Limitations on the number of patients that DATA 2000-waivered providers can treat with buprenorphine can seriously constrain the treatment capacity of prisons and jails and can compromise the integrity and outcomes of treatment of Opioid Use Disorder (OUD) in these settings. Patient limits will become more problematic as OUD treatment programs in prisons and jails increase in scale from pilot projects to treat the full complement of persons with OUD throughout the duration of incarceration. This brief illustrates steps prisons and jails can take to assure that prescribing capacity is optimized at all times, including temporary increases during qualified emergencies.

Changes in Patient Limits Over Time

Historically, the Drug Addiction Treatment Act of 2000 (DATA 2000) enabled physicians who met certain qualifications to treat either 30 or 100 patients with buprenorphine at any one time, and allowed physicians with 30-patient limits to increase to 100 patients after one year. The Comprehensive Addiction & Recovery Act of 2016 expanded buprenorphine prescribing to nurse practitioners and physician assistants who met certain criteria. In July 2016, the Substance Abuse and Mental Health Services Administration (SAMHSA) released its final rule on MAT for OUD, which allowed eligible physicians to request approval to treat up to 275 patients after prescribing at the 100-patient limit for one year. It also allows physicians with 100-patient limits who are not eligible for a 275-patient waiver to request a temporary increase to treat up to 275 patients for up to 6 months in an emergency situation. The SUPPORT Act of 2018 allowed for qualified practitioners (physicians and qualifying other practitioners) to treat up to 100 patients in their first year, rather than 30. Qualifications include holding board certification in addiction medicine or addiction psychiatry or providing MAT in a qualified practice setting (see page 3). A concise summary of this history can be found here. A narrative description of the final rule regarding the 275 patient limit can be found here.

On April 1, 2020, SAMHSA issued an email message notifying all qualified practitioners (defined below) who hold a DATA waiver at the 30 patient limit that they are potentially eligible to treat up to 100 patients in the first year if they meet certain criteria, and encouraging all DATA 2000 waivered providers to consider whether their limits could be increased. The criteria are described below.
Patient Limits in Prisons and Jails

Whether the patient limit for a provider is 30, 100, or 275, the limit applies to patients under treatment with any formulation of buprenorphine for OUD by that provider on a given day. In jails, populations move in and out of incarceration frequently. In prisons, inmates move from prisons to prison frequently, and the buprenorphine prescriber may change along with inmate movement. Prisons also temporarily release inmates to jail jurisdictions.

If a patient is provided buprenorphine at release, the number of days of medication provided counts toward that prescriber’s patient limit on those days. Likewise, if a jail or prison provider writes a prescription to be filled by the patient in the community after release, the number of days of that prescription counts toward that prescriber’s patient limit on those days.

For providers who practice in prisons or jails and in community settings, the patient limit applies to all patients receiving buprenorphine from that provider on a given day.

Where a prison or jail provider manages patients in detoxification with buprenorphine, those patients also count towards that provider’s patient limit.

In rare instances where prison or jail providers prescribe buprenorphine for pain management, those patients do not count toward that provider’s patient limit.

It is imperative that prisons and jails maintain an accurate count of the number of patients prescribed buprenorphine for OUD for each waivered provider every day, and to assure that no provider exceeds his/her daily limit. Providers practicing in both correctional and community settings will need additional measures to assure that limits are not exceeded.

Applying for a New DATA 2000 Waiver

Whether the applicant works in a prison or a jail, the following conditions apply. Limits are in effect unless a change request has been made.

<table>
<thead>
<tr>
<th>Provider Type Definitions</th>
<th>Patient Limit in First Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician without board certification in addiction medicine or addiction psychiatry</td>
<td>30</td>
</tr>
<tr>
<td><strong>Other Qualified Practitioners</strong> (nurse practitioners, physician assistants, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives)</td>
<td>30</td>
</tr>
<tr>
<td>Physician board certified in addiction medicine or addiction psychiatry</td>
<td>100</td>
</tr>
<tr>
<td>Physician and Other Qualified Practitioners practicing in a Qualified Practice Setting (described below)</td>
<td>100</td>
</tr>
</tbody>
</table>
Application to Begin Treatment with Buprenorphine while Waiting for Data 2000 Waiver Approval

Practitioners who have submitted application for a DATA 2000 Waiver can be given permission by SAMHSA to treat patients with buprenorphine in the interim, by submitting paperwork for each individual patient and meeting other requirements found here. While this carries an administrative burden, it is a viable option for prisons and jails to optimize OUD treatment.

