

HEALTH POLICY

Nurse practitioners' inability to prescribe buprenorphine: Limitations of the Drug Addiction Treatment Act of 2000

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Abstract

Purpose: To identify the limitations of the Drug Addiction Treatment Act of 2000 (DATA 2000) and to discuss the merits of one possible solution: granting nurse practitioners (NPs) the authority to prescribe buprenorphine.

Data sources: The DATA 2000 and related literature.

Conclusions: Abuse of prescription opioid medications is a significant economic and public health burden. Buprenorphine is a highly effective medication that is used in the outpatient treatment of opioid-dependent patients. However, the DATA 2000 permits only physicians to prescribe this medication, substantially reducing patient access to potentially life-sustaining treatment.

Implications for practice: Like diabetes and cardiovascular disease, addiction is a chronic condition that can be treated with lifestyle modifications, patient education, and appropriate medication. NPs are highly effective caregivers to patients with chronic disease. Granting NPs prescriptive authority for buprenorphine will improve access to treatment and patient outcomes. It will also enhance NP autonomy and authority, especially in states in which NPs practice independently.

The abuse and misuse of prescription opioid medications represents a significant economic and public health burden. During 2008, approximately 1.7 million persons in the United States were abusing opioids and physically dependent, yet only 35% received treatment (Substance Abuse and Mental Health Services Administration [SAMHSA], 2009). The total annual cost of opioid abuse in the United States is \$8.6 billion (Strassels, 2009). Buprenorphine is a highly effective medication that is used in the outpatient treatment of opioid-dependent patients. However, the Drug Addiction Treatment Act of 2000 (DATA 2000) permits only physicians to prescribe this medication, substantially reducing access to treatment, especially in underserved areas. The goal of this analysis is to identify the limitations of DATA 2000 and to discuss one possible solution to the problem: granting nurse practitioners (NPs) the authority to prescribe buprenorphine.

Background and scope of the problem

Prescription drug abuse is widespread and rising. Approximately 4.7 million persons in the United States used prescription opioids nonmedically during the pre-

vious month during 2008 (SAMHSA, 2009). Strassels (2009) concluded that the total annual cost of opioid abuse in the United States (including health care, workplace, and criminal justice expenditures) is \$8.6 billion. Annual per capita direct healthcare expenditures for persons abusing and misusing opioids (\$16,000) are significantly higher than for persons not abusing opioids (\$1800; Strassels, [2009]).

Methadone is a highly effective, evidence-based treatment for opioid dependence and is likely the most well-known treatment option, but it can only be dispensed through specialized clinics (Mattick, Breen, Kimber, & Davoli, 2009). The number of federally licensed methadone treatment slots has remained constant even though opioid dependence has been rising (SAMHSA, 2006). These clinics are regulated by the Food and Drug Administration (FDA) and are unevenly distributed geographically, which restricts the use and availability of methadone (SAMHSA, 2006).

DATA 2000 and buprenorphine

DATA 2000 is Title XXXV, Section 3502 of the Children's Health Act of 2000. DATA 2000 permits

“qualifying physicians” to prescribe FDA-approved medications for use in the maintenance and detoxification of patients with opioid use disorders (House Resolution 4365, 2000). To qualify, physicians not certified in addiction medicine must complete no fewer than 8 h of additional training in the treatment of opioid-dependent patients, have a Drug Enforcement Administration (DEA) license, and have the capacity to refer patients to counseling. Two medications are currently FDA approved for the outpatient treatment of opioid dependence: a buprenorphine–naloxone combination (Suboxone[®]) for general use, and buprenorphine monotherapy (Subutex[®]) which has been used to treat pregnant women. Exposure to naloxone in utero may produce hormonal changes in the fetus and the intravenous misuse of the combination buprenorphine–naloxone preparations may produce acute withdrawal (Jones et al., 2008). DATA 2000 allows qualifying physicians to treat no more than 30 opioid-dependent patients at a time. However, following an amendment to the Controlled Substances Act in 2006, physicians have been able to file a “notice of intent” to prescribe for up to 100 patients as long as at least 1 year has passed since being granted initial prescriptive approval of buprenorphine (Ullman, 2006). Buprenorphine is the only Schedule III medication that existing laws permit only physicians to prescribe (House Resolution 4365, 2000).

