Current Issues in the Treatment of Opioid Disorders: Buprenorphine Patient Limits
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I have no conflict of interest to disclose and no financial or other interest associated with buprenorphine or any entity that has a pecuniary or tangible interest in buprenorphine or the use of buprenorphine.

H. Westley Clark, MD, JD, MPH
The maximum number of patients a physician may treat with buprenorphine is limited by law; therefore, some physicians listed on the Locator may not be accepting new patients at this time.

Treatment programs are authorized under 21 U.S.C. Section 823 (g)(1) to dispense (but not prescribe) opioid treatment medications. Treatment programs registered under 21 U.S.C. Section 823 (g)(1) are not subject to patient limits.
In the United States, there are an estimated 897,000 professionally active physicians:
• 428,478 Primary Care Physicians
• 468,942 Physicians

March 2015

http://kff.org/other/state-indicator/total-active-physicians/
In 2011, 43% of US counties had no buprenorphine-waivered physicians and 7% had 20 or more waivered physicians.

Medicaid funding, opioid overdose deaths, and specific state guidance for office-based buprenorphine use were associated with more buprenorphine-waivered physicians, while encouraging methadone programs to promote buprenorphine use had no impact.

Stein BD et al
Geographic Maldistribution of Physicians With Waivers

Only 46.6% of US counties (1,465 of 3,143) had a physician who could prescribe buprenorphine; 90.3% of the US population resided in these counties. Thirty million people, or 9.7% of the US population, were living in counties that had no physician with a waiver, 21.2 million of them in rural counties and 8.8 million in metropolitan counties. Of the counties that had no physicians who could prescribe buprenorphine, 82.1% were in rural areas.

The percentage of physicians with waivers varied widely by state, from 0.6% in Nebraska to 6.8% in Vermont. The ratio of these physicians to 100,000 population varied 15-fold by state.

Buprenorphine Physicians and Treatment Programs listed on the SAMHSA locator website:

17,080 Physicians

1,833 Treatment Programs

About 7,700 of the approximately 26,000 currently waivered physicians are authorized to prescribe for up to 100 patients because they are in their second year of prescribing. It is estimated that less than half of all waivered physicians actually prescribe up to their limit (30 or 100 patients), and many do not prescribe for opioid addiction at all.
Of the 2.2% of US physicians who had obtained waivers to prescribe buprenorphine on the DEA DATA list, 41.6% were psychiatrists, and slightly more than one-third (36.7%) practiced in the primary care specialties of family or internal medicine.

Nationally, the 5 specialties with the highest rates of physicians with waivers were

- psychiatry (16.2%),
- pain management (15.2%),
- physical medicine and rehabilitation (5.3%),
- family medicine (3.6%),
- and internal medicine (2.1%)

THE BUPRENORPHINE CAP

• DATA 2000, as amended in December 2006, specifies that an individual physician may have a maximum of 30 patients on opioid therapy at any one time for the first year.

• One year after the date on which a physician submitted the initial notification, the physician may submit a second notification of the need and intent to treat up to 100 patients.

http://buprenorphine.samhsa.gov/bwns_locator/physician_faq.htm
“ACCORDING TO THE DRUG ENFORCEMENT ADMINISTRATION, WHEN POLICE CONDUCT A PRESCRIPTION DRUG BUST, THE 3RD MOST FREQUENTLY SEIZED DRUG BY LAW ENFORCEMENT IS BUPRENORPHINE. MORE THAN METHADONE. MORE THAN MORPHINE. MORE THAN CODEINE. AND UNLIKE CLINICS THAT ADMINISTER METHADONE, THERE ARE NO REQUIREMENTS FOR BUPRENORPHINE CLINICS TO OFFER OR EVEN DISCUSS NON-ADDICTIVE TREATMENT ALTERNATIVES WITH PATIENTS. NO REQUIREMENT TO DEVELOP TREATMENT PLANS. NO REQUIREMENTS TO PROTECT THE PUBLIC AGAINST BUPRENORPHINE BEING DIVERTED FOR ILLICIT USE.”

