



Supporting Recovery from Opioid Addiction: Community Care Best Practice Guidelines for Buprenorphine and Suboxone®

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for Buprenorphine and Suboxone[®]**

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Community Care Behavioral Health Organization
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TABLE OF CONTENTS
Supporting Recovery from Opioid Addiction:
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	<u>Page</u>
I. Introduction	1
II. Background	3
III. Scope and Purpose	4
IV. Intended Audience	5
V. Limitations and Clarifications	5
VI. Guiding Principles for Medication-Assisted Treatment (MAT) for Opioid Addiction	6
VII. Organization of Best Practice Guidelines for Buprenorphine	8
VII.A Screening and Assessment to Determine Candidacy	8
VII.B Selection of Candidates for Buprenorphine Treatment	9
VII.C Treatment Agreement with Person in Recovery	9
VII.D Appropriate Dosing	10
VII.D.1 Induction Phase	10
VII.D.2 Stabilization Phase	11
VII.D.3 Maintenance Phase	11
VII.D.4 Tapering Off Phase	11
VIII. Concurrent Psychosocial Treatment and Recovery Supports	12
IX. Co-occurring Mental Health Treatment	13
X. Summary	14
<u>Addendums</u>	
A. Buprenorphine	A-1
What Exactly is Buprenorphine?	A-2
How Buprenorphine Works	A-4
B. Drug Addiction Treatment Act of 2000	B-1
Summary of Drug Addiction Treatment Act of 2000	B-2
Physician Application for Waiver Form	B-4
Exceptions to the DATA 2000 Waiver	B-6

TABLE OF CONTENTS

Addendums (continued)

C.	Opiate Withdrawal	C-1
	Clinical Opiate Withdrawal Scale	C-2
	DSM-IV Criteria for Opioid Withdrawal	C-3
	Precipitated Withdrawal	C-4
D.	Resources & Bibliography	D-1
	Community Care Behavioral Health Information Line	D-2
	Single County Authorities (SCAs) for PA Drug and Alcohol Programs	D-2
	Licensed PA Substance Use Treatment Centers	D-2
	PA Medicaid (HealthChoices) Physical Health Plan Contact Information	D-2
	Buprenorphine Treatment – A Training for Multidisciplinary Addiction Professionals (Videos)	D-2
	Center for Substance Abuse Treatment (CSAT)	D-2
	CSAT Buprenorphine Information Center	D-2
	National Alliance of Advocates for Buprenorphine Treatment	D-2
	Clinical Tools	D-3
	1. Buprenorphine Training and Practice Tools (BupPractice)	D-3
	2. Sample Forms and Patient Information	D-3
	3. Mental Health Screening Tools	D-3
	a. Mental Health Screening Form III	
	b. Mental Health Status Exam	
	c. Hamilton Rating Scale for Depression	
	d. Hamilton Anxiety Scale	
	e. Beck Depression & Anxiety Scales	
	f. PRIME-MD – Screening Questionnaire for Depressive Symptoms	
	4. Treatment Improvement Protocols (TIPS)	D-3
	5. Technical Assistance Publications (TAPS)	D-3
	6. Drug Interactions	D-4
	Evidence-Based Treatment and Promising Practices	D-4
	Patient Information	D-4
	Recovery Support Services	D-4
	Recovery Resources	D-5
	Diversion	D-6
	Buprenorphine Bibliography	D-6
	Publications Related to Recovery and Recovery-Oriented Systems of Care	D-6
E.	Collaboration Models	E-1
	Carbon, Monroe, Pike County Model	E-2
	Lewistown Model	E-6
	RASE Model	E-11

Community Care Behavioral Health Organization

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I. Introduction

Opioid addiction continues to be a significant public health problem in the United States. The National Survey on Drug Use and Health of 2010 (NSDUH 2010) reported an estimated 22.6 million Americans aged 12 or older (8.9% of this population) were current (past month) illicit drug users.¹ Of these, 5.1 million were non-medical users of pain relievers, with 2 million new initiates in the past year. Of the 22.6 million, 7.1 million met the criteria for substance abuse or dependence on illicit drugs.² An estimated 1.9 million of these individuals were dependent on or abusing pain relievers, with an estimated 357,000 abusing or dependent on heroin. This survey and others demonstrate that these estimates have remained relatively stable in recent years, as has the average age of first use, estimated to be 19.1 years (21 years for non-medical prescription drug abuse).

The Drug Abuse Warning Network (DAWN) 2009 findings on drug-related emergency room visits indicated that while emergency room visits for illicit drugs other than pharmaceuticals, alcohol and underage drinking were generally stable between 2004 and 2009, emergency room visits involving the misuse or abuse of pharmaceuticals increased by 98.4%.³ About half of these visits involved pain relievers, most commonly narcotic pain relievers.

The Centers for Disease Control (CDC) reported that in 2008 drug overdoses caused 36,450 deaths in this country, with opioid pain relievers accounting for 73.8% of these deaths, exceeding the number of deaths involving heroin and cocaine combined.⁴ Death rates in 2007 were roughly three times the rate of 1991, with prescription drugs accounting for most of the death rates since 1999. Pennsylvania is one of the top twelve states for drug overdose deaths.⁵ Those most at risk for overdose include:⁶

- People who obtain multiple controlled substance prescriptions from multiple providers.
- People who take high daily dosages of prescription painkillers and those who misuse multiple abuse-prone prescription drugs.
- Low-income people and those living in rural areas – people on Medicaid are prescribed painkillers at twice the rate of non-Medicaid patients and are at six times the risk of prescription painkiller overdose.
- People with a mental illness and those with a history of substance abuse.

The Treatment Episode Data Set (TEDS) report indicated that the 2009 admission rate to treatment programs for opiates other than heroin averaged 430% higher than in 1999, with some states reporting an increase as much as 657% higher.⁷ Admissions where heroin is the primary drug have been in an overall decline since 2002.

The NSDUH 2010 survey also noted that only 19% of those who needed treatment for an illicit drug use problem received it in a specialty facility in the past year, with 6.4 million not receiving

treatment for their abuse or dependency. Of this number, only 392,000 (6.1%) felt that they needed any treatment, with 51% making no effort to obtain treatment for the following reasons:

- Lack of health insurance or could not afford the cost of treatment (41.8%).
- Not ready to stop using (30.7%).
- Concern about negative perceptions by neighbors and the community (14.6%).
- Possible negative effect on job (12.4%).
- Not knowing where to go for treatment (12.1%).
- Able to handle the problem without treatment (9.6%).

In summary, the overall abuse and dependence rates for all illicit drugs, including non-medical use of pain relievers, has remained relatively flat in recent years. However, the number of individuals abusing or dependent on the non-medical use of prescription pain relievers has dramatically increased as a percentage of the overall total. This increase is a factor in admissions to treatment facilities, emergency room visits, and drug overdose deaths. It is also of note that the Medicaid population is at higher risk for overdose deaths, as are those with a mental illness or prior history of substance abuse dependence. Yet only a very small percentage of those who meet the criteria for substance abuse or dependency actually seek treatment for their illness. Studies have indicated that individuals with a drug addiction averaged seven years from initiation of regular drug use prior to entering treatment for the first time.⁸

We are challenged with increasing our success in addressing the serious problem of drug abuse and addiction through:

- Routine screenings of individuals in health care and other settings to identify and address risky behavior and identify early patterns of abuse and addiction.⁹
- Assertive outreach to those with patterns of abuse and addiction to encourage them to engage in a pathway of treatment and recovery.
- Increased access to evidence-based and promising practices, including Medication-Assisted Treatment (MAT) and recovery.
- Expansion of community-based recovery supports, including certified recovery specialists, recovery coaches, safe housing options, educational and vocational services, recreational and spiritual supports, and other services that support long-term recovery.

Medication-Assisted Treatment (MAT) and Recovery

Opioid addiction, along with other drug addiction, is now viewed as a chronic disease, requiring a community-based recovery management approach to increase the likelihood of long-term recovery. MAT is the use of medications, in combination with counseling and behavioral therapies, to provide a whole-patient approach to the treatment of substance use disorders. In the United States, MAT has proven to be effective in the treatment of opioid dependence with the U.S. Food and Drug Administration (FDA) approved drugs of methadone, naltrexone, and buprenorphine.

Research shows that when treating substance use disorders, a combination of medication and behavioral therapies is most successful. Additionally, community-based recovery supports, such

as mutual aid groups (e.g., 12-step programs); certified peer recovery specialists; recovery coaches; safe housing; and attention to educational, vocational, social, and spiritual needs, are important in recovery management. MAT is clinically driven with a focus on individualized patient care. As part of a comprehensive treatment program, MAT has been shown to:¹⁰

- Improve survival.
- Increase retention in treatment.
- Decrease illicit opiate use.
- Decrease hepatitis and HIV seroconversion.
- Decrease criminal activities.
- Increase employment.
- Improve birth outcomes with perinatal addicts.

While research indicates MAT as the most effective approach in treating chronic opioid addiction for many individuals,¹¹ the 2010 National Survey of Substance Abuse Treatment Services (N-SSATS) reported that only 25% of individuals admitted to treatment facilities were in methadone programs.¹² This survey also indicated that only 2% were in buprenorphine treatment, although this did not include physician-based practices. Little data is currently available on the extent of use of naltrexone and its long-acting formulation, Vivitrol®, for treatment of opioid-addicted individuals. Increased access to MAT options can improve recovery rates from addiction. For those with a mild to moderate opioid addiction,^{13, 14} buprenorphine may be the medication of choice (see **Addendum A**).

The Drug Abuse Treatment Act of 2000 (DATA 2000) and the FDA's approval of buprenorphine in 2002 for the treatment of opioid addiction have allowed for expansion of traditional opioid treatment programs beyond just the utilization of methadone. Most significantly, it has allowed treatment to occur in office-based settings by physicians who have met the waiver requirements under DATA 2000 (see **Addendum B**). This expansion provides the opportunity for more individuals to access treatment and potentially to mitigate the stigma associated with treatment at traditional drug treatment facilities.

II. Background

In January 2011, Community Care, with support from the Institute of Research, Education, and Training in Addictions (IRETA), developed clinical guidelines for the use of buprenorphine in the treatment of opioid addiction designed to improve the quality of treatment for persons in recovery (PIR). These guidelines were released in a report titled *Best Practices in the Use of Buprenorphine: Final Expert Panel Report Prepared for Community Care Behavioral Health Organization*.¹⁵ Additionally, several other best practice guidelines for buprenorphine have been published, including ones from the Center for Substance Abuse Treatment (CSAT).^{16, 17, 18} The best practice guidelines included herein address new questions including the use of evidence-based treatment (EBT) services and how MAT can fit within the context of Recovery-Oriented Systems of Care (ROSC).

The development of the expert panel report involved a unique expert panel methodology — the

RAND/UCLA Appropriateness Method (RAM).¹⁹ The project included a comprehensive review of the literature on buprenorphine and best practice clinical guidelines, the development of proposed guidelines, and ratings by the expert panel. The expert panel report was issued based on a consensus of guidelines deemed appropriate for inclusion.

The present document incorporates the results of the above initiative, additional research, and stakeholder input, including that of providers, members, counties, and the Behavioral Health Alliance of Rural Pennsylvania (BHARP) — Buprenorphine Workgroup, into a final product that will serve to guide clinicians, members, family members, and agencies in the Community Care treatment provider network.

III. Scope and Purpose

The best practice guidelines herein encompass the following processes:

- Screening, assessing, provision, and discontinuation of buprenorphine and Suboxone®.
- Screening, assessing, and concurrent provision of the appropriate psychosocial treatment utilizing best practice approaches.
- Screening, assessing, and concurrent addressing of co-occurring mental health issues.
- Provision of a menu of community-based recovery support and wellness services, and activities as necessary to enhance and support recovery.

It is important to understand the terminology used in this document. The commonly accepted definition of clinical practice guidelines is “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”²⁰ Clinical protocols can be seen as more specific than guidelines. The phrase “best practice guidelines,” however, generally refers to a combination of both clinical and non-clinical guidelines. The term “guidelines” refers to recommendations based on a consensus of what is highly recommended.