Consistent with previous literature, the author was unable to locate any documents explaining the rationale for restricting NPs from prescribing buprenorphine (Fornili & Burda, 2009). However, a congressional aide involved in preparing DATA 2000 did “not recall a concerted effort to specifically exclude nonphysician prescribers,” but recalled a general opposition to DATA 2000 among legislators due to concern about diversion of opioid medications as well as the belief that psychiatrists, rather than primary care physicians, were better prepared to treat patients with addiction (Fornili & Burda, 2009).

Buprenorphine is a safe, effective alternative to methadone and has been associated with increased treatment retention and survival as well as fewer adverse side effects (Walley et al., 2008). Unlike methadone, buprenorphine has a ceiling effect that enhances patient safety by reducing the risk of overdose (SAMHSA, 2010). It also has poor oral bioavailability and is less likely to cause respiratory depression than other opioids (SAMHSA, 2010). Buprenorphine is prescribed as part of an outpatient office visit and, unlike methadone, does not require daily visits to a specialized clinic, reducing the potential stigma associated with treatment.

However, office-based physicians have shown low rates of buprenorphine certification (Fornili & Burda, 2009). Fewer than 10% of nonaddiction specialist psychiatrists

in the United States prescribe buprenorphine (Thomas et al., 2008). In addition, many physicians who are certified to prescribe buprenorphine are not actually doing so—Kissin, McLeod, Sonnefeld, and Stanton (2006) found that only 58% of certified physicians prescribe buprenorphine. Physicians cite multiple barriers to providing care to opioid-dependent patients although specific barriers tend to vary by whether the physician is certified to prescribe buprenorphine. Physicians who have not completed training in the outpatient management of opioid dependence using buprenorphine report that barriers include a lack of knowledge about opioid addiction treatment, lack of access to addiction experts, and concerns about the availability of substance abuse treatment programs, the diversion of buprenorphine and that these patients have “too many problems” (Cunningham, Kunins, Roose, Elam, & Sohler, 2007; Cunningham, Sohler, McCoy, & Kunins, 2006).

However, physicians who are certified to prescribe buprenorphine are less likely to be concerned about many of these barriers (Cunningham, Kunins et al., 2007). Certified physicians report that barriers to prescribing include insufficient office and/or institutional support, lack of time in their existing practice, lack of experience providing this care, and the unavailability of backup providers who prescribe buprenorphine (Gunderson, Fiellin, Levin, Sullivan, & Kleber, 2006; Walley et al., 2008). Certified physicians report that telephone access to experienced providers would improve their level of confidence providing this care (Gunderson et al., 2006). Factors associated with an increased willingness to prescribe buprenorphine also include training clinical staff about buprenorphine, available consultation or case conferences, and the availability and access to a variety of behavioral and mental health services (Cunningham, Sohler et al., 2006; Netherland et al., 2009).

Granting NPs prescriptive authority for buprenorphine

Under DATA 2000, NPs are not allowed to prescribe medications for the outpatient treatment of opioid dependence, as the term “qualifying physician” is specifically defined to include only physicians licensed under state law (House Resolution 4365, 2000). In states where NPs practice independently and autonomously, they are often the sole healthcare provider in many underserved communities. Many NPs care for particularly vulnerable patients in areas with physician shortages.

According to the National Institute on Drug Abuse (NIDA, 2008), drug addiction is a chronic disease similar to diabetes and cardiovascular disease. It shares many of the same attributes including an onset and course that

may be influenced by a patient's environment and behavior, its ability to respond to treatment including long-term lifestyle modifications as well as a significant likelihood of relapse (McClellan, Lewis, O'Brien, & Kleber, 2000).

