



## Full length article

## Prescribing patterns of buprenorphine waived physicians



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## ABSTRACT

**Background:** DATA 2000 enabled physicians with approved training to be waived to prescribe buprenorphine for the treatment of opioid use disorders (OUD) for a limited number of patients. A rule change in 2016 increased the patient limit for certain buprenorphine waived physicians from 100 to 275. This study examines the prescribing patterns of buprenorphine prescribers by waiver limit status (30- or 100-patient limit).

**Methods:** Prescription Monitoring Program (PMP) data from Ohio, California, and Maine were used to identify prescriptions for buprenorphine for OUD from January 2010 to April 2015. Analysis of prescribing patterns by prescriber waiver status included monthly patient censuses and treatment episode duration by state, year, and the frequency with which prescribers were near their respective patient limits.

**Results:** In the three states, 8638 physicians initiated 468,148 buprenorphine episodes. The adjusted mean monthly patient census was 42.9 for 100-patient waived prescribers, 13.6 patients for 30-patient waived prescribers, and 7.6 patients for prescribers unassociated with a waiver. Half (48.5%) of episodes were associated with 100-patient waived prescribers, 26.9% with 30-patient waived prescribers, and 24.4% with non-waived prescribers. 30-patient waived physicians were more likely to have no buprenorphine treatment episodes in a given month than 100-patient waived prescribers.

**Conclusions:** Most buprenorphine prescribers practice well under their current patient limit and have numerous months with no patient episodes. For the few high prescribers, increasing the maximum patient limit beyond 100 has the potential to improve access but alone may not have widespread impact unless integrated into complementary approaches toward increasing prescriber capacity.

## 1. Introduction

The United States is in the midst of a devastating epidemic of opioid overdoses that is closely linked with rising rates of opioid use disorders. In the U.S., an estimated 2.2 million people aged 12 and older, or nearly nine people per 1000, met diagnostic criteria for an opioid use disorder (OUD) (American Psychiatric Association, 2013) in the past year (Jones et al., 2015; Jones, 2016). Drug overdoses – largely driven by substantial increases in prescription opioid and heroin overdoses – are now the leading cause of injury death in the U.S. (Murphy et al., 2013), and the annual economic costs of prescription opioid use disorders and overdoses alone are estimated at over \$78 billion (Florence et al., 2016). Medication-assisted treatment (MAT), the use of medications such as methadone, buprenorphine, or naltrexone in combination with behavioral health services, is recognized as an effective evidence-based practice for treating OUD (Bart, 2012; Schackman et al., 2012; Thomas

et al., 2014). Despite the evidence base supporting MAT, it remains significantly underutilized due to a range of factors including insufficient capacity, inadequate reimbursement, long waiting lists in many communities, lack of institutional support, and a lack of consumer knowledge about MAT (Roman et al., 2011; Hutchinson et al., 2014; Sigmon, 2015).

The Drug Addiction Treatment Act of 2000 (DATA 2000) enabled qualified physicians (hereafter referred to as waived physicians) to obtain a waiver from the Controlled Substances Act allowing them to prescribe buprenorphine-containing medications approved for the treatment of OUD. DATA 2000 initially allowed waived physicians to only manage up to 30 patients concurrently on buprenorphine due to concerns about diversion (U.S. Congress, 2000). In 2006, the Office of National Drug Control Policy Reauthorization Act of 2006 modified restrictions to grant approval for treating up to 100 patients at a time to physicians waived at the 30 patient-limit for at least one year (Office

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of National Drug Control Policy (ONDCPRA, 2006), a change associated with a subsequent increase in the amount of buprenorphine dispensed (Stein et al., 2015b). Still, insufficient office-based opioid treatment capacity persists, particularly in rural areas (Sigmon, 2014; Knudsen, 2015; Sigmon 2015). In response to requests to further raise or eliminate the patient limit (U.S. Congress, 2015; Gitlow, 2014), the U.S. Department of Health and Human Services promulgated a final rule in July 2016 (The White House, 2016) which increased the buprenorphine patient limit to 275 for certain qualified physicians. In a related effort, recent Congressional passage of the Comprehensive Addiction and Recovery Act (CARA) authorized nurse practitioners and physician assistants to prescribe buprenorphine for OUD for up to 30 patients, or 100 patients after one year with 30 (U.S. Congress, 2016).

Raising waived prescribers' patient limits will allow prescribers to accept new patients while still treating ongoing patients, thereby increasing both the number of patients receiving buprenorphine and also potentially resulting in longer buprenorphine treatment episodes. However, factors such as concerns over increased DEA scrutiny of medical records (Providers' Clinical Support System (PCSS), 2011), the need to closely monitor patients for potential relapse or medication diversion (Center for Substance Abuse Treatment (CSAT), 2004), low insurance reimbursement rates for services associated with buprenorphine prescribing such as office visits and urine drug screens (Walley et al., 2008), insufficient access to behavioral health services for concurrent counseling (Hutchinson et al., 2014), and the challenges inherent and stigma associated with treating these complex patients may diminish physicians' willingness to prescribe buprenorphine. This potentially limits the impact of raising buprenorphine patient limits. Several prior studies (without respect to assessing accompanying psychosocial services) suggest that many buprenorphine prescribing physicians may be treating relatively few patients and that numerous waived prescribers may not be prescribing (Hutchinson et al., 2014; Sigmon, 2015), but studies examining buprenorphine prescribing patterns (Sigmon, 2015; Stein et al., 2016) have often been unable to identify prescribers' waiver status, preventing an examination of waived physicians approved to treat 100 patients, who are most likely to be affected by raising patient limits.