With pending healthcare reform, it is important to pay even more attention to the utilization of EBT and recovery approaches for MAT including methadone and to attend to fidelity issues associated with EBT. The development of the guidelines herein will serve to:²¹

- “[d]escribe appropriate care based on the best available scientific evidence and broad consensus;
- [r]educe inappropriate variation in practice;
- [p]rovide a more rational basis for referral;
- [p]rovide a focus for continuing education;
- [p]romote efficient use of resources;
- [a]ct as focus for quality control, including audit; [and]
- [h]ighlight shortcomings of existing literature and suggest appropriate future research.”

The purpose of this document is to convey a gold standard of treatment and recovery in the use of buprenorphine that is based in science, person-centered, person-driven and focused on long-term recovery within the context of Recovery-Oriented Systems of Care (ROSC).²²

IV. Intended Audience

These best practice guidelines are issued to guide all clinicians, agencies, and systems in the Community Care treatment and recovery network. The intent is to educate, improve access to care, promote safe and quality prescribing, and promote quality treatment and recovery practices overall. Specifically, these guidelines are for the following:

- Physicians and other authorized prescribers who are prescribing buprenorphine/Suboxone® and/or are otherwise treating a member addicted to opioids who may be a candidate for or is already receiving this medication.
- Physicians and other authorized providers who may not be prescribing, but are referring a member for treatment with buprenorphine/Suboxone®.
- Other clinicians and individuals in the health care, behavioral health care, and helping professions who may be screening, assessing, and/or providing treatment and recovery supports to members.

These guidelines shall also serve to inform and support PIRs and their families, thereby reflecting the principles of recovery²³ and focusing on wellness.

V. Limitations and Clarifications

These guidelines are not intended to supplant any requirement or obligation of law, licensure, accreditation, or certification. Nor are they to be used in place of sound clinical judgment as may be applied to address the unique needs of PIRs.

These guidelines supplement these SAMHSA publications:

- Treatment Improvement Protocol (TIP) 40, *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*.
- Technical Assistance Publication (TAP) 30, *Buprenorphine: A Guide for Nurses*.
- Treatment Improvement Protocol (TIP) 43, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*.

In addition, these guidelines supplement the *Model Policy Guidelines for Opioid Addiction Treatment in the Medical Office*, adopted as policy by the House of Delegates of the Federation of State Medical Boards of the United States, Inc., April 2002.

VI. Guiding Principles for Medication-Assisted Treatment (MAT) for Opioid Addiction

The following buprenorphine best practice guidelines are grounded in 11 guiding principles²⁴ that also serve as the anchor for best practice guidelines for MAT utilizing methadone and naltrexone.

1. An individual can be considered a Person in Recovery (PIR) if free from other drugs and non-prescribed medications while participating in MAT (now often referred to as Medication-Assisted Recovery [MAR]). While abstinence is considered the safest approach for those with substance use disorders, MAT encompasses evidence-based approaches that are proven to help certain individuals initiate or sustain recovery. These principles acknowledge that recovery is most likely to occur within the context of self-directed care and acknowledge individuals' rights to "define their own life goals and design their unique path(s)" to long-term recovery.²⁵
2. PIRs are to be fully informed about substance use disorder (SUD) treatment options (as evidenced by documentation in the medical/clinical record), including FDA approved MATs, such as methadone, buprenorphine, and naltrexone, at all levels of care. For programs that do not have MAT available, appropriate referral should be made and care coordinated for the PIR.²⁶
3. PIRs who are appropriate for and choose an MAT should be offered and provided the appropriate level of SUD treatment (in Pennsylvania, this determination is based upon the Pennsylvania Client Placement Criteria [PCPC]²⁷ and individual PIR needs) (as evidenced by documentation in the medical/clinical record). For programs that do not have the appropriate level of care available, appropriate referral should be made and care coordinated for the PIR.²⁸
4. MATs are to be provided in the context of a menu of services available to PIRs. This should include concurrently attending to physical and mental health disorders, as well as to all presenting SUDs. Psychosocial care should be provided and staged according to the individual needs of the PIR.²⁹
5. A PIR receiving MAT and presenting with acute pain or chronic non-cancer pain (CNCP) should be provided best practice pain management approaches³⁰ only in the context of collaboration between the PIR's primary care physician (PCP), pain clinician, and MAT prescriber.

6. Extreme caution should be used when PIRs receiving opioid agonist or partial agonist therapy use benzodiazepines or other pharmaceutical products that might put them at risk for overdose and death. Use of concomitant benzodiazepines should include documentation of informed consent regarding the risk of overdose and death.

7. As there are medical risks and other safety issues associated with any MAT, evidence-based tools and best practices should be utilized in concert with sound clinical judgment during the screening, assessment, and induction processes and throughout the duration of MAT, attending to elimination or reduction of risk.

8. Community-based recovery support services (RSSs), such as certified recovery specialists, recovery coaches, safe housing options, educational and vocational services, recreational and spiritual supports, and other services that support continued recovery, are essential components of care to ensure long-term recovery. RSSs, or other recovery-focused clinical and supportive services, should be made available to PIRs while involved in MAT – either directly or through referral.

9. Each PIR should be supported in the development of a recovery plan attending to the four dimensions of wellness and recovery:

Health: Overcoming or managing one’s disease(s), as well as living in a physically and emotionally healthy way.

Home: A stable and safe place to live.

Purpose: Meaningful daily activities, such as a job, school, volunteerism, family caretaking or creative endeavors, and the independence, income, and resources to participate in society.

Community: Relationships and social networks that provide support, friendship, love, and hope.

10. Prescribing physicians should be encouraged to continue their medical education regarding the use of MAT and to consult specialists certified by the American Board of Addiction Medicine or certified in addiction psychiatry by the American Board of Psychiatry and Neurology.

11. MAT guiding principles and practice guidelines should change as advanced scientific evidence becomes available. Community Care’s Guiding Principles and Best Practice Guidelines will be updated as necessary.

VII. Organization of Best Practice Guidelines for Buprenorphine

These guidelines are organized under the following categories:

- VII.A.** Screening and Assessment to Determine Candidacy
- VII.B.** Selection of Candidates for Buprenorphine Treatment
- VII.C.** Treatment Agreement with Person in Recovery (PIR)
- VII.D.** Appropriate Dosing—Induction, Stabilization, Maintenance, and Tapering Off
- VII.E.** Concurrent Psychosocial Treatment and Recovery Supports
- VII.F.** Co-occurring Mental Health Treatment

VII.A. Screening and Assessment to Determine Candidacy

The practitioner/prescriber will conduct an initial screen and assessment to determine the appropriateness of MAT for the PIR and, specifically, to determine if buprenorphine is the appropriate medication. Buprenorphine is recommended for consideration with individuals who have a moderate to mild opioid addiction severity.³¹ In the case where methadone treatment is not available, buprenorphine may be worth considering for those with severe to moderate addiction severity.

Prescribers are challenged to assess the level of addiction severity, as well as the psychosocial needs and other characteristics of each PIR, in order to identify the best MAT approach at the time the individual presents for treatment and continually as this person progresses in recovery. Licensed substance abuse intake and treatment centers and, in Pennsylvania, Single County Authorities (SCAs) can assist with determining the level of severity of addiction (see **Addendum D-2**).

Based on the consensus panel review and subsequent review of other consensus initiatives, the screening and assessment process should minimally:

1. Determine opioid dependence by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (Text Revision) (DSM-IV-TR) standards.³²
2. Assess psychiatric history with attention paid to current compliance with medication.
3. Assess medical history with attention paid to liver, cardiac and respiratory status, medications, and seizures.
4. Assess pregnancy status. For pregnant women, it is recommended that a comprehensive assessment be made to determine the appropriateness of buprenorphine vs. methadone treatment. If a pregnant woman is found to be appropriate for buprenorphine, then monotherapy (without a naloxone additive as present in Suboxone®) is recommended. Pregnancy testing should be considered as may be necessary throughout the treatment process.
5. Assess psychosocial and recovery supports, such as employment, family, safe and stable housing, mutual-aid support groups, recovery coaches, and certified recovery specialists.
6. Assess substance use history and current substance use, including alcohol and non-prescribed use of methadone, buprenorphine, and benzodiazepines.
7. Assess substance treatment history, including previous treatment episodes with buprenorphine and/or methadone.

8. Assess for current opioid agonist treatment or current non-prescribed use by conducting a witnessed urine screen (e.g., methadone, buprenorphine, and benzodiazepines).
9. Assess withdrawal status.
10. Assess addiction severity.
11. Assess potential treatment needs in relation to the physician's ability to accommodate those needs (e.g., intensive monitoring and interactions with legal system, employers, and others).
12. Assess pain.

Sample screening and assessments tools are referenced in **Addendum D-2, 3**.

VII.B. Selection of Candidates for Buprenorphine Treatment

Buprenorphine should be accessible and persons in recovery (PIRs) with less than ideal characteristics should not be automatically precluded from treatment. Good candidates include:

1. Individuals that have current opioid dependence that is moderate to mild in nature.³³
2. Individuals currently on methadone unable and/or unwilling to receive treatment from a methadone clinic.
3. Individuals that have not had prior adverse reactions to buprenorphine.
4. Individuals that have adequate psychosocial and recovery supports.
5. Individuals that are age 16 and above. The safety and effectiveness of buprenorphine in PIRs below the age of 16 have not been established. Buprenorphine should be administered with caution to elderly or debilitated patients.
6. Individuals that do not have a co-occurring mental health disorder or have a co-occurring disorder that is stable.
7. Individuals that are not suicidal.
8. Pregnant women may be good candidates.
9. Individuals that are expected to be adherent with treatment plans.
10. Individuals that are not dependent on central nervous system (CNS) depressants, including benzodiazepines and alcohol.
11. Individuals that are interested in and motivated for treatment.

VII.C. Treatment Agreement with Person in Recovery (PIR)

A written agreement with the PIR is strongly advised to communicate all understandings and instructions related to buprenorphine treatment. Sample agreements are available from the Buprenorphine Training and Practice Tools website, www.buppractice.com. This contract should, at minimum, address:

1. Voluntary participation in MAT after review of other treatment options and review of risks and potential side effects of this medication.
2. Pregnancy — patients must agree to notify prescribing physician if they are or plan to become pregnant.
3. A recommendation that the PIR inform their PCP and other prescribers of their participation in MAT.
4. Use of other medications only after review with the buprenorphine prescribing physician.
5. Avoidance of all use of alcohol and illicit drugs.

6. Use of buprenorphine only as prescribed.
7. Adherence to all scheduled appointments.
8. Adherence to required pill counts and drug tests.
9. Adherence to counseling and other referrals as recommended, including recovery support services.
10. Any evidence of intoxication at appointments may lead to termination of treatment with buprenorphine.
11. Understanding of addiction recovery pathways and relapse prevention strategies.
12. Any evidence of diversion may lead to termination of treatment with buprenorphine.
13. The PIR agrees to safely store the buprenorphine.
14. Review of conditions for termination and contingencies for treatment following termination.

VII.D. Appropriate Dosing—Induction, Stabilization, Maintenance, and Tapering Off

Dosing protocols are included in TIP 40 and TAP 30 and are referenced in the Suboxone® literature and other institutional protocols. Dosing is specific to the individual and the effective management of the individual’s cravings and withdrawal symptoms. Although our consensus process did not result in a specific dose or range recommendation, the majority thought dosing up to 16 mg was adequate for most patients. Generally, effective treatment can be accomplished within the 8-24 mg daily dosing range,³⁴ and it appears that over time, the daily dosing can be reduced without a loss of clinical effectiveness.³⁵

PCPs and other clinicians treating Community Care members with buprenorphine may call toll-free 1-866-484-7668 to speak with a Community Care psychiatrist about the clinical guidelines, effects, and side effects of buprenorphine.

Preauthorization requirements for individuals vary between Medicaid provider systems and other funding sources. Contact the member’s physical health plan for specific information about pre-authorization and other requirements relating to the prescribing of buprenorphine and the provision of psychosocial services for Community Care members.

VII.D.1 - Induction Phase

This phase typically has a one-week duration. Guidelines for this phase include:

1. Ensuring that the patient is experiencing objective signs of withdrawal. This can be from 6 to 12 hours (see **Addendum C**).
2. Minimizing the chance of precipitated withdrawal (see **Addendum C-4**).
3. The day 2 maximum dose is usually between 8 and 16 mg.
4. Induction for patients who have been in methadone treatment should be managed by experienced physicians only. Additional guidelines for this population include:
 - i. In coordination with the methadone program, the methadone dose should be gradually tapered to 30 mg per day and maintained at this dose (or lower) for 5-7 days.
 - ii. The patient should then abstain from any methadone for 48-72 hours prior to initiating buprenorphine.
 - iii. The patient should have clear objective signs of opiate withdrawal prior to receiving

buprenorphine.

5. **Use of buprenorphine in populations who are non-opioid tolerant** (These patients have a history of opioid dependence, are not currently using opioids, have a high risk of relapse due to recent release from controlled environment, and are seeking treatment.)
 - i. Initiation of treatment with no more than 2 mg dose daily.
 - ii. The dose should be increased slowly, by increments of no more than 2 mg every 5-7 days. This may vary, depending on the amount of time since the last use of an opioid.
6. **Use of buprenorphine in individuals who are using illicit buprenorphine at time of presentation** (These patients may not be in withdrawal as they are using Suboxone® to help manage their withdrawal on their own.)
 - i. Assess the amount and frequency with which the patient is using illicit Suboxone®. Many patients using Suboxone® in this way are only using whole tablets and have not tried intermediate doses of Suboxone®, such as 12 mg.
 - ii. Perform a rapid buprenorphine test to assess for the presence of buprenorphine in the urine.
 - iii. For these individuals, it is generally recommended to start at 8-12 mg of Suboxone® on the first day. Urine screens to detect alcohol and other drugs of abuse and the presence of the buprenorphine metabolite should be conducted weekly.

VII.D.2 - Stabilization Phase

This phase will usually have a one- to two-month duration and begins when the person in recovery (PIR) is experiencing no withdrawal symptoms, has minimal or no side effects, and minimal cravings. The following guidelines apply during this phase:

1. Adjust dose (as needed) in no more than 2-4 mg increments per week.
2. A daily dose has been established when the patient is not using illicit opioids, withdrawal symptoms are not present, and the patient is not experiencing cravings.
3. An alternate dosing schedule may be considered when observed dosing is necessary and the patient is not able to come every day: Two or three times a week or every two, three, or four days. Suggest dividing weekly dose by the number of days of dosing,³⁶ double dose for alternate day dosing, or triple for every three-day dosing.³⁷
4. Urine screens to detect alcohol and other drugs of abuse and the presence of the buprenorphine metabolite should be conducted weekly.
5. Consider on-site dispensing or observed taking of medication until the individual has a negative drug screen.

VII.D.3 - Maintenance Phase

This phase can last up to 18-24 months or more, depending on the individual.

1. After a period of time, which may vary with each patient but should reflect compliance with treatment, a prescription for up to 30 days may be written. Month-long prescriptions should be contingent on a patient's biopsychosocial stability, as well as urine screen results.
2. Urine screens to detect alcohol and other drugs of abuse and the presence of the buprenorphine metabolite should be conducted biweekly or monthly.

VII.D.4 - Tapering Off Phase

The duration of buprenorphine treatment should be individualized to meet the individual needs of each patient.

Before discontinuing buprenorphine, patients must:

1. Express a desire to discontinue.
2. Have stable housing and income.
3. Have adequate psychosocial and recovery support.
4. Agree to conditions for termination and contingencies for treatment and recovery support outlined in the treatment agreement.

VIII. Concurrent Psychosocial Treatment and Recovery Supports

MAT has the best outcomes when combined with psychosocial counseling and recovery support services. Effective buprenorphine treatment should include a psychosocial component in the induction, stabilization phases and, optionally, in the maintenance phase. Some funding sources, including the Pennsylvania Departments of Welfare and Drug and Alcohol Programs, require the individual to be engaged in psychosocial treatment while medicated with buprenorphine. Additionally, non-clinical recovery support services can increase the opportunity for long-term recovery in the community (see **Addendum D-4, 5**).

For information about referral sources for assessment or treatment for an SUD, contact the Community Care Provider Line toll-free at 1-888-251-2224. For non-Community Care members, contact the local SCA for substance abuse programming. The SCA can provide information regarding assessment and treatment sites, specialty case management, and recovery support services (see **Addendum D-2**).

Models of collaboration to enhance treatment outcomes that include partnerships with substance abuse treatment agencies, case management services, and recovery community support services are referenced in **Addendum E**. One model is a partnership between the SCA for Carbon, Monroe, and Pike counties and area physicians. This partnership enables the SCA and physicians to provide assessment, case management services, psychosocial treatment, funding for the buprenorphine, and coordinated care. The buprenorphine coordinator/case manager also monitors compliance (see **Addendum E-2**). The Lewistown model is a collaboration between a hospital (i.e., a program coordinator), a family practice clinic (i.e., physicians), and a counseling center, with shared funding for program components (see **Addendum E-6**). The Recovery, Advocacy, Service, Empowerment (RASE) Buprenorphine Coordinator Program is a unique peer recovery specialist-supported approach (see **Addendum E-11**).

Guidelines regarding concurrent psychosocial treatment and recovery supports include:

1. Patients receiving buprenorphine should receive simultaneous psychosocial counseling at the appropriate level of care according to PCPC recommendations.³⁸ Pennsylvania-licensed substance abuse treatment centers in the Community Care provider network can assist with this

- determination, as can a number of SCAs.
2. Physicians should establish linkages with a variety of psychosocial supports and be able to refer PIR to qualified providers.
 3. Patients starting buprenorphine should receive an evidence-based psychosocial treatment tailored to their needs. Effective treatment approaches include cognitive behavioral therapies, contingency management, relapse prevention training, and motivational interviewing. Information about evidence-based and promising practice approaches is referenced in **Addendum D-3**.
 4. Patients should receive weekly psychosocial therapy appointments during the stabilization phase.
 5. Early in treatment, patients should be contacted if the physician is aware that they are noncompliant with psychosocial therapy.
 6. During the maintenance phase, psychosocial therapy can be less frequent than during the stabilization phase, as best determined in collaboration with the provider of psychosocial services and in consideration of recommendations of the PCPC.
 7. Patients should be encouraged to develop a recovery plan addressing their global wellness goals in areas of health, home, purpose, and community. Additionally, they should be linked to local community recovery supports as available, including mutual-aid groups, recovery coaches, certified peer recovery specialists, vocational and educational services, and housing assistance programs. Participation in community recovery support services pre-, during and post-treatment is positively linked with long-term recovery from addiction (see **Addendum D-4**).

IX. Co-occurring Mental Health Treatment

Individuals with SUDs often have a co-occurring mental health disorder that should be treated concurrently with the addiction. The final expert panel report indicates that depression and anxiety are relatively common among individuals with an opioid dependency seeking treatment. The consensus panel recommended specific screening and assessment guidelines, including consideration of the patient's previous history of mental disorders and treatment with a focus on the temporal relationship of symptoms to substance use and response to previous treatment.³⁹

For information about referral sources for assessment or treatment for a mental health disorder, contact the Community Care Provider Line toll-free at 1-888-251-2224.

1. Screen for depression and anxiety (Suggested tools: Mental Health Screening Form III, Mental Status Examination, Hamilton Rating Scale for Depression, Hamilton Anxiety Inventory, Beck Depression Inventory, Beck Anxiety Inventory and PRIME-MD) (see **Addendum D-3**).
2. Assess previous history of mental disorders and treatment, focusing on the temporal relationship of symptoms to substance use and on the patient's response to previous treatment.
3. Assess type, quantity, frequency, and time of last use of illicit substances or prescribed psychotropic drugs.
4. Assess family history of mental disorders.
5. Assess severity of depression and/or anxiety.
6. Reassess symptoms of depression and anxiety with regularity.

7. Refer to specialized behavioral health care if the patient fails to respond to treatment provided by the prescribing physician or as individually indicated by current behavior and needs.
8. Refer to concurrent evidence-based psychosocial treatment, such as cognitive behavioral therapy, motivational interviewing, relapse prevention training, contingency management, and supportive therapy.
9. Refer to mutual-aid facilitation, such as Dual Recovery Anonymous.
10. Once stabilized, if a patient continues to present symptoms of depression and/or anxiety, consider prescribing medications with low potential for abuse, such as SSRIs or tricyclic antidepressants.
11. Consider alternatives to benzodiazepines. Patients should be strongly advised against self-medicating with benzodiazepines and warned of the danger of overdose and death.
12. If a patient has a prescription for benzodiazepines at the outset of treatment, use caution when taking him or her off the benzodiazepines. Do not discontinue abruptly.
13. Integrate treatment for opiate dependence and depression and/or anxiety to the greatest degree possible, as on-site integrated care is associated with better outcomes than referrals off-site.

X. Summary

Community Care issues these guidelines with the hope of expanding the availability of buprenorphine services, while attending to the quality of the services provided and to person-centered treatment and recovery. We encourage an on-going dialogue about these guidelines and the guideline development process. Please address your comments to Marge Hanna, Senior Director, Substance Use Disorder Initiatives, at hanname@ccbh.com.

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¹⁰ Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment, Division of Pharmacologic Therapies. (n.d.). *Pharmacotherapy for Substance Use Disorders*. Retrieved from dpt.samhsa.gov/medications/medsindex.aspx.

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²⁷ Commonwealth of Pennsylvania Department of Health – Bureau of Drug and Alcohol Programs. (1999). *Pennsylvania Client Placement Criteria, Second Edition*. Retrieved from http://www.portal.state.pa.us/portal/server.pt/document/1285114/pcpc_manual.pdf?qid=89421326&rank=1.

- ²⁸ Commonwealth of Pennsylvania Department of Health – Bureau of Drug and Alcohol Programs. (1999). *Pennsylvania Client Placement Criteria, Second Edition*. Retrieved from http://www.portal.state.pa.us/portal/server.pt/document/1285114/pcpc_manual_pdf?qid=89421326&rank=1.
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ADDENDUM A

BUPRENORPHINE



What Exactly Is Buprenorphine?*

Buprenorphine (BYOO-pre-NOR-feen) is an opioid medication used to treat opioid addiction in the privacy of a physician's office.¹ Buprenorphine can be dispensed for take-home use, by prescription.¹ This, in addition to buprenorphine's pharmacological and safety profile, makes it an attractive treatment for patients addicted to opioids.²

Buprenorphine is different from other opioids in that it is a **partial opioid agonist**³. When compared with full opioid agonists (such as oxycodone and heroin), this property of buprenorphine may allow for:

- Less euphoria and physical dependence.³
- Lower potential for misuse.³
- A ceiling on opioid effects.³
- A relatively mild withdrawal profile.³

At the appropriate dose, buprenorphine treatment may:

- Suppress symptoms of opioid withdrawal.²
- Decrease cravings for opioids.²
- Reduce illicit opioid use.²
- Block the effects of other opioids.²
- Help patients stay in treatment.²

Buprenorphine (C₂₉H₄₁NO₄) is a semi-synthetic opioid derived from thebaine, an alkaloid of the poppy *Papaver somniferum*. Buprenorphine is an opioid partial agonist. This means that although buprenorphine is an opioid, and thus can produce typical opioid effects and side effects (such as euphoria and respiratory depression), its maximal effects are less than those of full agonists like heroin and methadone. At low doses, buprenorphine produces a sufficient agonist effect to enable opioid-addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms. The agonist effects of buprenorphine increase linearly with increasing doses of the drug until it plateaus and no longer continues to increase with further increases in dosage. This is called the "ceiling effect." Thus, buprenorphine carries a lower risk of abuse, addiction, and side effects compared to full opioid agonists. In fact, buprenorphine can actually block the effects of full opioid agonists and can precipitate withdrawal symptoms if administered to an opioid-addicted individual while a full agonist is in the bloodstream. This is the result of the high affinity buprenorphine has to the opioid receptors. The affinity refers to the strength of attraction and likelihood of a substance to bind with the opioid receptors.

Buprenorphine has a higher affinity than other opioids and, as such, will compete for the receptor and win. It will "knock off" other opioids and occupy that receptor blocking other opioids from attaching to it. If there is enough buprenorphine to knock the opioids off the receptors but not enough to occupy and satisfy the receptors, withdrawal symptoms can occur; in which case the treatment is more buprenorphine until withdrawal symptoms disappear.

In October 2002, the Food and Drug Administration (FDA) approved Subutex[®] (buprenorphine hydrochloride) and Suboxone[®] tablets (buprenorphine hydrochloride and naloxone

*Adapted from the **National Alliance of Advocates for Buprenorphine Treatment** website: www.naatp.org.

hydrochloride) for the treatment of opiate dependence. These are the only buprenorphine-based products approved to treat opioid dependence (addiction). On October 9, 2009, the FDA approved a generic version of Subutex. In 2011, Reckitt Benckiser Pharmaceuticals Inc. announced the discontinuation of the sale and distribution of all strengths of Subutex®.

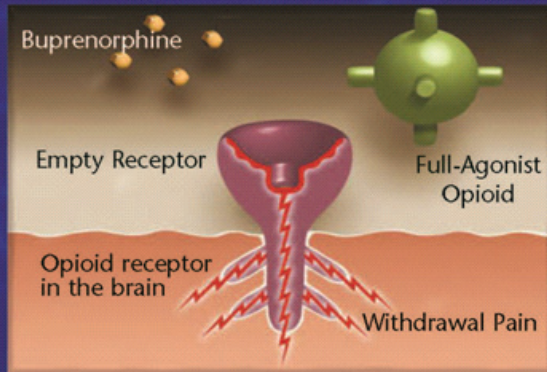
Suboxone contains both buprenorphine and the opiate antagonist naloxone. Naloxone has been added to Suboxone to guard against intravenous abuse of buprenorphine by individuals physically dependent on opiates. If misused by injection, the naloxone will cause immediate withdrawal in opioid dependent people; however, when taken sublingually, as indicated, the naloxone is clinically insignificant.

¹ U.S. Food and Drug Administration. (2002, October 8), *FDA Talk Paper, T02-38, Subutex and Suboxone approved to treat opiate dependence.*

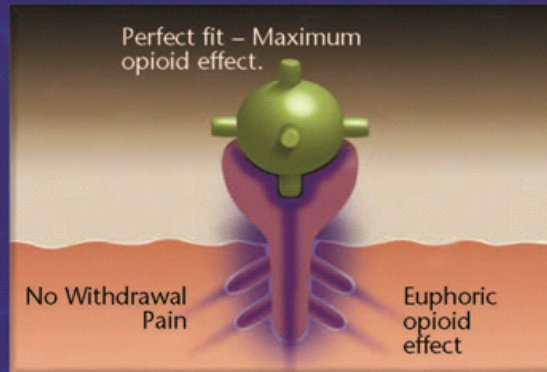
² Center for Substance Abuse Treatment. (2004) *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction, Treatment Improvement Protocol (TIP) Series 40* (DHHS Publication No. (SMA) 04-3939). Rockville, MD: Substance Abuse and Mental Health Services Administration.

³ Walsh SL, Eissenberg T. (2003). The clinical pharmacology of buprenorphine: extrapolating from the laboratory to the clinic. *Drug Alcohol Depend*, 70 (suppl 2): S13-S27.

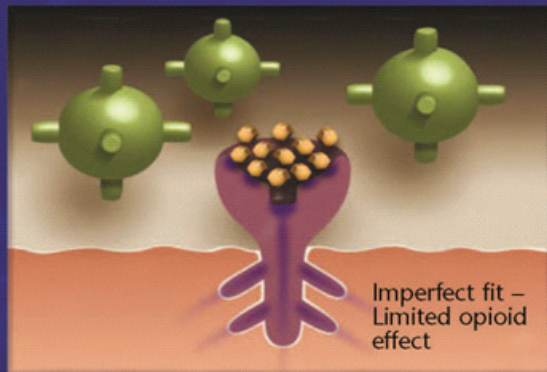
How Buprenorphine Works



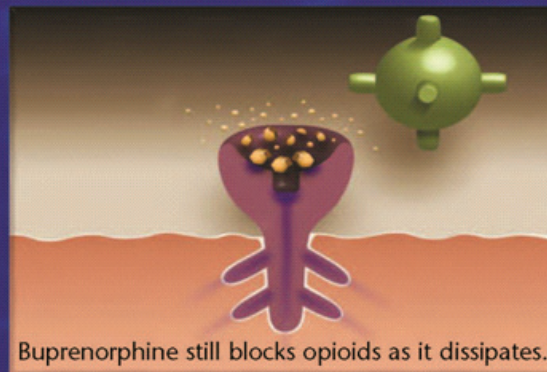
Opioid receptor is empty. As someone becomes *tolerant* to opioids, they become less sensitive and require more opioids to produce the same effect. Whenever there is an insufficient amount of opioid receptors activated, the patient feels discomfort. This happens in withdrawal.



Opioid receptor filled with a full-agonist. The strong opioid effect of heroin and painkillers can cause euphoria and stop the withdrawal for a period of time (4-24 hours). The brain begins to crave opioids, sometimes to the point of an uncontrollable compulsion (addiction), and the cycle repeats and escalates.



Opioids replaced and blocked by buprenorphine. Buprenorphine competes with the full agonist opioids for the receptor. Since buprenorphine has a higher affinity (stronger binding ability) it expels existing opioids and blocks others from attaching. As a partial agonist, the buprenorphine has a limited opioid effect, enough to stop withdrawal but not enough to cause intense euphoria.



Over time (24-72 hours) buprenorphine dissipates, but still creates a limited opioid effect (enough to prevent withdrawal) and continues to block other opioids from attaching to the opioid receptors.

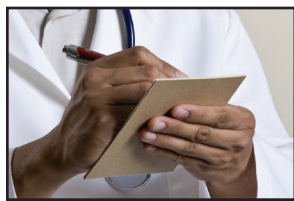
The above illustrations are for educational purposes and do not accurately represent the true appearance.



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for Buprenorphine Treatment
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ADDENDUM B
DRUG ADDICTION
TREATMENT
ACT OF 2000

Summary of the Drug Addiction Treatment Act of 2000 (DATA 2000)

Physician Waiver Qualifications

This act enables qualifying physicians to receive a waiver from the special registration requirements in the Controlled Substances Act for the provision of medication-assisted opioid therapy. This waiver allows qualifying physicians to practice medication-assisted opioid addiction therapy with Schedule III, IV, or V narcotic medications specifically approved by the Food and Drug Administration (FDA). On October 8, 2002, Subutex® (buprenorphine hydrochloride) and Suboxone® tablets (buprenorphine hydrochloride and naloxone hydrochloride) received FDA approval for the treatment of opioid addiction.

To receive a waiver to practice opioid addiction therapy with approved Schedule III, IV, or V narcotics, a physician must notify the Center for Substance Abuse Treatment (CSAT, a component of the Substance Abuse and Mental Health Services Administration) of his or her intent to begin dispensing or prescribing this treatment. This Notification of Intent must be submitted to CSAT before the initial dispensing or prescribing of opioid therapy. The “Waiver Notification” section of the U.S. Department of Health and Human Services’ buprenorphine website (<http://buprenorphine.samhsa.gov/howto.html>) provides information on how to obtain and submit a Notification of Intent form. The Notification of Intent can be submitted online from the website, via ground mail, or fax.

The Notification of Intent must contain information on the physician’s qualifying credentials (as defined below) and additional certifications, including that the physician has the capacity to refer such addiction therapy patients for appropriate counseling and other non-pharmacologic therapies, and that the physician will not have more than 30 patients on such addiction therapy at any one time for the first year. (Note: The 30-patient limit is not affected by the number of a physician’s practice locations. One year after the date on which the physician submitted the initial notification, the physician will be able to submit a second notification stating the need and intent to treat up to 100 patients.)

The Drug Enforcement Administration (DEA)

The Drug Enforcement Administration (DEA) assigns the physician a special identification number. DEA regulations require this identification number to be included on all buprenorphine prescriptions for opioid addiction therapy, along with the physician’s regular DEA registration number.

To qualify for a waiver under DATA 2000, a licensed physician (MD or DO) must meet one or more of the following criteria:

- Hold a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.
- Hold an addiction certification from the American Society of Addiction Medicine.
- Hold a subspecialty board certification in addiction medicine from the American Osteopathic Association.

*Adapted from the U.S. Department of Health and Humans Services; the full document can be accessed at <http://buprenorphine.samhsa.gov/data.html>.

- Has, with respect to the treatment and management of opioid-addicted patients, completed not less than eight hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause.
- Has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.
- Has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability to treat and manage opioid-addicted patients.
- Has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opioid-addicted patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective for three years after the date on which the criteria are promulgated, but may be extended for such additional discrete three-year periods, as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the three-year period involved.

<p align="center">Notification of Intent to Use Schedule III, IV, or V Opioid Drugs for the Maintenance and Detoxification Treatment of Opiate Addiction under 21 USC § 823(g)(2)</p>	<p>Form Approved: 0930-0234 Expiration Date: 05/31/2012 See OMB Statement on Reverse</p>														
	<p>DATE OF SUBMISSION</p>														
<p>Note: Notification is required by § 303(g)(2), Controlled Substances Act (21 USC § 823(g)(2)). See instructions on reverse. For second notifications, you must complete items 6, 8, 9, 10, and sign and date the form (item 12).</p>															
<p>1a. NAME OF PRACTITIONER</p>															
<p>b. State Medical License Number</p>	<p>c. DEA Registration Number</p>														
<p>2. ADDRESS OF PRIMARY LOCATION <i>(Include Zip Code)</i> (See instruction below)</p>	<p>3. TELEPHONE NUMBER <i>(Include Area Code)</i></p>														
<p>4. FAX NUMBER <i>(Include Area Code)</i></p>	<p>5. EMAIL ADDRESS <i>(Optional)</i></p>														
<p>6. PURPOSE OF NOTIFICATION <i>(See instruction below)</i></p> <p><input type="checkbox"/> New Notification <input type="checkbox"/> New Notification, with the intent to immediately facilitate treatment of an individual (one) patient <input type="checkbox"/> Second Notification of need and intent to treat up to 100 patients</p>															
<p>7. CERTIFICATION OF USE OF NARCOTIC DRUGS UNDER THIS NOTIFICATION</p> <p><input type="checkbox"/> I certify that I will only use Schedule III, IV, or V drugs or combinations of drugs that have been approved by the FDA for use in maintenance or detoxification treatment and that have not been the subject of an adverse determination.</p>															
<p>8. CERTIFICATION OF QUALIFYING CRITERIA</p> <p>I certify that I meet at least one of the following criteria and am therefore a qualifying physician <i>(Check and provide copies of documentation for all that apply):</i></p> <p><input type="checkbox"/> Subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties <input type="checkbox"/> Addiction certification from the American Society of Addiction Medicine <input type="checkbox"/> Subspecialty board certification in addiction medicine from the American Osteopathic Association</p> <table border="0" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">Completion of not less than eight hours of training for the treatment and management of opioid-dependent patients provided by the following organization(s):</td> <td style="width: 40%;">Date and location of training</td> </tr> <tr> <td><input type="checkbox"/> American Society of Addiction Medicine</td> <td>_____</td> </tr> <tr> <td><input type="checkbox"/> American Academy of Addiction Psychiatry</td> <td>_____</td> </tr> <tr> <td><input type="checkbox"/> American Medical Association</td> <td>_____</td> </tr> <tr> <td><input type="checkbox"/> American Osteopathic Association</td> <td>_____</td> </tr> <tr> <td><input type="checkbox"/> American Psychiatric Association</td> <td>_____</td> </tr> <tr> <td><input type="checkbox"/> Other <i>(Specify, include date and location)</i></td> <td>_____</td> </tr> </table> <p><input type="checkbox"/> Participation as an investigator in one or more clinical trials leading to the approval of a Schedule III, IV, or V narcotic drug for maintenance or detoxification treatment <input type="checkbox"/> State medical licensing board-approved experience or training in the treatment and management of opioid-dependent patients <input type="checkbox"/> OTHER <i>(Specify)</i> _____</p> <p><input type="checkbox"/> For Second Notifications - I certified qualifications in my initial notification and these qualifications have not changed.</p>		Completion of not less than eight hours of training for the treatment and management of opioid-dependent patients provided by the following organization(s):	Date and location of training	<input type="checkbox"/> American Society of Addiction Medicine	_____	<input type="checkbox"/> American Academy of Addiction Psychiatry	_____	<input type="checkbox"/> American Medical Association	_____	<input type="checkbox"/> American Osteopathic Association	_____	<input type="checkbox"/> American Psychiatric Association	_____	<input type="checkbox"/> Other <i>(Specify, include date and location)</i>	_____
Completion of not less than eight hours of training for the treatment and management of opioid-dependent patients provided by the following organization(s):	Date and location of training														
<input type="checkbox"/> American Society of Addiction Medicine	_____														
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<input type="checkbox"/> American Medical Association	_____														
<input type="checkbox"/> American Osteopathic Association	_____														
<input type="checkbox"/> American Psychiatric Association	_____														
<input type="checkbox"/> Other <i>(Specify, include date and location)</i>	_____														
<p>9. CERTIFICATION OF CAPACITY</p> <p><input type="checkbox"/> I certify that I have the capacity to refer patients for appropriate counseling and other appropriate ancillary services.</p>															
<p>10. CERTIFICATION OF MAXIMUM PATIENT LOAD</p> <p><input type="checkbox"/> I certify that I will not exceed 30 patients for maintenance or detoxification treatment at one time. <input type="checkbox"/> Second Notification - I need to treat up to 100 patients and I certify that I will not exceed 100 patients for maintenance or detoxification treatment at one time.</p>															

<p>11. CONSENT TO RELEASE IDENTIFYING INFORMATION TO SAMHSA BUPRENORPHINE PHYSICIAN AND TREATMENT PROGRAM LOCATOR WEB SITE <i>(Read instruction 11 below before answering)</i></p> <p><input type="checkbox"/> I consent to the release of my name, primary address, and phone number to the SAMHSA Buprenorphine Physician and Treatment Program Locator Web site.</p> <p><input type="checkbox"/> I do not consent to the release of my name, primary address, and phone number to the SAMHSA Buprenorphine Physician and Treatment Program Locator Web site.</p>	
<p>12. I certify that the information presented above is true and correct to the best of my knowledge. I certify that I will notify SAMHSA at the address below if any of the information contained on this form changes. Note: Any false, fictitious, or fraudulent statements or information presented above or misrepresentations relative thereto may violate Federal laws and could subject you to prosecution, and/or monetary penalties, and or denial, revocation, or suspension of DEA registration. (See 18 USC § 1001; 31 USC §§ 3801-3812; 21 USC § 824.)</p>	
Signature _____	Date _____
<p><i>Please send the completed form to:</i> Substance Abuse and Mental Health Services Administration Division of Pharmacologic Therapies Attention: Opioid Treatment Waiver Program One Choke Cherry Road, Rm 2-1063 Rockville, MD 20857 Fax 240-276-1630 Phone 1-866-287-2728 (1-866-BUP-CSAT)</p>	
<p>This form is intended to facilitate the implementation of the provisions of 21 USC § 823(g)(2). The Secretary of DHHS will use the information provided to determine whether practitioners meet the qualifications for waivers from the separate registration requirements under the Controlled Substances Act (21 USC § 823(g)(1)). The Drug Enforcement Administration will assign an identification number to qualifying practitioners and the number will be included in the practitioner's registration under 21 USC § 823(f).</p>	
<p>This form may be completed and submitted electronically (including facsimile) to facilitate processing.</p>	
<p>1. The practitioner must identify the DEA registration number issued under 21 USC § 823(f) to prescribe substances controlled in Schedules III, IV, or V.</p>	<p>2. Only one address should be specified. For the practitioner to dispense the narcotic drugs or combinations to be used under this notification, the primary address listed here must be the same primary address listed in the practitioner's registration under § 823(f).</p>
<p>6. Purpose of notification:</p> <p>New Notification - an initial notification for a waiver submitted for the purpose of obtaining an identification number from DEA for inclusion in the registration under 21 USC § 823(f).</p> <p>New Notification, with the intent to immediately facilitate treatment of an individual (one) patient - an initial notification submitted for the purpose described above, with the additional purpose of notifying the Secretary and the Attorney General of the intent to provide immediate opiate addiction treatment for an individual (one) patient pending processing of this waiver notification.</p> <p>Second Notification - For physicians who submitted a new notification not less than one year ago and intend and need to treat up to 100 patients. (See Office of National Drug Control Policy Reauthorization Act of 2006.)</p>	
<p>11. The SAMHSA Buprenorphine Physician and Treatment Program Locator Web site is publicly accessible at http://buprenorphine.samhsa.gov/bwns_locator/. The Locator Web site lists the names and practice contact information of physicians with DATA waivers who agree to be listed on the site. The Locator Web site is used by the treatment-seeking public and health care professionals to find physicians with DATA waivers. The Locator Web site additionally provides links to many other sources of information on substance abuse. No physician listings on the SAMHSA Buprenorphine Physician and Treatment Program Locator Web site will be made without the express consent of the physician.</p>	
<p align="center">PRIVACY ACT INFORMATION</p> <p>Authority: Section 303 of the Controlled Substances Act of 1970 (21 USC § 823(g)(2)). Purpose: To obtain information required to determine whether a practitioner meets the requirements of 21 USC § 823(g)(2). Routine Uses: Disclosures of information from this system are made to the following categories of users for the purposes stated: A. Medical specialty societies to verify practitioner qualifications. B. Other federal law enforcement and regulatory agencies for law enforcement and regulatory purposes. C. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes. D. Persons registered under the Controlled Substance Act (PL 91-513) for the purpose of verifying the registration of customers and practitioners.</p> <p>Effect: This form was created to facilitate the submission and review of waivers under 21 USC § 823(g)(2). This does not preclude other forms of notification.</p> <p align="center">Paperwork Reduction Act Statement</p> <p>Public reporting burden for completing this form is estimated to average 4 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the completed form. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0930-0234. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to SAMHSA Reports Clearance Officer; Paperwork Reduction Project (0930-0234); Room 71-1044, One Choke Cherry Road, Rockville, MD 20857</p>	



THE NATIONAL ALLIANCE OF ADVOCATES FOR BUPRENORPHINE TREATMENT

www.naabt.org

Are there exceptions when Subutex and Suboxone may be administered by a practitioner without the DATA 2000 waiver?

Under the Narcotic Addiction Treatment Act of 1974, all practitioners who use narcotic drugs for treating opiate addiction must obtain a separate registration under 21 U.S.C. Section 823(g)(1) or a DATA 2000 Waiver under 21 U.S.C. Section 823(g)(2). However, according to the Drug Enforcement Administration (DEA), an exception to the registration requirement, known as the "three-day rule" (Title 21, Code of Federal Regulations, Part 1306.07(b)), allows a practitioner who is not separately registered as a narcotic treatment program or certified as a "waivered DATA 2000 physician," to administer (but not prescribe) narcotic drugs to a patient for the purpose of relieving acute withdrawal symptoms while arranging for the patient's referral for treatment, under the following conditions: 1) not more than one day's medication may be administered or given to a patient at one time? 2) this treatment may not be carried out for more than 72 hours? and 3) this 72hour period cannot be renewed or extended.

The intent of 21 CFR 1306.07(b) is to provide practitioner flexibility in emergency situations where he or she may be confronted with a patient undergoing withdrawal. In such emergencies, it is impractical to require practitioners to obtain a separate registration. The 72-hour exception offers an opioid-dependent individual relief from experiencing acute withdrawal symptoms, while the physician arranges placement in a maintenance/detoxification treatment program. This provision was established to augment, not to circumvent, the separate registration requirement. The three-day (72hour) emergency exception cannot be renewed or extended. Because this is a Drug Enforcement Administration (DEA) rule, for further details consult DEA.

This information may be found at <http://www.dea diversion.usdoj.gov/drugreg/faq.htm>

More FAQ for the DEA by physicians about buprenorphine treatment.
<http://www.dea diversion.usdoj.gov/drugreg/faq.htm>



ADDENDUM C

OPIATE

WITHDRAWAL

Clinical Opiate Withdrawal Scale¹

For each item, circle the number that best describes the patient's signs or symptom. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increase pulse rate would not add to the score.

Patient's Name: _____ Date and Time: _____	
Reason for this Assessment: _____	
Resting Pulse Rate: _____ beats/minute <i>Measured after patient is sitting or lying for one minute</i> 0 pulse rate 80 or below 1 pulse rate 81-100 2 pulse rate 101-120 4 pulse rate greater than 120	GI Upset: <i>over last 1/2 hour</i> 0 no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhea 5 multiple episodes of diarrhea or vomiting
Sweating: <i>over past 1/2 hour not accounted for by room temperature or patient activity</i> 0 no report of chills or flushing 1 subjective report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face 4 sweat streaming off face	Tremor <i>observation of outstretched hands</i> 0 no tremor 1 tremor can be felt but not observed 2 slight tremor observable 4 gross tremor or muscle twitching
Restlessness <i>observation during assessment</i> 0 able to sit still 1 reports difficulty sitting still but is able to do so 3 frequent shifting or extraneous movements of legs/arms 5 unable to sit still for more than a few seconds	Yawning <i>observation during assessment</i> 0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute
Pupil Size 0 pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 5 pupils so dilated that only the rim of the iris is visible	Anxiety or Irritability 0 none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable anxious 4 patient so irritable or anxious that participation in the assessment is difficult
Bone or Joint aches <i>If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored</i> 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort	Gooseflesh skin 0 skin is smooth 3 piloerection of skin can be felt or hairs standing up on arms 5 prominent piloerection
Runny nose or tearing <i>Not accounted for by cold symptoms or allergies</i> 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks	<p style="text-align: right;">Total Score _____</p> The total score is the sum of all 11 items. Initials of person completing Assessment: _____
Score: 5-12 = mild; 13-24 = moderate; 25-36 = moderately severe; more than 36 = severe withdrawal	

¹Wesson, D. R., & Ling, W. (2003). The Clinical Opiate Withdrawal Scale (COWS). *Journal of Psychoactive Drugs*, 35(2), 253-259.

DSM IV Criteria for Opioid Withdrawal

Description:

Lists DSM-IV Criteria for Opioid Withdrawal

A. **Either** of the following:

1. Cessation of (or reduction in) opioid use that has been heavy and prolonged (several weeks or longer).
2. Administration of an opioid antagonist after a period of opioid use.

B. **Three (or more)** of the following, developing within minutes to several days after Criterion A:

1. Dysphoric mood
2. Nausea or vomiting
3. Muscle aches
4. Lacrimation or rhinorrhea
5. Pupillary dilation, piloerection, or sweating
6. Diarrhea
7. Yawning
8. Fever
9. Insomnia

C. The symptoms in Criterion B cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

D. The symptoms are not due to a general medical condition and are not better accounted for by another mental disorder.



naabt.org

The National Alliance of Advocates for Buprenorphine Treatment
Precipitated Withdrawal. What it is. How to avoid it.

What Is Precipitated Withdrawal?

It is a **rapid and intense onset** of withdrawal symptoms initiated by a medication. In the case of Buprenorphine, because it has a higher binding strength at the opioid receptor, it competes for the receptor, "kicks off" and replaces existing opioids. If a significant amount of opioids are expelled from the receptors and replaced, the opioid physically dependent patient will feel the rapid loss of the opioid effect, initiating withdrawal symptoms.