Many studies have illustrated that chronic disease health outcomes for patients treated by NPs are comparable to patients cared for by physicians. Mundinger et al. (2000) found that patients randomly assigned to NPs had similar chronic disease health outcomes and overall satisfaction as patients assigned to physicians. Similarly, Lenz, Mundinger, Kane, Hopkins, and Lin (2004) found no significant difference in health outcomes, patient satisfaction, or the use of specialists in a study of more than 400 patients randomly assigned to either an NP or family physician in the primary care setting. Systematic reviews of studies comparing care provided by NPs to that provided by physicians have supported these findings. In a meta-analysis of 11 randomized controlled trials and 23 observational studies conducted in developed countries, Horrocks, Anderson, and Salisbury (2002) determined that patients were more satisfied with care provided by NPs and that there was no significant difference in health outcomes between care provided by physicians and NPs in both the outpatient and urgent care settings. Similarly, Laurant et al.'s (2004) meta-analysis of 16 studies involving more than 26,000 patients in the United States, United Kingdom, and Canada found no appreciable differences in health outcomes between care provided by physicians and NPs. When compared to physicians, NPs achieved higher patient satisfaction scores and tended to provide more health advice (Laurant et al., 2004).

Only one study was found that analyzes the potential interest of NP and physician assistant (PA) clinicians in prescribing buprenorphine. Roose, Kunins, Sohler, Elam, and Cunningham (2008) found that, within a subset of clinicians caring for patients with HIV, 48.6% of NPs and PAs were interested in prescribing buprenorphine. NPs and PAs were at least as likely to be interested in prescribing the medication (adjusted odds ratio [AOR] 2.89, 95% confidence interval [CI] 1.22–6.83) when compared to generalist physicians (AOR 2.04, 95% CI 1.09–3.84), and significantly more likely to be interested in prescribing buprenorphine than specialist physicians (AOR 1.00). It is difficult to determine to what extent the results of Roose et al. (2008) are generalizable to the broader NP population and further study is needed.

The costs of training NPs to treat patients with buprenorphine are similar to the costs of training physicians. In most cases, NPs already have DEA licenses and NPs are permitted to prescribe Schedules III–V medications in 46 states and the District of Columbia; legislation has been passed and is pending DEA approval in

Hawaii and Missouri (American Academy of Nurse Practitioners [AANP], 2011; Byrne, 2009). NPs are not permitted to prescribe controlled substances in Alabama, or Florida (AANP, 2011; Byrne, 2009). The cost of obtaining buprenorphine certification is limited to a 1-day training course, which is offered by the American Society of Addiction Medicine (ASAM) and other organizations for \$175 (ASAM, 2010). In fact, many NPs involved in the care of patients maintained on buprenorphine have already completed the course for continuing education credit and would only need to submit the relevant paperwork if NPs were granted authority to prescribe the drug.

Granting NPs prescriptive authority for buprenorphine could potentially reduce some of the barriers that physicians experience providing this care, as NPs and physicians could be available to each other as backup prescribers. NPs and physicians might be able to collaborate and share resources such as licensed professional support staff who can provide some of the monitoring activities such as obtaining urine drug screens and conducting pill counts. This staff may also be able to facilitate the necessary paperwork for counseling referrals.

Prohibiting NPs from prescribing buprenorphine limits patient access to life-sustaining treatment, is associated with significant costs to society, and substantially restricts NP autonomy and authority, particularly in states in which NPs practice independently. Given that DATA 2000 is a federal law, action is needed at the national level. During its third Buprenorphine Summit in 2008, SAMHSA and NIDA noted the continuing need to enhance and expand access to buprenorphine treatment and recommended that "future training initiatives should be broadened to encompass training of other health care professionals," including NPs (SAMHSA, 2008). However, the organizations did not specifically address expanding prescriptive authority to NPs. NP professional organizations, such as the AANP, should consider developing position statements about granting NPs prescriptive authority for buprenorphine and should also play an active role in any potential amendments to DATA 2000. An opportunity may also exist for NP professional organizations to collaborate with SAMHSA, NIDA, other advanced practice nursing professional organizations such as the American College of Nurse-Midwives, and other related organizations such as the National Alliance of Advocates for Buprenorphine Treatment. With the implementation of healthcare reform and recent positive developments in addiction treatment such as the removal of the ban on federal funding for needle exchange programs from the most recent appropriations bill signed by the president, it may be an excellent opportunity to revisit DATA 2000 (Schwartzapfel, 2009).

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