



## **FEDERATION OF STATE PHYSICIAN HEALTH PROGRAMS, INC**

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### **Position Statement:**

### **Safety Considerations for Medication Treatment of Opioid Use Disorders in Monitored Health Professionals**

**August 2022**

#### **Purpose:**

To provide guidance to member physician health programs and other stakeholders regarding safety considerations for medication treatment of opioid use disorders (OUD), specific to the monitored health professional.

#### **General Considerations:**

Medication treatment, in combination with counseling and behavioral therapies, is recommended for individuals with OUD. <sup>1,2</sup> FDA-approved medications for the treatment of OUD should be available to all patients, including those who are health professionals. Clinicians should consider a patient's preferences, past treatment history, current state of illness, and treatment setting when deciding between the use of methadone, buprenorphine, and naltrexone.<sup>2</sup> Additional considerations apply to health professionals who are actively engaged in, or planning to return to, safety-sensitive work.

Physicians and other health professionals are safety-sensitive workers. Safety-sensitive workers have an ethical and legal obligation to take reasonable measures to mitigate identifiable safety risks. A fundamental role of Physician Health Programs (PHPs) is to support health professionals with their rehabilitative needs thereby contributing to optimal patient care. Medication treatment of OUD exemplifies the challenges and complexities inherent in balancing the treatment needs of the health professional with their ability to practice with reasonable skill and safety.

## **Physician Health Programs and Medication Treatment of Opioid Use Disorders**

Treatment providers and PHP participants must always make individualized, shared decisions regarding proposed treatments that consider the risks, benefits, and alternatives of different treatment options. The PHP, in collaboration with evaluation and treatment providers involved in the determination of fitness for duty, must then decide whether such treatment is compatible with monitoring and safe practice. Such decisions must also consider the PHP's obligations to other entities responsible for patient safety (such as regulatory agencies and credentialing bodies) as well as the advocacy needs of the participant. It is the shared responsibility of the participant, their treatment providers, the physician health program, and medical regulatory agencies to determine that a health professional is safe to continue or return to practice.

Outcomes associated with the PHP model have been well-documented.<sup>2-7</sup> Participants in PHPs have achieved unprecedented long-term recovery rates that approach 80% at 5 years.<sup>8-10</sup> PHP outcome studies span some of the longest time frames in addiction outcomes research and report the highest long-term remission rates when compared with other care management approaches. This outcome data is validated and verified by random toxicological testing during the entire period of monitoring. Such outcomes were observed during an era of treatment in which medications for OUD were not typically recommended for monitored health professionals.

As medications for OUD increased in terms of options and availability, PHPs became strong advocates for medication use within the monitoring paradigm. Among the available medication options for the treatment of OUD, long-acting injectable (LAI) naltrexone was widely adopted for use in the monitored health professional because it has no abuse potential, is easily monitored, is not known to negatively impact cognition and is highly protective against return to use, overdose, and impairment should return to use occur. In addition, standard monitoring protocols are protective against abrupt or unsupervised discontinuation of the medication which could put the monitored professional and patient safety at risk. With successful induction, LAI naltrexone is as effective as agonist/partial agonist therapies in head-to-head comparison studies and has similar effectiveness in return to use and overdose prevention.<sup>11-17</sup> Studies of physicians and other health professionals who are highly motivated toward

treatment demonstrate high rates of successful medication induction with a protective effect against return to use and adverse professional consequences in this population.<sup>18-20</sup>

Opioid agonist or partial agonist medications are among the most effective methods of preventing return to use and overdose deaths in the general population.<sup>21</sup> However, opioid agonist/partial agonist medications present certain challenges for the monitored health professional and the PHP. Unsupervised discontinuation with resultant withdrawal symptoms and the potential for return to use, overdose, and death may be perilous for the practicing professional and their patients. Importantly, PHP monitoring protocols cannot reliably detect self-directed dose variations (including abrupt discontinuation) which could adversely impact physician performance and patient care. Use of LAI formulations of partial agonist medication might mitigate such risks, but there is little experience or data to guide current practice.