Congressman Tim Murphy
Chairman, Subcommittee on Oversight & Investigations,
House Committee on Energy & Commerce
March 26, 2015
THE FEARS

- Patient Misbehavior
  - Diversion
  - Accidental Ingestion
    - Especially Children
  - Accidental Death
- Physician Misbehavior
  - Poor Record Keeping
  - Exceeding the Patient Limits
  - Predatory Pricing of Services
  - No focus on Recovery without MAT
  - Medicaid/Medicare Fraud
- Buprenorphine “Clinics” without the regulations of opioid OTPs
Evidence is mounting that certain drugs used to treat heroin users are themselves being sold on the streets – and may even be a 'gateway' to heroin or opioid use. As some experts herald their value for treating addiction, others ask if the 'cure' is making things worse.

Elizabeth Barber
The Christian Science Monitor
May 30, 2014
Upper Peninsula Substance Enforcement Team (UPSET) arrested fourteen people in Escanaba Wednesday on drug charges.

All fourteen people are charged with felony delivery of buprenorphine. These arrests stemmed from multiple investigations conducted by UPSET into the sale and distribution of Buprenorphine. The investigation remains ongoing with additional arrests pending. An additional three people were also arrested on charges unrelated to these investigations.

Buprenorphine, also known as Suboxone/Subutex, is a prescribed medication used to battle drug addiction and is also used for pain management.

UPSET was assisted by Escanaba Public Safety, Delta County Sheriff Department, Delta County Prosecutor’s Office and the Michigan State Police.


All Buprenorphine | Buprenorphine-Naloxone

<table>
<thead>
<tr>
<th>Year</th>
<th>All Buprenorphine</th>
<th>Buprenorphine-Naloxone</th>
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<tbody>
<tr>
<td>2004</td>
<td>4,440</td>
<td>3,669</td>
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<td>2005</td>
<td>6,208</td>
<td>7,136</td>
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<td>2006</td>
<td>11,004</td>
<td>12,544</td>
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<td>2007</td>
<td>14,266</td>
<td>15,778</td>
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<td>2008</td>
<td>14,501</td>
<td>19,300</td>
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<td>2009</td>
<td>21,483</td>
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</tr>
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Note: The graph shows the number of emergency department visits related to buprenorphine and buprenorphine-naloxone from 2004 to 2011.
Subutex (Buprenorphine) 8mg
$0.70 per pill
Subutex (Buprenorphine) 8mg pills/tablets:
Subutex (Buprenorphine) treats moderate to severe chronic pain. This medicine is a narcotic analgesic. You can buy Subutex (Buprenorphine) 8mg tablets online without prescription (No RX) from Silkroad – Online Pharmacy.

http://silkroad-pharmacy.com/online-pharmacy/buy-subutex-8mg-online/

Silk Road was an online black market, best known as a platform for selling illegal drugs. As part of the Deep Web, it was operated as a Tor hidden service, such that online users were able to browse it anonymously and securely without potential traffic monitoring. It got busted by the feds.
“Suboxone, a popular and highly touted medicine designed to get people off opioids such as painkillers and heroin, is increasingly being abused, sold on the streets and inappropriately prescribed, according to doctors and drug control and law enforcement officials.”

Laura Unger, Reporter
The Courier-Journal [Kentucky]
07/05/2014
“The U.S. government lists 330 Kentucky physicians authorized to prescribe buprenorphine. A Courier-Journal analysis shows that 45, or 14 percent, have a history of discipline by the medical board.”

Laura Unger, Reporter
The Courier-Journal [Kentucky]
07/05/2014
"Gov. Steve Beshear, who has touted the state's pill mill crackdown, said, "Buprenorphine is a promising medication that has shown to be effective in the treatment of opioid-addicted people." But, he said, the state will pursue solutions to "ensure that buprenorphine is used appropriately."

"[T]he medical board is drafting regulations on Suboxone prescribing and aggressively investigating complaints against doctors. Law enforcement officials say they are pursuing cases against doctors and dealers — while working to ensure that Suboxone remains available for patients who truly need it."

Laura Unger, Reporter
The Courier-Journal [Kentucky]
07/05/2014
On the basis of 1513 surveillance cases, 9490 estimated emergency hospitalizations (95% confidence interval: 6420-12,560) occurred annually in the United States for unsupervised prescription medication ingestions among children aged <6 years from 2007 through 2011; 75.4% involved 1- or 2-year old children.

Opioids (17.6%) and benzodiazepines (10.1%) were the most commonly implicated medication classes. The most commonly implicated active ingredients were buprenorphine (7.7%) and clonidine (7.4%).

Accounting for the number of unique patients who received dispensed prescriptions, the hospitalization rate for unsupervised ingestion of buprenorphine products was significantly higher than rates for all other commonly implicated medications and 97-fold higher than the rate for oxycodone products (200.1 vs 2.1 hospitalizations per 100,000 unique patients).

Lovegrove MC et al
Pediatrics, 134:4e 1009-e1016 (2014)
A physician in the State of Florida failed to maintain adequate records of 47 Subutex and Suboxone bottles he purchased and failed to maintain adequate records of the Subutex and Suboxone tablets he dispensed between February of 2007 and October of 2009. This violated several Florida statutes and rules. The physician described himself as one who assists in the detoxification and rehabilitation of patients who have opiate dependencies.

The Florida State Surgeon General requested that the physician suffer one or more of the following: the permanent revocation or suspension of his license, a restriction on his practice, the imposition of an administrative fine, issuance of a reprimand, being put on probation, corrective action, refund of fees billed or collected, remedial education or some other action that the Medical Board deemed appropriate.
INDIANAPOLIS - Federal agents and local police arrested four Indiana doctors for allegedly handing out prescription drugs for cash. Investigators accuse them of peddling powerful prescription drugs.

The bust includes four doctors, several clinic employees and an attorney, with agents targeting clinics and homes in Hamilton, Howard, Wayne and Delaware Counties. The 11 people facing charges are accused of taking part in an illegal drug operation that was allegedly based in an office at 23 E. Main St. in Carmel.

Authorities say the individuals were selling prescriptions for Suboxone in Carmel and at four other sites. Suboxone is a prescription medicine used for maintenance treatment of opioid dependence, used in conjunction with counseling. The Suboxone treatment program's goal is to wean addicts off opiates.

Maj. Aaron Dietz with the Hamilton Boone County Drug Task Force says the investigation was prompted by complaints from residents. He said patients received no medical exam, no physical or mental evaluation and were not asked to write any medical history.

A Clarion psychiatrist who operated four Suboxone maintenance clinics in northwestern Pennsylvania was arrested Tuesday on charges of illegally prescribing and distributing pills in exchange for money and sex.

Attorney General Kathleen Kane identified Dr. Thomas Radecki, 67, as the largest purchaser and distributor of Subutex in the United States.

Subutex and Suboxone are commonly used to treat opiate dependency. The investigation resulted in the closure of his clinics in Clarion, Venango, Mc-Kean and Clearfield counties.

A statewide investigating grand jury recommended the criminal charges, Kane said. According to the presentment, Radecki operated the clinics under the name Doctors and Lawyers for a Drug Free Youth to dispense and sell controlled substances, including Subutex, Adderall and Ritalin, drugs commonly used to treat symptoms of attention deficit hyperactivity disorder.

08/23/2013

In the May 7, 2013 issue of the New Republic, Graeme Wood wrote about an epidemic of buprenorphine abuse in the Republic of Georgia, the former Soviet Union country in Europe. Wood discussed how buprenorphine led an upsurge in opioid addiction which resulted in 1 in 20 Georgians affected. The brand name of the product used was Subutex or SUBU.

It was assumed that the buprenorphine in Georgia originated from France, where one tablet coast one euro at a pharmacy, which became 10 euros when sold on the street which could then be exported to Georgia where it would fetch 100 euros.