What is a “Qualified Practice Setting?”

Permission to expand patient limits for physicians who are not board certified in addiction treatment and for Other Qualified Practitioners is available if the provider works in a “qualified practice setting,” defined as follows:

1. Provides professional coverage for patient medical emergencies during hours when the practice is closed.

2. Provides access to case management services for patients, including referral and follow-up services for programs that provide or financially support medical, behavioral, social, housing, employment, educational, or other related services.

3. Uses health information technology if it is already required in the practice setting.

4. Is registered for their state prescription drug monitoring program (PDMP) where operational and in accordance with federal and state law.

5. Accepts third-party payment for some services, though not necessarily for buprenorphine-related services and not necessarily all third-party payers.

In at least one instance, SAMHSA officials expressed an understanding that incarcerated persons prescribed buprenorphine for OUD are not reported to state PDMPs unless they leave incarceration with buprenorphine or a prescription for it, and that third parties are not billed for services while incarcerated. Therefore, those requirements did not apply to the correctional setting and it was deemed a Qualified Practice Setting.

Prisons and jails must make individual determinations as to whether their institutions meet the requirements of a Qualified Practice Setting and may need to reach out to SAMHSA for clarification.
Applying to Increase Limits on Existing Data 2000Waiver

Whether the applicant works in a prison or a jail, the following conditions apply.

<table>
<thead>
<tr>
<th>Increase</th>
<th>Who is Eligible</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>From 30 to 100 patients</td>
<td>Physician without board certification in addiction medicine or addiction psychiatry</td>
<td>After one year of 30 patient limit or working in a qualified practice setting</td>
</tr>
<tr>
<td></td>
<td>Other Qualified Practitioners</td>
<td>After one year of 30 patient limit or working in a qualified practice setting</td>
</tr>
<tr>
<td>From 100 to 275 patients</td>
<td>Physician board certified in addiction medicine or addiction psychiatry</td>
<td>After one year at 100 patient limit and must certify compliance with eight conditions</td>
</tr>
<tr>
<td></td>
<td>Physician and Other Qualified Practitioners practicing in a Qualified Practice Setting (described below)</td>
<td>After one year at 100 patient limit and must certify compliance with eight conditions</td>
</tr>
<tr>
<td>From 30 to 275 patients</td>
<td>Not allowed</td>
<td></td>
</tr>
</tbody>
</table>

Conditions for increasing patient limit to 275

Eligible practitioners who want to increase their patient limit to 275 must submit a completed Request for Patient Limit Increase form and a statement certifying that they meet the following conditions:

1. Adhere to nationally recognized evidence-based guidelines for treating patients with opioid use disorder.
2. Provide patients with necessary behavioral health services either directly or through a formal agreement with another entity.
3. Provide appropriate releases of information in accordance with federal and state laws and regulations to permit coordination of care with behavioral health, medical, and other practitioners.
4. Use patient data to inform improvement of outcomes.
5. Adhere to a diversion control plan to reduce the possibility of diversion of buprenorphine.
6. Have considered how to ensure continuous access in the event of an emergency situation.
7. Notify all patients above the 100-patient limit that they will no longer be able to provide Medication-Assisted Treatment (MAT) services using buprenorphine in
the event that their request for the higher patient limit is not renewed or the renewal request is denied, and will also make every effort to transfer patients to other treatment providers.

8. Practitioners must also provide any additional documentation to demonstrate compliance as requested by the Substance Abuse Mental Health Services Administration (SAMHSA).

Definitions of evidence-based practices, behavioral health services, diversion control plan, and continued access are in the document found here. Prisons and jails must make individual determinations as to whether their institutions meet these conditions and may need to reach out to SAMHSA for clarification.