Data on cognitive impairment with opioid agonists/partial agonists is mixed.<sup>22</sup> Given this uncertainty, along with the above-mentioned concerns, a judicious approach that errs on the side of public safety is indicated when considering the special needs of this population. There may be circumstances in which a case-specific approach favors the use of opioid agonist/partial agonist therapy in the monitored health professional. As is true for any potentially impairing medication or treatment, PHPs should take measures to assess and mitigate risks to public safety. Higher medication dose, concomitant use of other potentially impairing medications, below-expected performance on cognitive screening tests, and job-specific demands that are sensitive to psychomotor performance, processing speed, or high sustained attention may indicate the need for further evaluation. To this end, the PHP should continuously reassess and adjust monitoring in response to changes in medication regimen, clinical status, and workplace feedback. Given the special risks associated with discontinuation of medications for OUD, the PHP should monitor the professional during and after any planned cessation of this treatment modality to promote stable and sustained remission of illness.

## **Conclusions**

1. FDA-approved medications for the treatment of OUD should be available to all patients including healthcare professionals.

2. PHP participants with OUD experience excellent outcomes with and without medication treatment..
3. A treatment provider and patient must always make case-specific, shared decisions that consider the risks, benefits, and alternatives of proposed treatment options for OUD, including opioid antagonist and agonist/partial agonist medications.
4. Effective communication, collaboration, and accountability among the participant, treatment providers, and the physician health program are critical to addressing the health needs of the medical professional while decreasing risk of impairment.
5. LAI naltrexone is the preferred medication treatment option from the perspective of clinical performance and safety to practice. It has an established record of safe and effective use among healthcare professionals. LAI naltrexone has no abuse potential, adherence is easily verified, there is no evidence to suggest cognitive or functionally impairing side effects, and is highly protective against return to opioid use, opioid-related impairment, and overdose.
6. Further research investigating safety and efficacy, of FDA-approved medications and non-pharmacologic treatment modalities for OUD in monitored healthcare professionals is needed.
7. Additional education and outreach are recommended to assist the treatment providers of monitored health professionals to address the unique needs and circumstances of this population.

**References:**

1. Substance Abuse Mental Health Services Administration. Medications for Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series, No. 63. Rockville Maryland, USA: SAMSHA; 2020.
2. Crotty K, Freedman KI and Kampman KM. Executive Summary of the Focused Update of the ASAM National Practice Guideline for the Treatment of Opioid Use Disorder. J Addict Med. 14(2): May/June 2020: 99-112.
3. DuPont RL, McLellan AT, Carr G, Gendel M and Skipper GE. How Are Addicted Physicians Treated? A National Survey of Physician Health Programs. J Subst Abuse Treat. 37(1); July 2009: 1-7.
4. McLellan AT, Skipper GE, Campbell M and DuPont RL. Five Year Outcomes in a Cohort Study of Physicians Treated for Substance Use Disorders in the United States. BMJ 337; Nov 2008: 1-6.