Georgia turned to draconian measures such as empowering police to toxicology screen anyone anytime for no reason. Sanctions for a positive urine ranged from a fine to incarceration. In 2007, 53,000 people were reported to have been stopped, with a third with urines positive for drugs.

With a radical strategy in place, by 2010, a buprenorphine epidemic that had started around 2000 had largely disappeared, with only a residual number of affected individuals.

http://www.newrepublic.com/article/113051/georgias-war-drugs-how-its-subutex-addiction-ended
ProPUBLICA’s Top Prescribers of Suboxone Under Medicare Part D

In 2012, there were 413,000 Medicare Part D Claims filed with CMS for a retail cost of $147 million.

<table>
<thead>
<tr>
<th>Provider Type</th>
<th>Claims</th>
<th>City</th>
<th>State</th>
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<tr>
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<td>2,583</td>
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<td>Psychiatry</td>
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<tr>
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<td>Carmel</td>
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<td>Family Medicine</td>
<td>861</td>
<td>Southgate</td>
<td>MI</td>
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<tr>
<td>Addiction Medicine</td>
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<td>Livonia</td>
<td>MI</td>
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<tr>
<td>Family Medicine</td>
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<td>Haleyville</td>
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<table>
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<tr>
<th>Provider Type</th>
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<tr>
<td>Emergency Medicine</td>
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<tr>
<td>Adult Medicine</td>
<td>671</td>
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<td>PA</td>
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<tr>
<td>Specialist</td>
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<td>Newark</td>
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<tr>
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<td>620</td>
<td>West Springfield</td>
<td>MA</td>
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</tbody>
</table>
CMS is Concerned
HAZARD, Ky.

Couch, 25 years old and one month sober, is one of thousands of young Appalachian drug users recently diagnosed with hepatitis C. Yet public health officials warn that it could get much worse.

Two-hundred miles north, Scott County, Indiana, is grappling with one of the worst American HIV outbreaks among injection drug users in decades. Kentucky, with the nation’s highest rate of acute hepatitis C, might be just a few dirty needles away from a similar catastrophe.
PART 5
BUPRENORPHINE

Background

Buprenorphine is recommended for the treatment of opioid use disorder. Buprenorphine relieves drug cravings without producing the euphoria or dangerous side effects of other opioids. In addition to its pharmacological properties, an important feature of buprenorphine is its ability to be prescribed in office-based treatment settings. The FDA approved buprenorphine in 2002, making it the first medication eligible to be prescribed by certified physicians through the Drug Addiction Treatment Act of 2000 (DATA 2000). Through DATA 2000, physicians may apply for waivers to prescribe certain narcotic Schedule III, IV, or V medications, including buprenorphine, from their office settings. This provision of the Act expands accessibility of community-based treatment options and mitigates the need to receive treatment through more specialized, and often less available, OTPs. However, buprenorphine may also be administered in an OTP setting with structure and administration requirements identical to those for methadone.
ASAM NATIONAL PRACTICE GUIDELINES: BUPRENORPHINE TOPICS

- FORMULATIONS OF BUPRENORPHINE
- PATIENT SELECTION & TREATMENT GOALS
- PRECAUTIONS
  - Alcohol or Sedative, Hypnotic or Anxiolytic Use
- COURSE OF TREATMENT
  - Induction
  - Dosing
  - Psychosocial Treatment
  - Monitoring Treatment
  - Length of Treatment
  - Switching Treatment Medications
    - Switching to Naltrexone
    - Switching to Methadone

