

# The CARA & Buprenorphine Prescribing for APNs & PAs

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# Summary of the Comprehensive Addiction & Recovery Act (CARA)

Some Highlights

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# The CARA

- Signed into law on July 22, 2016
- Addresses the full continuum of care from primary prevention to recovery support.
- Includes criminal justice and law enforcement-related provisions

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### Section 107: Improving Access to Overdose Treatment

- Awards grants of up to \$200,000/year to:
  - Federally qualified health centers (FQHCs)
  - Opioid treatment programs (OTPs)
  - Any practitioner waived to prescribe buprenorphine
- Purpose:
  - To establish a naloxone co-prescription program
  - Train health care providers on naloxone co-prescribing
  - Purchase naloxone
  - Offset co-payments for naloxone
  - Establish protocols to connect patients who have experienced an overdose with appropriate treatment

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### Section 110: Opioid Overdose Reversal Medication Access & Education Grant Program

- Provide grants to states to implement strategies for pharmacists to dispense naloxone pursuant to a standing order and to develop naloxone training materials for the public

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### Section 301: Evidence-based Prescription Opioid & Heroin Treatment & Interventions

- Awards grants to state substance abuse agencies, local governments, or nonprofit organizations in areas with high rates of or rapid increases in heroin or other opioid use to expand the availability of medication-assisted treatment.
- Authorizes \$25 million for each fiscal year between 2017 and 2021

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## Section 303: MAT for Recovery from Addiction

- Expands prescribing privileges to NPs & PAs for 5 years (until October 1, 2023).
- NPs & PAs must complete 24 hours of training to be eligible for a waiver to prescribe and must be supervised by or work in collaboration with a qualifying physician if required by law
- The American Academy of Addiction Psychiatry (AAAP) in collaboration with APNA has free training totally on-line.
- Excludes from the patient limit those patients to whom medications are directly administered.

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## Patient-Prescribing Limit

- NPs & PAs are limited to 30 active patients at any given time.
- This restriction lasts for a minimum of one year.
- After one year, NPs & PAs can apply for a maximum of 100 active patients at any given time.

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## Risk Evaluation & Mitigation Strategy (REMS)

To ensure safe use

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### Measures That Must Be Documented – Pt. 1

- Verify the patient meets appropriate diagnostic criteria for opioid use disorder
- Discuss the risks (including misuse and abuse) and side effects associated with buprenorphine-containing products.
- Explain what patients should do if they experience side effects
- Provide induction doses under appropriate supervision
- Prescribe a limited amount of medication to the patient that will last until the next visit
- Explain how to safely store the medication out of reach of children

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### Measures That Must Be Documented – Pt. 2

- Schedule patient appointments commensurate with patient stability
  - weekly or more frequent visits recommended for the first month
- Consider "pill/film count" or other dose reconciliation method
- Assess whether the patient is receiving the counseling/psychosocial support considered necessary for treatment, and if not, encourage them to do so.
- Assess whether the patient is making progress toward treatment goals, including, as appropriate, urine toxicology testing.
- Continually assess appropriateness of maintenance dose.
- Continually assess whether or not benefits of treatment outweigh the risks.

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### Serious Risks: Communicate & Document

- Accidental or deliberate ingestion by a child may cause respiratory depression that can result in death. If a child is exposed to one of these products, medical attention should be sought immediately.
- It is extremely dangerous to self-administer non-prescribed benzodiazepines or other central nervous system depressants (including alcohol).
  - If controlled substances are prescribed, used only as directed.
- Never give these products to anyone else, even if he or she has the same signs and symptoms.
- Selling or giving away buprenorphine-containing products is against the law.

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## CAUTION

- If a patient continues to abuse various drugs or is unresponsive to treatment, including psychosocial intervention, it is important that you assess the need to refer the patient to a specialist and/or a more intensive behavioral treatment environment.

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## Buprenorphine Products

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## SUBUTEX Buprenorphine sublingual tablets

- Dose Strengths Available
  - 2 mg buprenorphine
  - 8 mg buprenorphine
- Route of Administration
  - Sublingual

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**SUBOXONE**  
Buprenorphine/Naloxone Sublingual Tablets

- Dose Strengths Available
  - 2 mg buprenorphine/0.5 mg naloxone
  - 8 mg buprenorphine/2 mg naloxone
- Route of Administration
  - Sublingual

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**SUBOXONE**  
Buprenorphine/Naloxone Sublingual Films

- Dose Strengths Available
  - 2 mg buprenorphine/0.5 mg naloxone
  - 4 mg buprenorphine/1 mg naloxone
  - 8 mg buprenorphine/2 mg naloxone
  - 12 mg buprenorphine/3 mg naloxone
- Route of Administration
  - Sublingual
  - Buccal
- Mfg: Indivior

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**ZUBSOLV**  
Buprenorphine/Naloxone Sublingual tablets

- Dose Strengths Available
  - 1.4 mg buprenorphine/0.36 mg naloxone
  - 2.9 mg buprenorphine/0.71 mg naloxone
  - 5.7 mg buprenorphine/1.4 mg naloxone
  - 8.6 mg buprenorphine/2.1 mg naloxone
  - 11.4 mg buprenorphine/2.9 mg naloxone
- Route of Administration
  - Sublingual
- Mfg: Orexo

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## BUNAVAIL

### Buprenorphine/Naloxone Buccal Films

- Dose Strengths Available
  - 1 mg buprenorphine/0.2 mg naloxone
  - 2.1 mg buprenorphine/0.3 mg naloxone
  - 4.2 mg buprenorphine/0.7 mg naloxone
  - 6.3 mg buprenorphine/1 mg naloxone
- Route of Administration
  - Buccal
- Mfg: BioDelivery Sciences, Int'l.

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## Prescribing Buprenorphine-Containing Products

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## Screening Patients for Outpatient Buprenorphine Treatment

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|--|---|
| <p><b>Pros</b></p> <ul style="list-style-type: none"> <li>• Compliant           <ul style="list-style-type: none"> <li>• Appointments</li> <li>• Medications for other medical/psychiatric conditions</li> </ul> </li> <li>• Employed</li> <li>• Limited legal problems</li> <li>• Intact family/support system</li> </ul> | <p><b>Cons</b></p> <ul style="list-style-type: none"> <li>• In MMT</li> <li>• Extensive legal problems</li> <li>• Non-compliant</li> <li>• Limited/no support</li> <li>• Extensive psychiatric problems</li> <li>• Multiple substance use problems</li> </ul> |
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### Selecting treatment modalities

- Consider:
  - Patient expectations of treatment
  - Patient goals
  - Stages of change
  - Current circumstances
  - Available resources
  - Past history of treatment outcome
  - Evidence regarding safety, efficacy and effectiveness
- Informed consent

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### Pre-Induction Protocol

- Prior to induction, consideration should be given to:
  - the type of opioid dependence (i.e., long- or short-acting opioid)
  - The time since last opioid use
  - The degree or level of opioid dependence
- Note: Gradual induction over several days led to a high rate of drop-out during the induction period.
  - It is recommended that an adequate maintenance dose, titrated to clinical effectiveness, should be achieved as rapidly as possible to prevent undue opioid withdrawal signs and symptoms

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### Initiating Treatment

- Day 1
  - A total induction dosage of the equivalent of 8mg of buprenorphine in Suboxone is recommended.
  - Start with an initial dose of 2 mg or 4 mg
  - Titrate upwards in 2mg or 4mg increments at approximately 2-hour intervals, under supervision to 8mg total based on the control of acute withdrawal signs
- Day 2
  - A single dose of up to 16 mg is recommended

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## Maintenance Dosing for Stabilized Patients

- The recommended target dose is:
  - 16 mg buprenorphine/4mg naloxone per day for Suboxone sublingual tablets and film including generic equivalents
  - 11.4 mg buprenorphine/2.8mg naloxone per day for Zubsolv SL tablets
  - 8.4 mg buprenorphine/1.4 mg naloxone per day for Bunavail buccal film
- Upper limit recommendations:
  - 24mg per day for Suboxone tablets and film
  - 17.1 mg per day for Zubsolv
  - 12.6 mg per day for Bunavail

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## Scheduling Office Visits

- During the induction period, it is recommended that the initial dose(s) be provided under supervision.
- No more than 1 to 2 days of product for take-home use be provided on each of the 2 or 3 visits during the first week of treatment
- Patients should be seen at reasonable intervals (e.g., at least weekly during the first month of treatment) based upon the individual circumstances of the patient.
- Provision of multiple refills is not advised early in treatment or without appropriate patient follow-up visits
- Periodic assessment is necessary to determine compliance with the dosing regimen, effectiveness of treatment plan, and overall patient assessment

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## Regular Follow-up

- Once a stable dosage has been achieved and toxicological tests do not indicate illicit drug use, less frequent follow-up visits may be appropriate.
- A once-monthly visit schedule may be reasonable.
  - Patient should be making progress toward the treatment objectives

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## Modification of Pharmacotherapy

- Evaluation of the following:
  - Absence of buprenorphine toxicity
  - Absence of medical or behavioral adverse effects
  - Responsible handling of buprenorphine-containing product by the patient
- Patient's compliance with all elements of the treatment plan, such as:
  - Recovery-oriented activities
  - Psychotherapy
  - Other psychosocial modalities
- Abstinence from illicit drug use including problematic alcohol and/or benzodiazepine use
- If treatment goals are not being achieved, reevaluate the appropriateness of continued treatment

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## Management of the Non-Adherent Patient

- Assess whether to refer the patient to a specialist and/or more intensive behavioral treatment environment.
- Decisions should be based on a treatment plan established and agreed upon with the patient at the beginning of treatment

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## Patients Who Want to Discontinue Treatment

- Patients should be advised not to change the dose of buprenorphine-containing products without consulting the prescriber.
- Patients seeking to discontinue treatment should be apprised of the potential to relapse to illicit drug use associated with discontinuation.
- If a dependent patient abruptly discontinues use of these products, an opioid abstinence or withdrawal syndrome may develop.
- If cessation of therapy is indicated, taper the dose, rather than abruptly discontinuing.
- The prescriber can provide a dose reduction schedule.

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## Preventing Diversion and Abuse

- Initiate treatment with supervised administration, progressing to unsupervised administration as the patient's clinical stability permits.
- Check the applicable state Prescription Drug Monitoring Programs to identify behaviors that may represent abuse.
- Have a plan to deal with patient requests for replacement of prescriptions or supplies of medication that are described as lost or stolen.
- Keep tight control of your prescription pads. Never leave them in the examination room, even inside a desk drawer. Never sign an incomplete prescription blank.
- Write all numbers (quantity and strength) in both numbers and letters – like you would write a personal check whenever possible.

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## Psychosocial Support

- Psychosocial counseling is an essential component of treatment for opioid dependence
- Patients should be strongly encouraged to obtain such support and counseling for safe and effective treatment.

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## Additional Information

- CSAT Buprenorphine Information Center website:
  - <http://buprenorphine.samhsa.gov>
- American Society of Addiction Medicine website:
  - [www.asam.org](http://www.asam.org)
- American Academy of addiction Psychiatry website:
  - [www.aaap.org](http://www.aaap.org)
- Physician Clinical Support System – Buprenorphine:
  - <http://pcssmat.org>

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That's All Folks!!!

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Questions & Comments



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