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Understanding the Buprenorphine Final Rule for a Patient Limit of 275

Jinhee Lee, PharmD

Center for Substance Abuse Treatment

Substance Abuse Mental Health Services Administration

U.S. Department of Health & Human Services

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Buprenorphine Patient Limits
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Disclosure Statement

- I have nothing to disclose.

Overview of Buprenorphine Final Rule

- 42 CFR Part 8, subpart A sets forth the general provisions of the rule
- Current subparts A, B, and C have changed to subparts B, C, D, respectively, and apply only to OTPs
- Subpart E is reserved
- Subpart F contains the final rule which increases the highest number of patients a practitioner can treat to 275

8.610 - Which practitioners are eligible for a patient limit of 275?

- To be eligible, practitioners must have had a waiver to treat up to 100 patients for at least one year and either:
 - Possess additional credentialing

OR

- Practice in a qualified practice setting

8.615 - What are the requirements to be eligible for the qualified practice setting pathway?

- Provide professional coverage for medical emergencies during hours when his or her practice is closed
- Ensure access to patient case-management services
- Use health information technology systems if it is already required in the practice setting
- Register for his or her state PDMP where operational and in accordance with applicable laws
- Ability to accept third-party payment for costs in providing health services

8.620 - What is the process to request a patient limit of 275?

Practitioners must complete the Request for Patient Limit Increase form and provide assurance that they will:

- 1) Adhere to nationally recognized evidence-based treatment guidelines
- 2) Provide patients with or connect patients to necessary behavioral health services
- 3) Provide appropriate releases of information to permit care coordination with behavioral health, medical, and other service practitioners
- 4) Use patient data to inform the improvement of outcomes

8.620 - What is the process to request a patient limit of 275? (cont)

- 5) Adhere to a diversion control plan to reduce the possibility of buprenorphine diversion
- 6) Develop a plan to assure continuous access in the event of an emergency situation
- 7) Notify all patients above the 100 patient limit that they will not be able to provide buprenorphine to them if higher patient limit is not renewed or renewal request is denied. Ensure that patients are transferred to another practitioner.

Definitions

Nationally recognized evidence-based guidelines

Documents produced by a national or international medical professional association, public health entity, or governmental body with the aim of ensuring the appropriate use of evidence to guide individual diagnostic and therapeutic clinical decisions.

Behavioral health services

Any non-pharmacological interventions carried out in a therapeutic context at an individual, family, or group level. Interventions may include structured, professionally administered interventions (e.g., cognitive behavior therapy or insight oriented psychotherapy) delivered in person, interventions delivered remotely via telemedicine shown in clinical trials to facilitate MAT outcomes, or non-professional interventions.

Definitions (cont)

Diversion Control Plan

Means a set of documented procedures that reduce the possibility that controlled substances will be transferred or used illicitly

Emergency Situation

Means that an existing State, tribal, or local system for substance use disorder services is overwhelmed or unable to meet the existing need for medication-assisted treatment as a direct consequence of a clear precipitating event. This precipitating event must have an abrupt onset, such as practitioner incapacity; natural or human-caused disaster; an outbreak associated with drug use; and result in significant death, injury, exposure to life-threatening circumstances, hardship, suffering, loss of property, or loss of community infrastructure.

8.625 - How will a Request for Patient Limit increase be processed?

- Not later than 45 days after the date on which SAMHSA receives a practitioner's initial or renewal Request for Patient Limit Increase, SAMHSA shall approve or deny the request.
- A practitioner's Request for Patient Limit Increase will be approved if the practitioner satisfies all applicable requirements.
- A practitioner's approval to treat up to 275 patients under this section will extend for a term not to exceed 3 years

8.625 - How will a Request for Patient Limit increase be processed? (cont)

SAMHSA may deny a practitioner's Request for Patient Limit Increase if SAMHSA determines that:

- The Request for Patient Limit Increase is deficient in any respect; or
- The practitioner has knowingly submitted false statements or made misrepresentations of fact in the practitioner's Request for Patient Limit Increase.