More precisely, precipitated withdrawal can occur when an antagonist (or partial agonist, such as Buprenorphine) is administered to a patient who is physically dependent on full agonist opioids. Due to the high affinity but low intrinsic activity



Full Agonist Opioid.
Perfect receptor fit. Maximum intrinsic activity (opiate effect).



Partial Agonist Opioid (Buprenorphine). Imperfect fit. Less intrinsic activity (opiate effect).

of Buprenorphine at the μ -receptor, the partial agonist displaces full agonist opioids from the μ -receptors, but activates the receptor to a lesser degree than full agonists which results in a net decrease in agonist effect, thereby precipitating withdrawal.¹

A common misconception is that the naloxone in the buprenorphine/naloxone combination medication initiates precipitated withdrawal. Naloxone may only initiate withdrawal if injected into a person physically dependent on opioids. Taken sublingually, as directed, naloxone is clinically insignificant and has virtually no effect. (Except in rare cases of an allergic reaction or naloxone hypersensitivity.)²

Avoiding Precipitated Withdrawal

Patient education and developing realistic expectations are essential before beginning treatment.

To **avoid** precipitated withdrawal, physically dependent patients must no longer be experiencing the agonist effects of an opioid. One way to gauge this is to observe objective symptoms of withdrawal sufficient to score a minimum of 5 to 6 on the COWS (Clinical Opioid Withdrawal Scale). Scores of >10 are preferable. Due to patient individuality, required abstinence times may vary considerably from patient to patient. Only use the time since last use as an estimate to anticipate the onset of withdrawal symptoms.⁴

The **induction begins** by assessing last use of all opioids, short and long acting, objective and subjective symptoms and a COWS score calculation. If not in sufficient withdrawal (mild to moderate: COWS of 5 to 24), it is in the patient's best interest to wait. Long-acting opioids will require a longer period of abstinence, than short-acting opioids.

Short-acting Opioids

(*Heroin, Crushed OxyContin®, Percocet®, Vicodin®, Oxycodone and others*)

Prior to induction, patients must abstain from all short-acting opioids for 12 to 24 hours **and/or** have objective withdrawal symptoms sufficient to produce a score of 5 to 24 on the COWS.¹

Long-acting Opioids

OxyContin® (Taken Orally)

Discontinue use for at least 24 hours prior to induction. A minimal score of at least 5 on the COWS is recommended, although some physicians prefer scores of 15 or higher.⁵

Methadone

It is recommended that patients transitioning from methadone to Buprenorphine slowly taper to 30 mg./day of methadone, for at least one week. Last dose must be no less than 36 hours prior to induction, and may be 96 hours or more. A minimal score of at least 5 on the COWS is recommended, although some physicians prefer scores of 15 or higher.⁵

Patients transferring from methadone or another long-acting opioid to Buprenorphine may experience discomfort for several days and dysphoria for up to 2 weeks.³

The **goal of induction** is to safely suppress opioid withdrawal as rapidly as possible with adequate doses of Buprenorphine. Failure to do so may cause patients to use opioids or other medications to alleviate opioid withdrawal symptoms or may lead to early treatment dropout.³ To achieve this, some physicians have found they may need to dose as high as 32 mgs. the first day with some methadone to Buprenorphine transfers.⁵

¹Center for Substance Abuse Treatment. *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Treatment Improvement Protocol (TIP) Series 42.* DHHS Publication No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004. http://naabt.org/links/TIP_40_PDF.pdf

²FDA. Full Prescribing Information on Subutex® (buprenorphine)/Suboxone® (buprenorphine/naloxone). www.fda.gov/cder/foi/label/2002/2073281.pdf

³Dosing Guide: Maintenance Therapy for Opioid Dependence. Subutex®/Suboxone® www.suboxone.com/pdfs/DosingGuides.pdf

⁴Practical Considerations for the use of Buprenorphine. Hendrie E. Jones, Ph.D., Johns Hopkins University School of Medicine, Baltimore, MD

⁵Physician Clinical Support System: www.pcssmentor.org. Transfer from Methadone to Buprenorphine. Paul P. Casadonte, MD, PCSS guidance paper. 8/9/2006. http://www.pcssmentor.org/pcssdocuments2/PCSS_MethadoneBuprenorphineTransfer.pdf

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ADDENDUM D

RESOURCES AND BIBLIOGRAPHY

Resources and Bibliography

- A. **Community Care Behavioral Health Buprenorphine Information Line:** 1-866-484-7668.
Primary care physicians and other clinicians who are treating Community Care Behavioral Health members with buprenorphine can call toll-free to speak with a Community Care psychiatrist about clinical guidelines, effects, and side effects of buprenorphine.
- B. **Single County Authorities (SCAs) for PA Drug and Alcohol Programs:**
www.portal.state.pa.us/portal/server.pt/community/need_help_now_/20933
Resources for assessment, treatment, case management and recovery support services.
This is also a source of funding for those who are not Community Care Behavioral Health members.
- C. **Licensed PA Substance Use Treatment Centers — Facility Locator:**
<http://app2.health.state.pa.us/commonpoc/Content/PublicWeb/DAFind.aspx>
To locate agencies in the Community Care Behavioral Health Network, use the online provider locator at www.ccbh.com/ProviderDirectory/Home/ChooseLocation or call Community Care Provider Line toll-free at 1-888-251-2224.
- D. **PA Medicaid (HealthChoices) Physical Health Plan Contact Information:**
The local [County Assistance Office](#) can provide contact information for physical health plans providing Medicaid managed care services.
- E. **Buprenorphine Treatment – A Training for Multidisciplinary Addiction Professionals (Videos):**
Lauren Broyles, PhD, RN and Richard Silbert, MD, Community Care Behavioral Health Organization and the Institute for Research, Education and Training in Addictions (IRETA)
Part 1 <http://files.ireta.org/video-webinar-20111005.wmv>.
Part 2 <http://files.ireta.org/video-webinar-20111026.wmv>.
Part 3 <http://files.ireta.org/video-webinar-20111109.wmv>.
- F. **Center for Substance Abuse Treatment (CSAT):**
Substance Abuse and Mental Health Services Administration (SAMHSA)
1-866-287-2728; info@buprenorphine.samhsa.gov.
- G. **CSAT Buprenorphine Information Center:** <http://buprenorphine.samhsa.gov/index.html>.
- H. **National Alliance of Advocates for Buprenorphine Treatment (NAABT):** www.naabt.org.
Provides information for prescribers and pharmacists, a treatment locator and physician matching tool and other information and resources.
- I. **Clinical Tools:**
1. **Buprenorphine (Suboxone) Training and Practice Tools — BupPractice:**
www.buppractice.com.
Development of this website was funded entirely by grant #R44DA12066 and contract

#HHSN271200655304C from the National Institute on Drug Abuse (NIDA) (www.drugabuse.gov) and the National Institutes of Health (www.nih.gov).

The **BupPractice** website includes sample:

- Patient contracts.
- Intake questionnaire for treatment planning.
- Initial patient contact about buprenorphine form.
- Patient assessment aids.

2. **Sample Forms and Patient Information:**

American Osteopathic Academy of Addiction Medicine

www.aoaam.org/content.php?pg=41

3. **Mental Health Screening Tools:**

- **Mental Health Screening Form III:** www.idph.state.ia.us/bh/common/pdf/substance_abuse/integrated_services/jackson_mentalhealth_screeningtool.pdf
- **Mental Status Exam:** <http://emedicine.medscape.com/article/293402-overview>
- **Hamilton Rating Scale for Depression:** www.medafile.com/cln/HDRS.html
- **Hamilton Anxiety Scale:** www.psy-world.com/hama_print1.htm
- **Beck Depression and Beck Anxiety Scales** (purchase information): www.pearsonassessments.com/pai/ca/cahome.htm
- **PRIME-MD (Primary Care Evaluation of Mental Disorders)** screening questionnaire for depressive symptoms: www.psy-world.com/prime-md_print1.htm

4. **Treatment Improvement Protocols (TIPS):**

www.kap.samhsa.gov/products/manuals/tips/numerical.htm

- **TIP 40 — Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction**
- **TIP 43 — Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs**
- **TIP 54 — Managing Chronic Pain in Adults With or in Recovery From Substance Use Disorders**

5. **Technical Assistance Publications (TAPS):**

www.kap.samhsa.gov/products/manuals/taps/index.htm

- **TAP 30 — Buprenorphine: A Guide for Nurses**

6. **Drug Interactions:**

Clinically Relevant Drug Interactions: Buprenorphine or Methadone with Other Frequently Prescribed Drug, Elinore F. McCance-Katz, M.D., Ph.D. Update 9/24/10.

PCSS-B

<http://pcssb.org/educational-and-training-resources/clinical-guidances/>

J. Evidence-Based Treatment and Promising Practices:

Psychosocial treatment approaches are ideally matched to the specific client need. Evidence-based and promising practices with opioid users include medication-assisted therapy matched with mutual aid groups and psychosocial approaches including use of cognitive behavioral therapy models, motivational interviewing, motivational enhancement therapy (MET), Contingency Management, Dialectal Behavior Therapy (DBT), Family Therapy, and others. Complimentary medicine and approaches can play a role in addressing anxiety, sleep problems and wellness needs although research is limited and inconclusive. A few treatment centers offer acupuncture, acupressure, yoga, tai chi and other alternatives to assist in easing detoxification and as an assist in ongoing recovery.

- **NIDA’s Principles of Effective Treatment:**
www.drugabuse.gov/publications/principles-drug-addiction-treatment/principles-effective-treatment
- **SAMHSA’S Integrated Treatment for Co-Occurring Disorders Evidence-Based Practices (EBP) Kit:**
<http://store.samhsa.gov/product/SMA08-4367>
- **SAMHSA National Registry of Evidence-Based Programs and Practices:**
www.nrepp.samhsa.gov

K. Patient Information:

- *NCADD’s Consumer Guide to Medication-Assisted Recovery*, National Council on Alcoholism and Drug Dependence Inc. 201:
www.ncadd.org/images/stories/PDF/Consumer-Guide-Medication-Assisted-Recovery.pdf

L. Recovery Support Services:

“Recovery support services (RSSs) are nonclinical services that assist individuals and families to recover from alcohol or drug problems. They include social support, linkage to and coordination among allied service providers, and a full range of human services that facilitate recovery and wellness contributing to an improved quality of life. These services can be flexibly staged and may be provided prior to, during, and after treatment. RSSs may be provided in conjunction with treatment, and as separate and distinct services, to individuals and families who desire and need them. Professionals, faith-based and community-based groups, and other RSS providers are key components of ROSCs.

Recovery support services are typically provided by volunteers or paid staff members who are familiar with their community’s support for people seeking to live free of alcohol and drugs. Often recovery support services are provided by peers—people in recovery or family members. Some services require reimbursement, while others, such as mutual support groups, may be available in the community free of charge. As described in the Access to Recovery grant program, recovery support services may include the following:

- Employment services and job training;
- Case management and individual services coordination, providing linkages with other

services (e.g., legal services, Temporary Assistance for Needy Families, social services, food stamps);

- Outreach;
- Relapse prevention;
- Housing assistance and services;
- Child care;
- Transportation to and from treatment, recovery support activities, employment, etc.
- Family/marriage education;
- Peer-to-peer services, mentoring, and coaching;
- Self-help and support groups (e.g., 12-step groups, SMART Recovery®, Women for Sobriety);
- Life skills;
- Spiritual and faith-based support;
- Education;
- Parent education and child development support services; and
- Substance abuse education.”¹

Recovery Resources:

- **Selected Papers of William L. White: Recovery Toolkit:**
(assists for persons in their recovery journey)
www.williamwhitepapers.com/recovery_toolkit/
- **Faces & Voices of Recovery: Online Recovery Resources:**
http://facesandvoicesofrecovery.org/resources/online_recovery_supports/online_resources.php
- **Faces & Voices of Recovery: Guide To Mutual Aid Resources:**
(12-step groups, etc.)
www.facesandvoicesofrecovery.org/resources/support/index.html
- **Faces & Voices of Recovery: Recovery Community Organizations in Pennsylvania:**
<http://facesandvoicesofrecovery.org/regions/result.php?state=PA>
- **Pathways to Recovery:**
(Faces and Voices of Recovery toolkit)
http://www.facesandvoicesofrecovery.org/pdf/Advocacy_Toolkit/recovery_pathways.pdf
- **Mapping your Recovery Journey:**
(sample recovery plan)
www.facesandvoicesofrecovery.org/pdf/Advocacy_Toolkit/recovery_pathways.pdf

M. Diversion:

- **Identifying Abuse and Diversion:**
BupPractice Buprenorphine (Suboxone) Training and Practice Tools
www.buppractice.com/howto/challengingpatients/diversion
- ***Illicit use of buprenorphine/naloxone among injecting and noninjecting opioid users.***
Bazazi AR, Yokell M, Fu JJ, Rich JD, Zaller ND. J Addict Med. 2011 Sep;5(3):175-80.
www.ncbi.nlm.nih.gov/pubmed/21844833

¹Kaplan, L. (2008). The Role of Recovery Support Services in Recovery-Oriented Systems of Care (DHHS Publication No. (SMA) 08-4315). Rockville, MD: Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration.

- ***Buprenorphine and Buprenorphine/Naloxone Diversion, Misuse, and Illicit Use: An International Review.***
Michael A. Yokell, Nickolas D. Zaller, Traci C. Green and Josiah D. Rich
www.ncbi.nlm.nih.gov/pmc/articles/PMC3154701/?tool=pubmed
- ***Diversion and Abuse of Buprenorphine: A Brief Assessment of Emerging Indicators Final Report***
JBS International, Inc. Center for Health Services & Outcomes Research, Submitted to Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment, Division of Pharmacologic Therapies Ray Hylton, Jr., R.N., M.S.N., Project Officer. 2006.
http://buprenorphine.samhsa.gov/Buprenorphine_FinalReport_12.6.06.pdf

N. Buprenorphine Bibliography:

- www.coretext.org
A comprehensive and regularly updated bibliography on buprenorphine related topics as provided by Reckitt Benckiser Pharmaceuticals.

O. Publications Related to Recovery and Recovery Oriented Systems of Care:

- William L. White Papers
www.williamwhitepapers.com



ADDENDUM E

COLLABORATION MODELS

Carbon-Monroe-Pike Drug & Alcohol Commission (SCA 211) Buprenorphine Policy/Procedure

Background

Buprenorphine is a medication used to treat opiate addiction in a community setting. This medication blocks the receptors, has a high affinity, and inhibits an individual's ability to get a euphoric experience from the opiate. The Carbon-Monroe-Pike Drug and Alcohol Commission (ed. Single County Authority or SCA administrative offices in Stroudsburg, PA) will utilize this therapy through contracted, certified physicians, on a limited basis based on time and established eligibility criteria. In addition, treatment and case management services are in place to assist the individual's recovery in a team-based approach.

Procedure

An eligible client must meet the following criteria to be considered for SCA funding in the buprenorphine program:

- Complete a level of care assessment determining opiate dependence.
- Agree to buprenorphine treatment after being provided all options of treatment by the assessor And Buprenorphine Coordinator.
- Meet income and residence eligibility for SCA funding.
- Follow rules and safety precautions for compliance in the program outlined in a contract.
- Comply with treatment and remain on an active status to be funded.
- Have no contraindications to buprenorphine therapy.

Potential clients will enter the system in the traditional manner through the Referral Center. The client will meet with the assessor to determine opiate dependence and level of care. If the client chooses to be referred to the Buprenorphine Coordinator after being presented all options, including detox, methadone, or buprenorphine, the assessor will complete a Suboxone Referral Form and set the appointment to meet with the Buprenorphine Coordinator (case manager). The Buprenorphine Coordinator (case manager) will determine if the client is appropriate and if funding is available. The Buprenorphine Coordinator (case manager) will:

- Schedule an appointment with an SCA contract physician for an initial examination.
- Submit a request for the authorization of funding to the clerical staff. The clerical staff will input the date into the Client Suite System for Treatment Program Manager and approve/deny authorization for the funding of treatment, case management, physician, and pharmacy.

At the time of the induction appointment with the physician, the client will be assessed co-pay towards the pharmacy bill based on a sliding scale starting at 10%. The Buprenorphine Coordinator (case manager) will assess the amount based on a price per pill, and require the client to pay the amount in order to obtain the voucher for the pharmacy. The client will present this voucher to the participating pharmacy as payment for the medication with either the paper prescription or will notify the pharmacy if the voucher is sent electronically.

The client will be required to meet with the Buprenorphine Coordinator (case manager) and the physicians as clinically needed from once a week to once a month frequency and a new voucher and prescription will be issued each time. The client will NOT under any circumstances receive

more than one voucher per month.

Note that in determining authorizations for the SCA liable client, BDAP (ed. PA Department of Health, Bureau of Drug and Alcohol Programs) funding will be used as a last resort. BHSI funding as well as funds made available by grants will first be utilized. Clients will have to pay for any physicians appointments as long as funding remains available. If a client's fees are abated for Outpatient Services, this will follow through to any Suboxone services received. The SCA does believe that the client should assume some responsibility in the cost of the Suboxone services and this will be through the co-pay using a sliding scale for the prescriptions itself. A client will not receive a voucher to go to the pharmacy without paying this minimal co-pay.

The SCA Program will pay for the medication for a 12-month period, provided the client adheres to the following conditions:

- Signing and adhering to the Suboxone Program Agreement (see attached).
- Participation in the recommended level of treatment determined through the PCPC.
- Participation in appropriate community support groups.
- Compliance with physician's requirements.
- Refrains from any activity that would result in criminal charges.
- Reports any lost or stolen prescriptions/medications immediately to the Buprenorphine Coordinator.
- Participates in urine screenings and random pill counts.
- Participates in a weekly Suboxone group focusing specifically on issues related to the medication, side effects, and family involvement.
- Refrains from diversion.

Outpatient counselors and the Buprenorphine Coordinator will meet weekly to discuss any concerns about treatment compliance. The Coordinator will then discuss with the physician prior to starting the weekly clinic any concerns from the staff and suggest interventions. Decisions to remove a client from the Suboxone program will be made at the recommendation of the team including the physician, Buprenorphine Coordinator, primary counselor, and outpatient supervisor.

If the client is non-compliant with any of the requirements, buprenorphine services will be revoked and the finding/slot offered to another client. The client may appeal this decision through use of the house grievance process. The client may be offered a taper prescription or detox services at the discretion of the treatment team and physician.

Outcome Measurements

In SFY 10-11 Suboxone, specific outcome measures have been added to the discharge process. These measures examine changes since admission to discharge in the following areas: stable housing, employment/schooling, support group involvement, and drug and alcohol use patterns.

Contact: Jamie Drake, Treatment Program Manager jdrake@cmpda.cog.pa.us; 610-377-5177
x105 Website: <http://cmpda.cog.pa.us/index.php/scaservices/medical-assisted-treatment>.

**Agreement for Treatment with Suboxone®/Subutex®
at Carbon-Monroe-Pike Drug and Alcohol Commission**

Name of Patient: _____ Date of Birth: ____/____/____

Social Security Number: ____/____/____ Phone Number: ____-____-____

By signing below, I agree to comply with the following:

1. I will attend all outpatient D&A counseling sessions (frequency determined by counselor).
2. I understand that on the day I start buprenorphine, I should come in the office already in opiate withdrawal. I will stop all drug and alcohol use no later than Tuesday night prior to being inducted on Thursday afternoon. If I am not having observable signs of opiate withdrawal, induction into the buprenorphine may be delayed at least a week.
3. I will take buprenorphine as prescribed at the dosage determined by the prescribing physician and will not allow anyone else to take medication prescribed for me.
4. **I will not take other medications with buprenorphine without prior permission from my doctor.** I understand that overdose deaths have occurred when patients have taken other medications and/or alcohols with buprenorphine.
5. I understand that buprenorphine itself is an opiate drug and can produce physical dependence.
6. I understand that the goal of treatment is to learn to live without drugs or alcohol by developing healthier coping skills during my course of buprenorphine treatment.
7. The length of buprenorphine treatment will be determined by the prescribing physician and will vary for each individual.
8. I understand that I will be randomly tested for drugs & alcohol to detect relapse, to determine compliance with my buprenorphine regimen, and document my progress in treatment.
9. I understand relapse while taking buprenorphine may result in being discharged from the MAT program.
10. I understand that when I receive a call to submit urine and do not call back within 24 hours, my urine will be considered a positive one.

11. I understand that I must have a valid phone number where I can be reached at all times. I also understand having a full mailbox on my phone or not having a mailbox set up will not be tolerated.
12. I understand that my buprenorphine will be prescribed in quantities to last from visit to visit and the frequency of visits depends on how I am progressing *as determined by the doctor*.
13. Lost prescriptions or buprenorphine tablets are a serious issue and will not be replaced by the doctor. Loss or misplacement of buprenorphine may result in discontinuation of buprenorphine treatment.
14. I agree to bring my pill bottle to CMP D&A every time I enter the building to submit to a pill count even if the bottle is empty. I understand that failure to bring my bottle with me will result in failure to get a script from the doctor.
15. I understand that if I no show for an outpatient appointment or no show for group once, I will be asked to sign a treatment contract.
16. I understand that I am required to have reliable transportation for all outpatient, individual and group sessions, appointments with the doctor, and to submit to urine drug screens.
NOT HAVING TRANSPORTATION IS NOT A VALID EXCUSE FOR A NO SHOW! ALWAYS HAVE A BACK-UP PLAN!
17. I agree to tell the doctor if I become pregnant or even think I may be pregnant.
18. I understand that MAT treatment team consists of: The Primary Outpatient Counselor, the Buprenorphine Case Manager, Outpatient Supervisor/Lead Counselor, Treatment Program Manager, the Physician and Yourself.

I have read and understand these details about buprenorphine treatment and I wish to be treated with buprenorphine.

Client Signature: _____ Date: ____/____/____

Witness Signature: _____ Date: ____/____/____

The keys to working this program successfully are: *HONESTY, COMMUNICATION, and COMPLIANCE WITH OUTPATIENT TREATMENT!*

**Buprenorphine Treatment Program
of Family Health Associates
Lewistown, PA**

Brief Synopsis of Program

1. Program’s goals and methods.

The overall goal of the Buprenorphine Treatment Program of Family Health Associates is to provide comprehensive, affordable outpatient opioid addiction treatment for its community members. Such treatment includes both medical and psychosocial services. In addition, it seeks to provide ongoing education about addiction, recovery, and medication therapy to participants, families, other healthcare providers, and the community at large through a variety of venues, including public meetings, lectures, and the media.

2. Initial and current collaborative partners in this program.

Direct services:

Lewistown Hospital (the Coordinator)
Family Health Associates (the physicians)
Clear Concepts Counseling (the counselors)

Indirect services:

Hospital Laboratory (at-cost drug screens)
Total Life Care Pharmacy (at-cost medication)
Tri-County D & A (organized training of physicians)
County Commissioners and District Attorney (funded training of physicians)
Regional Police Department (time and support)
Heroin Task Group (educational venue)
Communities that Care® (educational venue)

3. What are the unique elements of this program?

The unique elements of this program are the use of a hospital-funded Coordinator to develop, implement, and maintain a program that combines the resources of local physicians with that of local drug and alcohol counselors, and the involvement of the key leadership of the community in maintaining the program through in-kind services, including funds, time, educational venues, and support.

4. What elements are easily replicable by other communities?

By mobilizing key community leaders, including local physicians and counselors, this model is easily replicable by both urban and rural communities. Through this mobilization, funds for physician training and the hiring of a Coordinator can be secured, and education of the community as well as implementation of a comprehensive treatment protocol can be initiated.

