

Practice Protocol

Buprenorphine Guidance Protocol



**Developed by the
Arizona Department of Health Services
Division of Behavioral Health Services**

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Title

Buprenorphine Guidance Protocol

Goal/What Do We Want to Achieve Through the Use of this Protocol?

The purpose of this document is to provide guidance to Behavioral Health Medical Practitioners within the State of Arizona. This document addresses practice which is consistent with Arizona Department of Health Services (ADHS) Office of Behavioral Health Licensing (OBHL) and Division of Behavioral Health Services (DBHS) standards. This document describes diagnostic requirements, prescribing and dosing strategies, laboratory monitoring strategies and recommendations and physical assessment prior to dosing recommendations. Guidance on psychotherapies that are consistent with buprenorphine treatment, patient selection recommendations, opiate withdrawal assessment protocols and issues relevant to special populations will be reviewed. Additionally, record storage and maintenance, informed consent, patient education, patient residential storage and confidentiality recommendations will be covered in this document.

Target Audience

Waived buprenorphine providers and OBHL licensed facilities within the State of Arizona.

Target Population(s)

Tribal and Regional Behavioral Health Authorities (T/RBHA) enrolled individuals above the age of 16 with the diagnosis of opiate dependency.

Definitions

[Buprenorphine \(Subutex, Suboxone\)](#)

[Opiate Dependency](#)

[Opiate Withdrawal](#)

[Waived physician prescriber](#)

[Informed Consent](#)

Background

The prevalence of opioid dependency has had a dramatic impact in the U.S. There are 810,000 to 1,000,000 chronic users of heroin in the U.S. (Office of National Drug Control Policy, 2003). The National Survey on Drug Use and Health (NSDUH) indicates that 53% of individuals who abused heroin become dependent.

The lifetime use of opioid analgesics reached 29,611,000 in the U.S. in 2002 (NSDUH). Opioid dependency resulted in an increase in emergency room visits from 36,000 to 72,000 between 1991 and 1995 in the U.S. During the same time period, opioid-related

deaths increased from 2,300 to 4,000 in the U.S. (Substance Abuse and Mental Health Services Administration (SAMHSA) Mortality Data from DAWN, 2002).

The prevalence of opioid abuse is increasing. Office-based buprenorphine treatment is intended to make opioid addiction treatment more available and to place the treatment of opioid dependency into mainstream medical practice.

Recommended Process/Procedures

A. Diagnostic requirements:

DSM-IV-TR Criteria for Opioid Dependence: A maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by three (or more) of the DSM-IV-TR criteria occurring over a 12-month period. Examples of drugs which can lead to dependency include:

1. diacetylmorphine (heroin);
2. hydromorphone (Dilaudid),
3. oxycodone (OxyContin, Percodan, Percocet, and Tylox);
4. meperidine (Demerol);
5. hydrocodone (Lortab, Vicodin);
6. morphine (MS Contin, Oramorph), fentanyl (Sublimaze);
7. propoxyphene (Darvon);
8. methadone (Dolophine);
9. codeine and opium.

Special Diagnostic Considerations for Individuals released from Corrections:

Diagnostic decisions shall be based on the following factors before starting opioid dependency treatment which requires a review of clinical history:

1. length of incarceration;
2. post release addiction patterns and cycles;
3. addiction treatment history;
4. self-help involvement; and
5. reported triggers of illegal drug use and addiction upon release. ([SAMHSA's TIP 40](#))

B. Prescribing requirements:

DATA 2000 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).

The Drug Enforcement Administration (DEA) assigns the physician a special identification number. DEA regulations require this ID 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 any one or more of the following criteria:

1. The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties;
2. The physician holds an addiction certification from the American Society of Addiction Medicine;
3. The physician holds a subspecialty board certification in addiction medicine from the American Osteopathic Association;
4. The physician 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.
5. The physician 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.
6. The physician 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 of the physician to treat and manage opioid-addicted patients.
7. The physician has such other training or experience as the Secretary of U.S. Department of Health and Human Services (DHHS) 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 only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-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 3-year period involved.