Approvals for a 275 patient limit are in effect for three years unless changed by request in the interim. Renewals must be requested at least 90 days before expiration. Practitioners who have been approved for a 275 patient limit must adhere to strict annual reporting requirements. The report is normally due before the anniversary of the waiver approval date. If it is not received on time, SAMHSA will automatically rescind the 275 patient prescribing authority and the patient limit will return to 100 as previously authorized. Additionally, all patients under the provider’s care beyond the 100 patient limit must be notified of the reduced patient capacity and directed to alternative resources for treatment. A summary of the reporting requirements can be found here.

Applying for an Emergency Increase in Patient Limits
Practitioners with a current waiver to prescribe up to 100 patients and who are not otherwise eligible to treat up to 275 patients may request a temporary increase for up to 6 months to address emergency situations. Practitioners may be eligible for temporary patient limit increase in emergency situations even if they do not hold additional credentialing or practice in a qualified practice setting. Conditions for emergency increases are included in the reference “Understanding the Final Rule for Patient Limit if 275.”

An emergency situation is defined as any situation during which an existing substance use disorder system is overwhelmed or unable to meet the existing need for MAT as a direct consequence of a clear precipitating event. The precipitating event must have an abrupt onset, such as practitioner incapacity; a natural or human-caused disaster; or an outbreak associated with drug use. It must also result in significant death, injury, exposure to life-threatening circumstances, hardship, suffering, loss of property, or loss of community infrastructure.

A temporary emergency increase in patient limits may be supported by documentation of prisons or jails where large numbers of detainees have an OUD and associated overdoses and/or morbidity related to comorbid conditions, e.g. Hepatitis C.
To obtain the temporary increase, practitioners must provide documentation that:

- Describes the emergency situation in enough detail to allow a determination to be made
- Identifies a period, not longer than 6 months, in which the higher patient limit should apply
- Provides a rationale for the time requested
- Describes a plan to meet public and individual health needs of patients once the temporary approval expires

To the extent possible, before approving the temporary request, SAMHSA will consult with appropriate governmental authorities (such as the state opioid authority) to determine that the emergency situation justifies the immediate increase. If the temporary increase is approved, SAMHSA will notify the practitioner.

If the practitioner wants to extend the temporary approval, he or she must submit a request at least 30 days before the expiration and certify that the emergency situation is still taking place. Again, to the extent possible, SAMHSA will consult with appropriate governmental authorities to determine that the emergency situation justifies continuation of the increase.
References

Understanding the Final Rule for a Patient Limit of 275;
SAMHSA website Buprenorphine Information Center 866-287-2728:

SAMHSA Apply for A Practitioner Waiver:
https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/apply-for-practitioner-waiver

Buprenorphine Patient Limits Increased in First Year to 100 for Qualifying Practitioners:
https://mailchi.mp/58328dee1d46/buprenorphine-patient-limits-increased-in-first-year-to-100-for-qualifying-practitioners-1796717?e=5b4d49a6cf


Drug Addiction Treatment Act of 2000:
https://www.deadiversion.usdoj.gov/pubs/docs/dwp_buprenorphine.htm

Comprehensive Addiction & Recovery Act of 2016:

SUPPORT Act of 2018: Kaiser Family Foundation Issue Brief:


Substance Abuse and Mental Health Services Agency. Understanding the Final Rule for a Patient limit of 275:

Substance Abuse and Mental Health Services Agency. Buprenorphine Patient Limits Increased in First Year to 100 for Qualifying Practitioners:
https://mailchi.mp/58328dee1d46/buprenorphine-patient-limits-increased-in-first-year-to-100-for-qualifying-practitioners-1796717?e=5b4d49a6cf

Substance Abuse and Mental Health Services Agency: Applying for a Practitioner Waiver:
https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/apply-for-practitioner-waiver

American Society of Addiction Medicine. Summary of the Final Rule on Annual Reporting Requirements for Practitioners Authorized to Treat 275 Patients with Buprenorphine: