

# WHAT DOES RAISING THE BUPRENORPHINE CAP MEAN?



**ASAM** American Society of  
Addiction Medicine

# Corey Waller, MD, MS, FACEP, DFASAM

- ◆ Chair, Legislative Advocacy Committee, ASAM
- ◆ Senior Medical Director of Education and Policy at Camden Coalition of Healthcare Providers.
- ◆ No disclosures



# Overview

- ◆ Highlights of Final Rule by SAMHSA Representative
- ◆ Implications for ASAM Members
- ◆ Resources to Support Application
- ◆ Highlights of CARA
- ◆ Questions and Answers



# SAMHSA PRESENTATION DELIVERED BY CDR JINHEE LEE



CDR Jinhee Lee, PharmD  
Senior Public Health Advisor  
Division of Pharmacologic Therapies  
Center for Substance Abuse Treatment



**ASAM** American Society of  
Addiction Medicine

# Behavioral Health is Essential To Health



Prevention Works



Treatment is Effective



People Recover



# 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

ASAM and SAMHSA Webinar on  
Buprenorphine Patient Limits  
August 1-2, 2016



# 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)

## **Diversions 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](mailto:info@buprenorphine.samhsa.gov) to receive the form and guidance when available.



# Thank you!

Jinhee Lee, PharmD  
[jinhee.lee@samhsa.hhs.gov](mailto:jinhee.lee@samhsa.hhs.gov)



# Behavioral Health is Essential To Health



Prevention Works



Treatment is Effective



People Recover

# WHAT DOES RAISING THE BUPRENORPHINE CAP MEAN FOR ASAM MEMBERS?



**ASAM** American Society of  
Addiction Medicine

# Key Considerations

## Qualifications to Apply:

- ◆ Certified Addiction Specialists
- ◆ Qualified Practice Setting

## Attestations and Reporting:

- ◆ Adhere to national guidelines
- ◆ Provide behavioral health services or provide through an agreement
- ◆ Provide releases of information
- ◆ Use patient data to inform outcomes
- ◆ Adhere to diversion control plan
- ◆ Assure patient access in the event of a practitioner incapacity or an emergency
- ◆ Notify patients if renewal denied
- ◆ Submit annual reports



# Certified Addiction Specialists

- ◆ Current ABAM Diplomates:
  - ◆ Stay current with Transitional Maintenance of Certification (TMOC)
  - ◆ If eligible, sit for ABPM exam within Practice Pathway
  - ◆ More information available: [www.ABAM.net](http://www.ABAM.net)
- ◆ Other eligible physicians:
  - ◆ ASAM Certified physicians
  - ◆ Addiction Psychiatrists
  - ◆ AOAAM



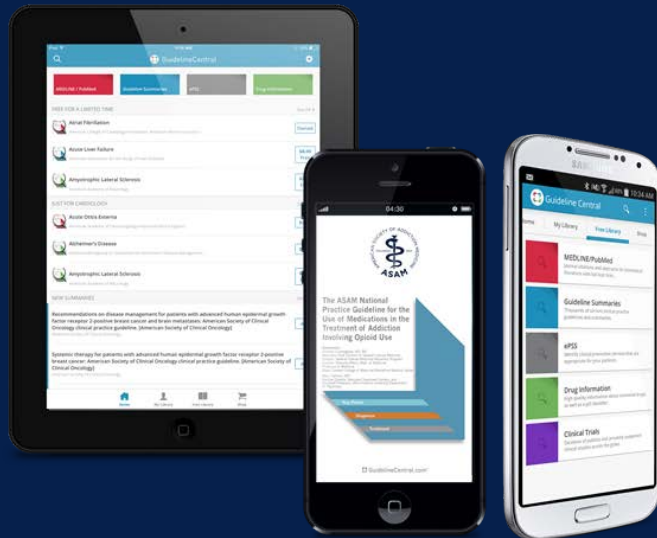
# Addiction Medicine Exam

- ◆ Addiction Medicine is now an ABMS multi-specialty subspecialty
- ◆ Currently, no exams are scheduled for 2016 or 2017
- ◆ Contact the American Board of Preventive Medicine (ABPM)
  - ◆ Ask them to schedule an exam
  - ◆ Sign up for email list for exam updates
- ◆ <https://www.theabpm.org/>



# ASAM National Guideline

- ◆ Addresses all FDA-approved medications
- ◆ Whole chapter on buprenorphine
- ◆ Additional resources available



ASAM  
THE **NATIONAL  
PRACTICE  
GUIDELINE**  
For the Use of Medications  
in the Treatment of  
Addiction Involving Opioid Use



**ASAM** American Society of  
Addiction Medicine

# Other Guideline Resources

- ◆ SAMHSA's Treatment Improvement Protocol 40: Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction
- ◆ The World Health Organization Guidelines for the Psychosocially Assisted Pharmacological Treatment of Opioid Dependence
- ◆ The Department of Veterans Affairs /Department of Defense/ Clinical Practice Guideline on Management of Substance Use Disorder
- ◆ The Federation of State Medical Boards' Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office



# Diversion Control Plan

- ◆ *"Set of documented procedures that reduce the possibility that controlled substances will be transferred or used illicitly"*
- ◆ ASAM's sample diversion control policy covers:
  - ◆ Prevention
  - ◆ Monitoring
  - ◆ Responding to diversion
  - ◆ Sample treatment plan





# Annual Reporting Requirements

- ◆ Proposed requirements open to comment by Aug 8:
  - ◆ Average monthly caseload
  - ◆ Percent of patients receiving psychosocial services
  - ◆ Percent of patients with PDMP check in past month
  - ◆ Number of patients who “completed” treatment or are no longer receiving buprenorphine
- ◆ ASAM will submit comments
- ◆ Submit comments here:  
<https://www.regulations.gov/comment?D=SAMHSA-2016-0001-0504>



# ASAM Resources for Attestation

- ◆ Sample diversion control policy
- ◆ Sample information release form
- ◆ National practice guideline resources:
  - ◆ Full guideline, summary & pocket guide
  - ◆ Phone app
  - ◆ Patient guide
- ◆ Plus more!

Available now at [www.ASAM.org/quality-practice/practice-resources](http://www.ASAM.org/quality-practice/practice-resources)



**ASAM** American Society of  
Addiction Medicine

# Other Resources

- ◆ PCSS-MAT project free resources and education:  
[www.pcssmat.org](http://www.pcssmat.org)
- ◆ SAMHSA resources
  - ◆ <http://www.samhsa.gov/medication-assisted-treatment>



# Comprehensive Addiction and Recovery Act (CARA)

- ◆ Expands prescribing to NPs and PAs
- ◆ Gives HHS Secretary authority
- ◆ HHS Secretary reviews limit every 3 years
- ◆ Contains requirements for 8-hour waiver training
- ◆ State authority to lower limit or enact additional requirements



# CARA Education Requirements

Education for NPs and PAs **must** include:

- ◆ Opioid maintenance and detoxification
- ◆ Clinical use of all FDA-approved drugs for MAT
- ◆ Patient assessment
- ◆ Treatment planning
- ◆ Psychosocial services
- ◆ Staff roles
- ◆ Diversion control

24 hours of training



# Special Member Alerts

- ◆ Members will receive alerts and information as available
- ◆ ASAM Weekly, Advocacy Alerts, other

*Connect. Advocate. Educate. Treat.*

The Voice of Addiction Medicine

ASAM is the leading professional society representing over 4,000 physicians, clinicians and associated professionals in the field of addiction medicine.

[Learn More >](#)



**ASAM** American Society of  
Addiction Medicine

# Frequently Asked Questions

1. Is the documentation required different, especially when visited by the DEA? Will having this increase require a regular DEA audit?
2. How will adherence to the diversion control plan and patient participation in behavioral health counseling be monitored/enforced?
3. How do you recommend waived physicians prepare for a transfer of care in the event that themselves or a nearby practitioner becomes incapable of prescribing to their patient limit?
4. What specifically fulfills the requirement for 24Hr emergency services?
5. What are the specifics of the insurance requirements by “qualified practice settings” applying for the increase?
6. What capability must an EMR have in a “qualified practice setting?”
7. What was the rationale behind the 275 number?
8. Can a waived physician prescribe to their 275 patients at two different locations?



# Thank You

- ◆ Please complete a short survey at the conclusion of this webinar
- ◆ Survey launches automatically
- ◆ Webinar recording will be available through ASAM's online [e-learning center](#).

Do you have follow-up questions?

Email: [advocacy@ASAM.org](mailto:advocacy@ASAM.org)

Phone: 301-656-3920



**ASAM** American Society of  
Addiction Medicine