake of such designated licenses, including the Advanced Practice Pharmacist (APh) in California, the Clinical Pharmacist Practitioner in Montana and North Carolina (CPP), and the Pharmacist Clinician (PhC) in New Mexico, due to barriers including lack of awareness, and to reimbursement.<sup>105,158</sup> For example, California's model authorizes all licensed pharmacists to order and interpret tests and monitor and manage medication therapy. The model also allows additional authorities to pharmacists who obtain the APh that previously required a CPA (i.e., pharmacists who meet certification or residency requirements, or who have provided one year of clinical services).<sup>159,160</sup> In 2022, two percent of licensed pharmacists had the APh in California.<sup>161</sup>

## Recommendations

The American Society of Addiction Medicine recommends that:

- 1) Congress amend federal law to exempt controlled medication formulations approved by the FDA for the treatment of SUD (only) from federal suspicious order reporting requirements.
- 2) In the absence of Congressional action, the Department of Justice (DOJ)/the DEA clarify that no action will be taken against any party for excluding controlled medication formulations approved by the FDA for the treatment of SUD (only) in suspicious order reporting, paving the way for removal of such formulations from any related algorithms, threshold limits, or automated checks by manufacturers, distributors, and pharmacies.
- 3) States enact or amend laws establishing pharmacy practice sites' and/or pharmacists' duty to dispense lawful prescriptions for addiction medications, including buprenorphine monoprodut tablets and buccal/sublingual buprenorphine products, without undue delay; pharmacies align corporate policies and store protocols accordingly.<sup>75</sup>
- 4) State attorneys general revisit and make necessary amendments to opioid settlement agreements to ensure adequate access to medications for OUD and overdose reversal, and remove provisions hindering access to controlled medication formulations approved by the FDA for the treatment of SUD (only).<sup>75</sup>
- 5) Federal and state authorities (including but not limited to those regulating license healthcare professionals or overseeing state prescription drug monitoring programs), public and private payers (and their drug utilization review boards and committees), and medical and pharmacy organizations carry out binding review processes to reconcile “red flag” or “suspicious order” policies currently subject to different policies, recommendations, and compliance requirements, including but not limited to those described in 21 USC 802(57)(A-C),<sup>77</sup> relevant case law,<sup>72</sup> *The DEA's Pharmacists' Manual*,<sup>162</sup> Injunctive Relief Distributors' settlement terms,<sup>28</sup> and *The Pharmacy Access to Resources and Medication for Opioid Use Disorder Guideline*; such binding review processes should update and synchronize all policies to the extend under their control, and, as fundamental to these processes, any red flag policies should be removed that:
  - a. Inappropriately or unreasonably limit geographic distance between patient and prescriber or patient and pharmacy, especially considering increased utilization of telemedicine.
  - b. Limit patients to payment through insurance coverage.
  - c. Suspect dose increases for an individual patient.
  - d. Suspect and/or distinguish between BUP and other BNX products that are approved by the FDA to treat OUD.
  - e. Suspect patients receiving prescriptions from multiple providers from the same medical practice.
  - f. Require patients to provide a diagnostic code on their prescription.
  - g. Require prescribers' verbal confirmation of prescription or practice details by telephone-only.
- 6) States exempt controlled medication products approved by the FDA for the treatment of SUD (only) from any state red flag laws and programs.<sup>75</sup>
- 7) The DEA and Department of Health and Human Services (HHS) enhance messaging that buprenorphine is a Schedule III medication and should be considered differently from other opioids which are Schedule II. The DEA and HHS consider partnerships with nongovernmental organizations to further disseminate clear and consistent messaging,

especially to Boards of Pharmacy and Controlled Substances Authorities at the state level.<sup>22</sup>

- 8) HHS make additional investments in educational opportunities to reduce stigmatization and clarify misperceptions about buprenorphine for the pharmacy and health care workforce, including as part of educational modules at residency programs, and during initial licensure and renewals for physicians, nurses, physician assistants, and pharmacists.<sup>22</sup>
- 9) HHS continue to consult the Office for Civil Rights (OCR) and Office of the General Counsel regarding denials of prescribed MOUD as possible violations of federal civil disability rights and federal civil rights laws governing other protected classes, including the Americans With Disabilities Act (ADA).<sup>22</sup>
- 10) HHS and state and local governments demonstrate and pilot programs enhancing access to MOUD, including programs that provide financial incentives to retail pharmacies to dispense such medications.<sup>22</sup>
- 11) States develop programs to promote best practices in, and incentivize appropriately qualified, licensed physicians and pharmacists to engage in, patient-specific collaborative practice agreements for addiction medications, including reimbursement for pharmacists' services, provided that the CPAs: (1) require physicians first diagnose patients with substance use disorder (SUD); (2) describe clearly pharmacists' physician-delegated authorities that may include initiating, modifying, or discontinuing prescribed medications; (3) require regular communication between physicians and pharmacists, (4) include qualifying requirements of some experience treating SUD or board certification in addiction medicine or addiction psychiatry for physicians, and accredited residency training or BPS board certification in a relevant specialty, such as the BCPP (Board Certified Psychiatric Pharmacist), for pharmacists.
- 12) As federal restrictions on methadone dispensing for OUD are modernized, states, with assistance from nongovernmental organizations, develop a model protocol for CPAs to serve as a method to formalize communication between addiction specialist physician prescribers and pharmacists dispensing methadone for OUD.
- 13) States permit pharmacists' administration of LAI addiction medications lawfully prescribed by a licensed clinician, provided such administration is not the first dose.
- 14) The FDA develop guidance clarifying the availability of REMS certification for Brixadi and Sublocade to *all* pharmacies that meet specified requirements, and widely disseminate such guidance; and further, the FDA clarify and widely disseminate its guidance that there is no requirement for REMS certification for healthcare settings intending to only obtain Brixadi or Sublocade from a REMS-certified pharmacy for practitioner administration at a specific-named patient's scheduled appointment.
- 15) Payers eliminate prior authorization requirements for all formulations of addiction medications and opt to cover pharmacist administration of LAI addiction medication with pharmacists as "*other licensed practitioner.*"<sup>163</sup>
- 16) States consider grant programs for piloting population-specific CPA models or non-CPA models for programs to improve access to addiction medications in high need communities, and states design, monitor, and evaluate such programs to generate data that informs policymakers on the safety, effectiveness, feasibility, and acceptability of those models.
- 17) Policymakers should consider, as best practice, physician-pharmacist CPA models to improve access to addiction medications in alignment with Recommendations 11 or 12, but if policymakers consider authorizing other models for addiction medications, policymakers should take the following measures at a minimum to ensure patient safety:
  - a. Prohibit pharmacists from making an SUD diagnosis independently;
  - b. Outline pharmacists' scope of practice and formulary clearly;



- c. Require some form of documentation and maintenance of records, including documentation of pharmacists' communication with patients' physicians or advanced practice clinicians; and
- d. Require pharmacists have accredited residency training or BPS board certification in a relevant specialty, such as the BCPP, as the minimal acceptable qualification.

**Adopted by the ASAM Board of Directors on July 18, 2024.**

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