If SAMHSA denies a practitioner's Request for Patient Limit Increase (or renewal), SAMHSA shall notify the practitioner of the reasons for the denial.

8.630 – What must practitioners do in order to maintain their approval to treat up to 275 patients?

A practitioner whose Request for Patient Limit Increase is approved in accordance with § 8.625 shall maintain all eligibility requirements specified in § 8.610, and all attestations made in accordance with § 8.620(b), during the practitioner's 3-year approval term. Failure to do so may result in SAMHSA withdrawing its approval of a practitioner's Request for Patient Limit Increase.

8.640 – What is the process for renewing a practitioner's Request for Patient Limit Increase approval?

- Practitioners who intend to continue to treat up to 275 patients beyond their current 3 year approval term must submit a renewal Request for Patient Limit Increase at least 90 days before the expiration of their approval term.
- If SAMHSA does not reach a final decision on a renewal Request for Patient Limit Increase before the expiration of a practitioner's approval term, the practitioner's existing approval term will be deemed extended until SAMHSA reaches a final decision.

8.645 – What are the responsibilities of practitioners who do not submit a renewal or whose renewal request is denied?

Practitioners who are approved to treat up to 275 patients, but who do not renew their Request for Patient Limit Increase, or whose renewal request is denied, shall notify, under § 8.620(b)(7) in a time period specified by SAMHSA, all patients affected above the 100 patient limit, that the practitioner will no longer be able to provide MAT services using covered medications and make every effort to transfer patients to other addiction treatment

8.650 – Can SAMHSAs approval of a practitioner’s Request for Patient Limit Increase be suspended or revoked?

SAMHSA, at any time during a practitioner’s 3 year approval term, may suspend or revoke its approval of a practitioner's Request for Patient Limit Increase if it is determined that:

- Immediate action is necessary to protect public health or safety;
- The practitioner made misrepresentations in the practitioner's Request for Patient Limit Increase;
- The practitioner no longer satisfies the requirements of this subpart; or
- The practitioner has been found to have violated the CSA

8.655 – Can a practitioner request to temporarily treat up to 275 patients in emergency situations?

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 to treat up to 275 patients if the practitioner provides information and documentation that:

- Describes the emergency situation in sufficient detail so as to allow a determination to be made regarding whether the situation qualifies as an emergency situation as defined in § 8.2, and that provides a justification for an immediate increase in that practitioner's patient limit;
- Identifies a period of time, not longer than 6 months, in which the higher patient limit should apply, and provides a rationale for the period of time requested; and
- Describes an explicit and feasible plan to meet the public and individual health needs of the impacted persons once the practitioner's approval to treat up to 275 patients expires.

8.655 – Can a practitioner request to temporarily treat up to 275 patients in emergency situations? (cont)

Prior to taking action on a practitioner's request under this section, SAMHSA shall consult, to the extent practicable, with the appropriate governmental authorities in order to determine whether the emergency situation that a practitioner describes justifies an immediate increase in the higher patient limit.

If SAMHSA determines that a practitioner's request under this section should be granted, SAMHSA will notify the practitioner that his or her request has been approved. The period of such approval shall not exceed six months.

If a practitioner wishes to receive an extension of the approval period granted under this section, he or she must submit a request to SAMHSA at least 30 days before the expiration of the six month period, and certify that the emergency situation necessitating an increased patient limit continues.

For more Rule Information

Final Rule

<https://www.federalregister.gov/articles/2016/07/08/2016-16120/medication-assisted-treatment-for-opioid-use-disorders#h-87>

Supplemental Notice of Proposed Rulemaking

<https://www.federalregister.gov/articles/2016/07/08/2016-16069/medication-assisted-treatment-for-opioid-use-disorders-reporting-requirements>

- HHS seeks further comment on the same reporting requirements outlined in the Notice of Proposed Rulemaking
- Comment period closes August 8, 2016 at 5PM

New Request for Patient Increase Form

- Contact SAMHSA CSAT at info@buprenorphine.samhsa.gov to receive the form and guidance when available.



Thank you!

Jinhee Lee, PharmD
jinhee.lee@samhsa.hhs.gov

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