Opinion

In Support of Buprenorphine Deregulation

RICHARD C. WATERS, MD, MSC

Family physicians should join the fight to remove limits on prescribing buprenorphine for opioid use disorder.

Facing an epidemic of opioid use disorder (OUD) throughout the United States, many communities are trying to address the public health crisis with evidence-based interventions.[1] Prescribing buprenorphine (brand names: Suboxone, Subutex, and Zubsolv, among others) for OUD is one key strategy. Federal regulations surrounding the prescribing of buprenorphine for OUD are increasingly the target of scrutiny.[2,3] In fact, the leaders of the departments of health for 18 states, the District of Columbia, and Puerto Rico in April asked U.S. Secretary of Health and Human Services Alex Azar to push Congress to deregulate buprenorphine so that it is treated as any other controlled substance.[4]

Family physicians and other primary care providers can play an important role in influencing what happens next, as primary care teams are on the front lines of dealing with the impact of substance use disorders in our communities. So, should we in primary care encourage — or fear — the idea of buprenorphine deregulation? There is a strong case that deregulation would be safe and would make it simpler for physicians to treat people with OUD, without negative consequences for those who do not plan to add this clinical area to their practice. Accordingly, this editorial makes the argument that primary care providers should actively advocate for buprenorphine deregulation.

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The current regulations for prescribing buprenorphine for OUD require physicians to get eight hours of training and certification prior to prescribing (the Drug Enforcement Administration's "Drug Addiction Treatment Act of 2000 X-waiver") and limit the number of patients for whom they may prescribe buprenorphine for OUD at a given time.[5] Current prescribing limits are 30 patients in the first year, 100 in the second and subsequent years (after federal approval is granted), and up to 275 if the physician is board-certified in addiction medicine. These limits are for actively engaged patients, so if a patient drops out of treatment, another patient can take that spot in the physician's buprenorphine panel. By comparison, there are no training requirements or prescribing limits for buprenorphine when prescribed for pain management in the absence of OUD.

ABOUT THE AUTHOR

Dr. Waters is a family physician and the medical director of the Homeless & Housing Care program at Neighborcare Health, a community health center network in Seattle, Wash. Author disclosure: no relevant financial affiliations disclosed.

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In many cases, regulations help keep pharmaceuticals safe, set minimum standards for health care professionals, and mitigate the risks of inappropriate use. The essential questions regarding buprenorphine are whether the buprenorphine regulations actually add value to individual or public health and whether they are useful to primary care providers.

Others have provided a larger overview of the history of buprenorphine regulations, their original intent, and a case for deregulation based on relative safety and other factors.[2] Indeed, buprenorphine is far safer in terms of risk of overdose than full-opioid agonists, and those who divert buprenorphine appear to use it overwhelmingly for its intended purposes of mitigating opioid withdrawal symptoms and reducing opioid cravings.[6] And based on others' experience, deregulation would likely result in expanded access and less stigma around using the medication, thus improving individual and public health outcomes.[2] In addition, at the end of 2017, 56 percent of rural U.S. counties did not have a single buprenorphine prescriber, so lowering the barriers to entry may have an outsized benefit for rural areas.[7]

But how would deregulation affect your practice? If you already have an X-waiver, you would no longer have to worry about exceeding the limit on the number of patients who could receive buprenorphine prescriptions. These prescribing limits can harm family physicians' ability to care for their community, especially in rural areas. I have also observed that the presence of such a limit appears to cause unnecessary apprehension among physicians who rarely reach their OUD-related limits. For group practices, deregulating buprenorphine would make cross-coverage more straightforward because any physician could continue a buprenorphine prescription if the patient's primary physician is not available. This may ease resistance from practice partners — a relatively small but notable barrier now.[8]

If you don't yet have an X-waiver but are considering it, deregulation would also be positive. Many family physicians say they don't adopt this clinical practice because the buprenorphine regulations are overly cumbersome.[9] The additional eight hours of training would no longer be required, and it is hard to argue that treating OUD is any more complex than many common clinical scenarios in primary care such as treating heart failure or diabetes, managing pregnancy and delivery, or caring for patients with multiple chronic conditions. Further, initiating and continuing buprenorphine for OUD is medically straightforward enough that it lends itself to algorithms and clinical pathways to guide those entering the field. Undoubtedly, training would still be available, and it is possible the DEA could recommend or require briefer training for license renewal, but these requirements would likely be less onerous than the current ones. In the meantime, clinicians who are considering getting an X-waiver should continue with the training and not wait for possible deregulation.

Physicians who are not interested in treating OUD should not be concerned about buprenorphine deregulation. While you might fear an influx of buprenorphine-seeking patients, you could address this by noting that you do not provide this clinical care and refer patients elsewhere — just as you currently do when patients seek other treatments or procedures you do not provide.

Some may worry that buprenorphine deregulation might lead to "pill mills" and other unscrupulous behavior. Yet the vast majority of states have prescription monitoring programs, so regulatory agencies or state departments of health could monitor concerning prescribing patterns. Some may be concerned that lesser-trained physicians could inadvertently cause patients to experience precipitated withdrawal from buprenorphine, which could dissuade patients from future treatment attempts. While a valid fear, this is likely to be rare, given that buprenorphine education materials regularly caution against this and most physicians would do some form of review prior to prescribing. Education, medication labeling, and pharmacist interventions at the point of dispensing could also mitigate these concerns.

Buprenorphine deregulation will not solve the OUD epidemic — a multipronged approach is needed — but it is a step in the right direction and one that won't require additional funding. The current regulations,

based on the research now available, do not appear to provide individual or public health benefits,[2] making their continuance a disconcerting precedent at a time of great public health need.

As recently discussed in this journal, family physicians can be effective advocates for legislative action[10] and new legislation has recently been introduced.[11] There is growing recognition of the need to remove the regulations that limit prescribing buprenorphine for OUD. Family physicians, other primary care providers, and organized medical professional groups should join this chorus for change. FPM

1. Carroll JJ, Green TC, Noonan RK. *Evidence-Based Strategies for Preventing Opioid Overdose: What's Working in the United States.* Atlanta: Centers for Disease Control and Prevention, National Center for Injury Prevention and Control; 2018. https://stacks.cdc.gov/view/cdc/59393. Accessed June 5, 2019.

2. Fiscella K, Wakeman SE, Beletsky L. Buprenorphine deregulation and mainstreaming treatment for opioid use disorder: X the X waiver. *JAMA Psychiatry.* 2019;76(3):229-230.

3. Kolodny A, Frieden TR. Ten steps the federal government should take now to reverse the opioid addiction epidemic. *JAMA.* 2017;318(16):1537-1538.

4. Smith N, Smith K, Pino R, et al. Letter to US Health and Human Services Sec. Alex Azar. April 8, 2019. https://www.health.ny.gov/press/docs/action_needed.pdf. Accessed June 11, 2019.

5. Buprenorphine waiver management. Substance Abuse and Mental Health Services Administration website. https://www.samhsa.gov/medication-assisted-treatment/training=materials-resources/buprenorphine-waiver. Updated May 2019. Accessed June 11, 2019.

6. Cicero TJ, Ellis MS, Chilcoat HD. Understanding the use of diverted buprenorphine. *Drug Alcohol Depend.* 2018;193:117-123.

7. Andrilla CHA, Moore TE, Patterson DG, Larson EH. Geographic distribution of providers with a DEA waiver to prescribe buprenorphine for the treatment of opioid use disorder: a 5-year update. *J Rural Health.* 2019;35(1):108-112.

8. Andrilla CHA, Coulthard C, Larson EH. Barriers rural physicians face prescribing buprenorphine for opioid use disorder. *Ann Fam Med.* 2017;15(4):359-362.

9. DeFlavio JR, Rolin SA, Nordstrom BR, Kazal LA. Analysis of barriers to adoption of buprenorphine maintenance therapy by family physicians. *Rural Remote Health.* 2015;15:3019.

10. Grivois-Shah R. Practical strategies to achieve your health policy goals. *Fam Pract Manag.* 2019;26(2):20-24.

11. Mainstreaming Addiction Treatment Act of 2019, H 2482, 116th Cong, 1st Sess (2019).