5. Domino KB, Hornbein TF, Polissar NL, Renner G, Johnson J, Alberti S, and Hankes L. Risk Factors for Relapse in Health Care Professionals with Substance Use Disorders. *JAMA* 293(12); March 2005: 1453-60.
6. Earley P. Physicians Health Programs and Addiction among Physicians. In *American Society of Addiction Medicine, Principles of Addiction Medicine 5<sup>TH</sup> Edition, Chapter 49*; Edited by S Miller, D Fiellin, R Rosenthal and R Saitz, 671-92. Philadelphia: Wolters Kluwer, 2019.
7. Carr GD, Hall PB, Finlayson AR, and DuPont RL. Physician Health Programs: The US Model. In *Physician Mental Health and Well-Being*, 265-94: Springer, 2017.
8. Coombs, RH. *Drug-Impaired Professionals*. Cambridge, Mass. Harvard University Press, 1997.
9. Rose JS, Campbell MD, Yellowlees P, Skipper, GE, and DuPont RL. Family Medicine Physicians with Substance Use Disorder: A 5-Year Outcome Study. *J Addict Med* 11, no. 2 (2017): 93-97.
10. Skipper GE, Campbell, MD, and DuPont, RL. Anesthesiologists with Substance Use Disorders: A 5-Year Outcome Study from 16 State Physician Health Programs. *Anesth Analg*, 109 (2009): 891–96.
11. Buhl A, Oreskovich M, Meredith C, Campbell MD, and DuPont RL. Prognosis for the Recovery of Surgeons from Chemical Dependency: A 5-Year Outcome Study. *Arch Surg* 146, no. 11 (2011): 1286-91.
12. Krupitsky E, Nunes EV, Ling W, Gastfriend DR, Memisoglu A, and Silverman BL. Injectable Extended-Release Naltrexone (Xr-Ntx) for Opioid Dependence: Long-Term Safety and Effectiveness. *Addiction* 108, no. 9 (2013): 1628-37.
13. Krupitsky E, Nunes EV, Ling W, Illeperuma A, Gastfriend DR, and Silverman BL. Injectable Extended-Release Naltrexone for Opioid Dependence: A Double-Blind, Placebo-Controlled, Multicentre Randomised Trial. *The Lancet* 377, no. 9776 (2011): 1506-13.
14. Nunes EV, Krupitsky E, Ling W, Zummo J, Memisoglu A, Silverman, BL and Gastfriend, DR. Treating Opioid Dependence with Injectable Extended-Release Naltrexone (Xr-Ntx): Who Will Respond? *J Addict Med* 9, no. 3 (2015): 238-43.
15. Lee JD, Friedmann PD, Kinlock TW, Nunes EV, Boney TY, Hoskinson Jr RA, Wilson D, et al. Extended-Release Naltrexone to Prevent Opioid Relapse in Criminal Justice Offenders. *New England Journal of Medicine* 374, no. 13 (2016): 1232-42.
16. Lee JD, Nunes EV, Novo P, Bachrach K, Bailey GL, Bhatt S, Farkas S, et al. Comparative Effectiveness of Extended-Release Naltrexone Versus Buprenorphine-Naloxone for Opioid Relapse Prevention (X:Bot): A

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- Multicentre, Open-Label, Randomised Controlled Trial. *The Lancet* (London, England) 391, no. 10118 (2018): 309-18.
17. Kunøe N, Opheim A, Solli KK, Gakeun Z, Sharma-Haase K, Tanum LJP, and Toxicology. Design of a Randomized Controlled Trial of Extended-Release Naltrexone Versus Daily Buprenorphine-Naloxone for Opioid Dependence in Norway (Ntx-Sbx). 17, no. 1 (2016): 18.
  18. Tanum L, Solli K, Latif Z and et al. Effectiveness of Injectable Extended-Release Naltrexone Vs Daily Buprenorphine-Naloxone for Opioid Dependence: A Randomized Clinical Noninferiority Trial. *JAMA Psychiatry* 74, no. 12 (2017): 1197-205.
  19. Oesterle TS, Thusius NJ, Rummans T, Gold MS. Medication-Assisted Treatment for Opioid-Use Disorder. *Mayo Clin Proc* 94, no. 10 (Oct 2019): 2072-86.
  20. Merlo LJ, Gold MS. Prescription Opioid Abuse and Dependence Among Physicians: Hypotheses and Treatment. *Harv Rev Psychiatry*. 2008;16(3):181-194.
  21. Merlo LJ, Greene WM, Pomm R. Mandatory Naltrexone Treatment Prevents Relapse Among Opiate-Dependent Anesthesiologists Returning to Practice. *J Addict Med*. 2011;5(4):279-283
  22. Clausen T, Anchersen K, Waal, H. Mortality Prior to, During and after Opioid Maintenance Treatment (OMT): A National Prospective Cross-Registry Study. *Drug and Alcohol Depend*. 94, no. 1-3 (2008): 151-57.
  23. Polles AG, Williams MK, Phalen BR, Teitelbaum S, Merlo LJ. Neuropsychological Impairment Associated with Substance Use by Physicians. *J Neurol Sci* 411 (April 15, 2020).