This study contributes to our understanding of waived prescribers' treatment of patients with OUD by examining prescribing trends among prescribers with a 30 or 100 patient limit, as well as prescribers whose DEA number is unassociated with a waiver. This information will contribute to the understanding of clinicians, advocates, and policy-makers of how changes in waived prescribers' patient limits are likely to affect buprenorphine treatment of OUD.

## 2. Methods

### 2.1. Population and data

We used Ohio, California, and Maine prescription monitoring program (PMP) data housed in Brandeis University's Prescription Behavior Surveillance System (PBSS) (Centers for Disease Control and Prevention (CDC), 2011; Paulozzi et al., 2015) to identify all prescriptions for oral (sublingual or buccal) buprenorphine or buprenorphine/naloxone formulations approved for OUD treatment. These three states were chosen because their regulations allow for use of PMP data in research, and because of their availability of resources and willingness of PMP officials to match physician waiver status with prescribing data and identify for the purpose of this study. Buprenorphine formulations solely approved for pain management were excluded. Data from the Substance Abuse and Mental Health Services Administration (SAMHSA) on all waived physicians in Ohio, California, and Maine were matched by Drug Enforcement Administration registration number to PMP prescribing records to categorize buprenorphine prescribers by waiver status (30-patient, 100-patient, no waiver). To distinguish between waived physicians and buprenorphine prescribing physicians we refer

to physicians prescribing buprenorphine as buprenorphine prescribers, and we refer to physicians waived to prescribe buprenorphine (irrespective of whether or not we observe them prescribing) as waived physicians. This study addresses the prescribing patterns for buprenorphine but does not examine psychosocial or other services accompanying the prescriptions. The Brandeis University Institutional Review Board approved the study.

### 2.2. Measures

#### 2.2.1. Patient-level measures

Using the National Drug Code for buprenorphine formulation and amount prescribed, we created patient-level buprenorphine treatment episodes. An episode was defined as the period starting with an observed buprenorphine prescription dispensed between January 1, 2010 and September 30, 2013 following a 30-day period where no buprenorphine prescription was dispensed. Episodes ended with either a 14-day gap in buprenorphine days supplied or on April 1, 2015, the last observed date in the data. Episodes longer than 730 days (1.53% of episodes) were censored at 730 days, and individuals could have multiple episodes. Each episode was assigned to a buprenorphine prescriber; episodes with multiple prescribers (18.7% of episodes) were assigned to the first prescriber in the episode. We identified 10,599 buprenorphine prescribers, 81.5% of whom ( $n = 8638$ ) were the first prescriber in one or more episodes, and 18.5% ( $n = 1961$ ) who only prescribed buprenorphine after another prescriber initiated treatment.

#### 2.2.2. Prescriber-level measures

Prescribers were categorized by waiver status (100-patient limit, 30-patient limit, no waiver). All physicians who were waived or who prescribed buprenorphine in the year were included in the study. Physician specialty was not available for this study, so all primary and specialty providers were pooled. For prescribers who changed waiver status between January 1, 2010 and September 30, 2013 (i.e., moved from 30 patients to 100 patients), the prescriber was included in the new waiver category for the month of change and thereafter. For each prescriber, we calculated a monthly patient census, defined as the number of patient episodes assigned to the prescriber during that month. For months in which 100-patient waived prescribers treated more than 74 patients, they were categorized as being near the patient limit. If they treated fewer than 75 patients, they were categorized as not near the patient limit. For months in which 30-patient waived prescribers treated more than 24 patients, they were categorized as being near the patient limit. If they treated fewer than 25 patients, they were categorized as not near the patient limit.

### 2.3. Data analysis

For prescriber measure outcomes (patients per prescriber, practicing near the patient limit), the denominator was months in which a prescriber treated at least one patient with buprenorphine. We excluded months during which a prescriber treated no patients. We first calculated the percentage of 30-patient and 100-patient waived prescribers who treated at least one patient annually. We also calculated univariate and bivariate statistics of prescribers' monthly patient census, episode duration, episode dosage by prescriber waiver category, state, year the treatment episode began, and the frequency with which prescribers were prescribing near their patient limit.

We performed a multivariate analysis, controlling for state and year to estimate outcomes of interest. To address non-linear distribution of observations, a general linear model (SAS PROC GENMOD) with a log link gamma distribution was used to estimate the adjusted mean number of patients per prescriber-month and mean episode length. Logistic regression was used to estimate the adjusted likelihood of prescribing near the patient limit in any one month.

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