DIVERSION:
- Clinicians should take steps to reduce the chance of diversion. Diversion has been reported with buprenorphine monotherapy and combination Buprenorphine/naloxone.
- Strategies to reduce the potential of diversion include: frequent office visits, urine drug testing including testing for buprenorphine and metabolites, observed dosing, and recall visits for pill counts.
- Patients receiving treatment with buprenorphine should be counseled to have adequate means to secure their medications to prevent theft. Unused medication should be disposed of safely.
There is no recommended time limit for treatment with buprenorphine. Buprenorphine taper and discontinuation is a slow process and close monitoring is recommended. Buprenorphine tapering is generally accomplished over several months. Patients and clinicians should not take the decision to terminate treatment with buprenorphine lightly. Factors associated with successful termination of treatment with buprenorphine are not well described but may include:

- Employment, engagement in mutual help programs, or involvement in other meaningful activities.
- Sustained abstinence from opioid and other drugs during treatment.
- Positive changes in the psychosocial environment.
- Evidence of additional psychosocial supports.
- Persistent engagement in treatment for ongoing monitoring past the point of medication discontinuation.
“Experts say abuse of addiction drug suboxone has dangerous consequences”

“Natalie Bollon, manager of community services for the Alcohol, Drug Addiction and Mental Health Services Board of Tuscarawas County, said illegal sales and trades of suboxone are a concern locally. In addition to preventing withdrawal symptoms, suboxone also blocks the receptors in the brain that give someone a high. If a heroin addict uses the prescription to hold them over until their next high, they are in danger of overdosing because it will take a larger amount of heroin to achieve a high, Bollon explained.”

“Oversight is in the hands of physicians. However, the number of doctors who dispense the medication is not known — and there are no licensing procedures that would allow state agencies to regulate them. “There isn’t a license or registration in place to regulate doctors or small groups of doctors who distribute that prescription — namely suboxone,” said Bill Schmidt, an attorney with the State Medical Board of Ohio’s investigative counsel.”

CantonRep.com, Nov. 22, 2014

http://www.cantonrep.com/article/20141122/NEWS/141129705
### Some States Limit Duration of Buprenorphine Treatment Under Medicaid

<table>
<thead>
<tr>
<th>State</th>
<th>Duration of Buprenorphine Treatment Under Medicaid</th>
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<tbody>
<tr>
<td>Arkansas</td>
<td>24 months</td>
</tr>
<tr>
<td>Illinois</td>
<td>12 months</td>
</tr>
<tr>
<td>Maine</td>
<td>24 months</td>
</tr>
<tr>
<td>Mississippi</td>
<td>24 months</td>
</tr>
<tr>
<td>Utah</td>
<td>36 months</td>
</tr>
<tr>
<td>Wyoming</td>
<td>24 months</td>
</tr>
</tbody>
</table>
1. The Problem of Heroin Use and Overdoses Demand a More concerted effort to provide MAT with buprenorphine
2. OTPs are not accessible
3. Current Reimbursement Policies Often Limit the Length of Treatment, while delaying access to treatment slots creating an administrative burden on physicians and treatment delays for patients
4. The problems of diversion, accidental ingestion and overdose are not restricted to buprenorphine
   • In fact, overdoses with buprenorphine are much less than with other prescription opioids and much less than with heroin
   • Accidental ingestion may result in a trip to the ED, but most often not fatal
5. The fear of mis-use should not be the reason to discourage a rational partial solution to a complex societal problem
Concerns about Increasing or Eliminating the Cap

• There is no evidence that increasing or eliminating the Cap will enhance access to care
  • The finding of Rosenblatt et al, in fact suggests that removing the cap would only concentrate care within the few practitioners already providing care, and let other physicians avoid their duty.
  • Many Physicians who have waivers for 30 patients are eligible for 100 patients, but choose not to expand
• Geographic access will not be enhanced unless strategies can be found to enhance interest
  • The minimum requirements to be eligible for a waiver can be easily met by most of the over 850,00 physicians who DO NOT have a waiver and who choose not to get one
• Buprenorphine “clinics” spawned by increasing or eliminating the caps would not have the federal and state regulatory controls that Opioid Treatment Programs have
  • Diversion would be stimulated
  • Quality of Care would be diminished
  • Recovery would not be promoted.
WHICH ARGUMENTS ARE TO BE THE MASTER?

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