Program Description

Participants in the Buprenorphine Treatment Program are led through a series of steps that provides a coherent, cohesive program of care. Those steps are as follows:

1. Initial Inquiry

All initial inquiries about the program are handled by the Coordinator. During the initial telephone conversation with a potential participant, basic information is gathered, a description of the program is provided verbally, and a packet of information about the program process, expectations, fees, and medication is mailed. Callers are informed of the expectations of the program (in the form of a treatment contract at the first appointment), including the fact that drug counseling is a required part of the treatment program and that a referral from a counselor is necessary to schedule an appointment. The potential participant is then placed on the list for appointments based on the date of the call.

2. Appointment Scheduling/Initial Intake

When an appointment is scheduled, the Coordinator contacts the potential participant and provides both verbal and written instructions about what to do and expect for the appointment. Each intake appointment is scheduled for a total of two hours, of which thirty minutes is physician time. Participants are strongly urged to bring a supportive, non drug-dependent family member to the appointment. After a urine drug screen, the participant and family member are greeted in the physician's office by the Coordinator who provides education regarding the nature of addiction, recovery, and buprenorphine. The participant contract is reviewed thoroughly, as are releases of information for drug and alcohol counselors and other healthcare providers. Four subscales of the Addiction Severity Index are administered, which includes an in-depth history of drug and alcohol use.

After the Coordinator, the participant is seen by the physician for a medical exam. Thus, not only do participants receive services for their opioid dependence, but they also receive comprehensive medical care. During the medical exam, the family member picks up the first prescription of buprenorphine from the pharmacy, and returns to the office with it so that the first dose of the medicine can be administered under medical observation.

3. Post-Intake

When the participant leaves the intake appointment, the Coordinator follows up with intensive telephone contact over the next 48 to 72 hours with a specific dosing protocol. Any concerns and questions are reviewed with the physician by the Coordinator. The participant returns for the second office visit one week after the first visit. The third office visit is typically two weeks after the second visit. If, at that time, the participant is stable, medical visits are scheduled monthly. Between the medical visits, participants are seen regularly by their outpatient drug counselors.

4. Drug Abuse Counseling

Clear Concepts Counseling (CCC) (www.clearconceptscounseling) provides both individual and group therapy. CCC has begun a group specifically for those in recovery with buprenorphine. The group provides not only social support, but also ongoing education about the nature of addiction and recovery. Some of the participants have provided feedback to the Coordinator that despite the medication being a powerful tool of recovery, the group has been the most meaningful part of the program for them.

5. Collaboration Among Providers

The program is designed to create a team around each participant. At the minimum, the team consists of the Coordinator, the physician, and the counselor. In addition, families and other support networks are encouraged to participate as much as possible within the boundaries of patient confidentiality. In order to maintain ongoing discussions about the process of the program as well as specific patient issues, the Coordinator has regular contact with CCC. The Coordinator is the primary contact for all team members, including the participant. In addition, the Coordinator tracks participant progress and compliance.

Team meetings are scheduled throughout the year between the physicians and the counselors. These meetings have provided a very important venue for the development of a collegial relationship between these two institutions that previously had little professional contact with each other. In addition, the meetings have provided a means by which the physicians have become better educated about addiction treatment, recovery, and management of relapses.

6. Community Preparation

In order to provide a quality service for the treatment of opioid dependence that was embraced and supported by the community, several steps were taken in the first three months of the program that were in addition to patient care.

The office staff (receptionists and nurses) of each participating physician was provided a 90-minute educational meeting regarding addiction as a chronic illness, the psychopharmacology of buprenorphine, the rationale for providing the treatment in an outpatient setting, and a step-by-step description of office visits. It was at this time that all staff members were given an opportunity to voice their concerns and anxieties about treating this population, and the issues

were addressed.

The hospital-affiliated pharmacy, Total Life Care, scheduled two meetings for their pharmacists with the Coordinator and one of the physicians to review the information about buprenorphine and determine a protocol for the prescriptions of buprenorphine.

Meetings took place with the Emergency Department physicians, the pain specialists, and psychiatrists to explain the medicine and discuss how to manage the treatment of patients who are taking buprenorphine. The program was also announced to the entire Medical/Dental staff, so that all providers in the hospital were informed.

Several meetings and educational presentations were held with key community leaders, interested organizations, and the public. In addition, educational press releases were provided to the local newspapers every few months to keep the public informed about the program and the medicine.

Outcome

The Buprenorphine Treatment Program of Family Health Associates has successfully provided outpatient treatment for community members struggling with addiction to opiates. It has done so through the direct collaboration between Lewistown Hospital (which funds the Coordinator), Family Health Associates (which provides the medication and ongoing medical care), and Clear Concepts Counseling (CCC) (which provides the counseling services). In addition, many organizations have provided in-kind or indirect services to initiate, support, and sustain the program, including Tri-County D & A, the County Commissioners, the District Attorney, the Heroin Task Group, *Communities that Care*[®], TLC Pharmacy, and the hospital laboratory.

The program has implemented many steps and strategies to provide all of its participants the following:

- Psychoeducation about addiction, recovery, and medication therapy on an ongoing basis to patients, families, and the community at large through a variety of venues.
- Comprehensive, affordable medical treatment.
- Comprehensive, affordable counseling services.
- A team of care providers who communicate about and coordinate their care.
- Ongoing planning and discussion of how to improve and sustain the process and program.
- Advice to others.

We believe that the Buprenorphine Treatment Program of Family Health Associates provides a model of treatment for opioid dependence that can be replicated across both urban and rural communities. We recommend that the following steps be taken by communities interested in providing treatment for heroin and painkiller abuse.

1. Mobilize Key Community Leaders

For Lewistown, it was imperative that the community leadership was involved in, knowledgeable about, and supportive of the program.

2. Identify a “Connector” and Mobilize Physicians

This role was instrumental in educating and training physicians.

3. Identify a Coordinator, a Drug and Alcohol Counseling Team, and a “Home” for the Program

The roles of the Coordinator, and the joint treatment with CCC, have been essential components of the program. Without them, physicians would not be able to provide the level of care necessary for the comprehensive outpatient treatment of addiction. Lewistown Hospital has provided the “home” for the Coordinator, and both Lewistown Hospital and Family Health Associates have provided administrative support when needed.

4. Design the Protocol

It was essential that the protocol for participants was planned and prepared prior to the opening of the program. This allowed physicians, counselors, pharmacists, office staff, hospital staff, and the community at large to know what to expect when the program began. It also provided participants with a process that was clearly communicated both by telephone and in writing.

5. Prepare the Community, Including Other Health Care Providers

The education of other health care providers as well as the public regarding the nature of addiction and the process of recovery was instrumental in garnering and maintaining support within the hospital and in the community at large.

6. Recognize Ongoing Issues and Monitor Diversion

Treatment Team meetings have been imperative in helping physicians to understand and manage the issues involved in addiction treatment, as well as in continuing to improve the quality of care by monitoring the program’s process and participant compliance.

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RASE Buprenorphine Coordinator Program^{xl} Harrisburg, PA

The RASE Buprenorphine Coordinator Program is an innovative and unique approach designed to assist individuals who are being prescribed buprenorphine/Suboxone. It incorporates client monitoring, referral, counseling, support groups, and mentoring to provide the most comprehensive service provision possible. Since it is a new program, it is evolving over time to ensure that individuals involved with the program are afforded the opportunity for ongoing recovery and success.

History

In our ever-changing times, new approaches to the treatment of substance use disorders are being researched and discovered every day. It is more and more common for addiction to be identified at earlier stages through the intervention of primary care physicians or other health professionals. It has also become evident that substance use disorders are multifaceted health issues and can be addressed by assuring the integration of treatment and support services. Research has found that addiction to opioids results in changes of the brain chemistry and function. Many individuals with such an addiction to opioids are in need of medication in conjunction with standard drug and alcohol treatment protocol. The Drug Treatment Act of 2000 permits qualified physicians to treat opioid addiction with medications approved by the Food and Drug Administration (FDA), such as buprenorphine.

On October 8, 2002, the FDA approved the use of Schedule III narcotic medications Subutex and Suboxone tablets (commonly known as buprenorphine) for the treatment of opioid addiction. This approval allows physicians in to utilize buprenorphine, if they meet the congressionally mandated training requirements and obtain a waiver from the Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Services.

Buprenorphine is the only medication that can be prescribed for the detoxification and maintenance of opioid addiction by a certified physician in an office-based setting (it can also be prescribed and administered in a methadone clinic setting). Buprenorphine is a safer alternative than methadone for individuals with a low or medium level of physical dependence on opioids and has a low abuse potential. Although buprenorphine is more expensive than methadone, the facts that it can be prescribed by a certified physician in an office setting and a 30-day supply can be dispensed from a pharmacy make access easier and can result in a reduction in stigmatizing visits to a methadone clinic as well as a reduction in transportation costs. In the Pennsylvania HealthChoices region of Dauphin, Cumberland, Perry, Lancaster, and Lebanon, buprenorphine meets all of the regulatory criteria for coverage under the Medical Assistance Program and is currently included on the NDC Fee Schedule.

While accessing buprenorphine can be accomplished in the privacy of a physician's office, there is a responsibility to the patient for referral to appropriate outpatient drug counseling and ongoing referrals to other necessary services that creates a burden on the prescribing physicians. This burden is directly affecting system capacity and physicians are reluctant to take on more buprenorphine patients.

Call for Proposals

In response to the need for buprenorphine patients to receive supplemental counseling services, a group of concerned individuals involved in Pennsylvania's HealthChoices Initiative (the Medical Assistance managed care program) decided to make reinvestment dollars available to implement a Buprenorphine Coordinator Program. Such a program could ensure that anyone prescribed buprenorphine would also be involved in outpatient drug treatment. The group invited some organizations to participate in a call for proposals. The RASE Project was one of the organizations invited to apply, and in January of 2007, was awarded the contract.

The program coordinates services for individuals through:

- Referrals and access to appropriate counseling.
- Assessments to determine emergent and ancillary needs.
- The development of Recovery Plans that address areas of need.
- The coordination of ancillary services to support the recovery process, such as housing, employment, and health care.
- Assisting individuals in the identification of recovery support groups.
- Providing ongoing monitoring of individuals' successes and/or challenges while enrolled in the Program.
- Developing specific peer support groups for those individuals receiving buprenorphine treatment.
- Educating physicians and psychiatrists on buprenorphine and the need for this pathway to recovery and the importance of recovery as a lifelong process.
- Increasing the number of outpatient providers willing to treat individuals who have been prescribed buprenorphine.

The program serves individuals in Cumberland, Perry, Dauphin, Lebanon, and Lancaster counties. The RASE Project was recently approved to provide coordination of care services in Franklin and Fulton counties. Coordinators work throughout the five counties providing services to individuals appropriate for buprenorphine treatment. Program staff seek strong collaboration with prescribing physicians and counseling services. This model is based upon a cooperative approach among the individual enrolled, the Coordinator, the prescribing physician's office, and the treatment provider. This team approach fosters a successful recovery from opioid dependence and the Coordinators' regular contact with the clients and rapid response to concerns and problems ensure a coordination of care and early intervention. Coordinators may stay involved in individuals' care until they are totally stabilized in the recovery process.

A Support Group has formed that meets monthly for individuals treated with the medication, buprenorphine for opioid addiction. There is no registration or cost required; the group meets each week in the program's Harrisburg, Lancaster, and Carlisle offices.

Addiction, Recovery, and the Family is a three part educational and supportive program for family and friends that are dealing with a loved one's substance use disorder. In order to provide support, information and resources, the RASE Project has developed this program to meet the needs of those who have been impacted by substance use disorder, in particular, those loved

one's involved in medication assisted (buprenorphine) treatment for opioid addiction.

The program goals include: introduction to office-based treatment with buprenorphine in a PCP setting; principles of addiction recovery; and identification of necessary social and emotional supports.

For further information, contact the Harrisburg office at 232-8535.

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^{x1} Extracted from www.RASEproject.org