C. Clinical observation at critical phases of treatment:

Waived buprenorphine providers must consider the entire process of treatment, which includes induction through stabilization, and then maintenance. Below are suggested algorithms developed by Center for Substance Abuse Treatment.¹

¹ Center for Substance Abuse Treatment, 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, 2004.

Figure 4-1

Induction Days 1-2

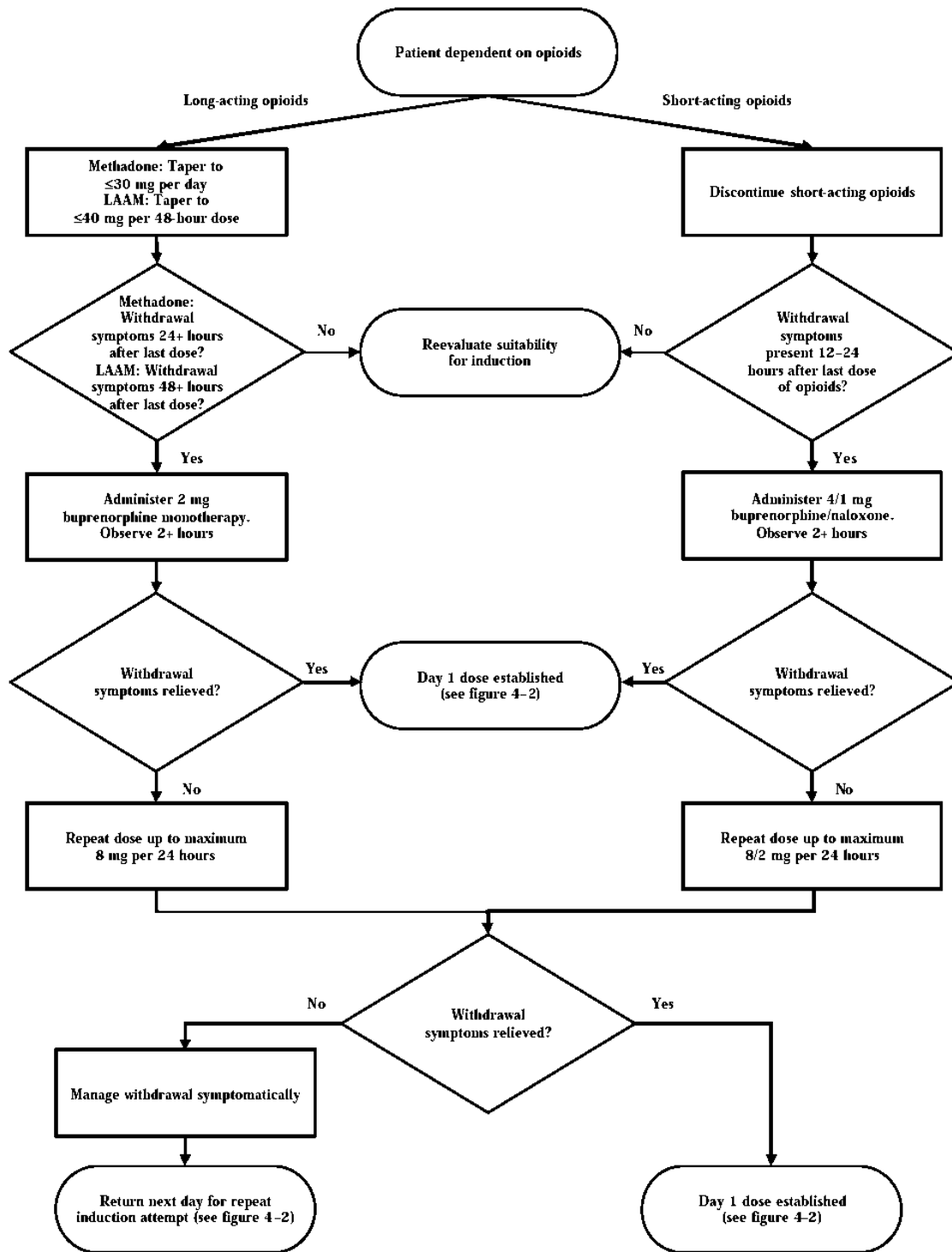
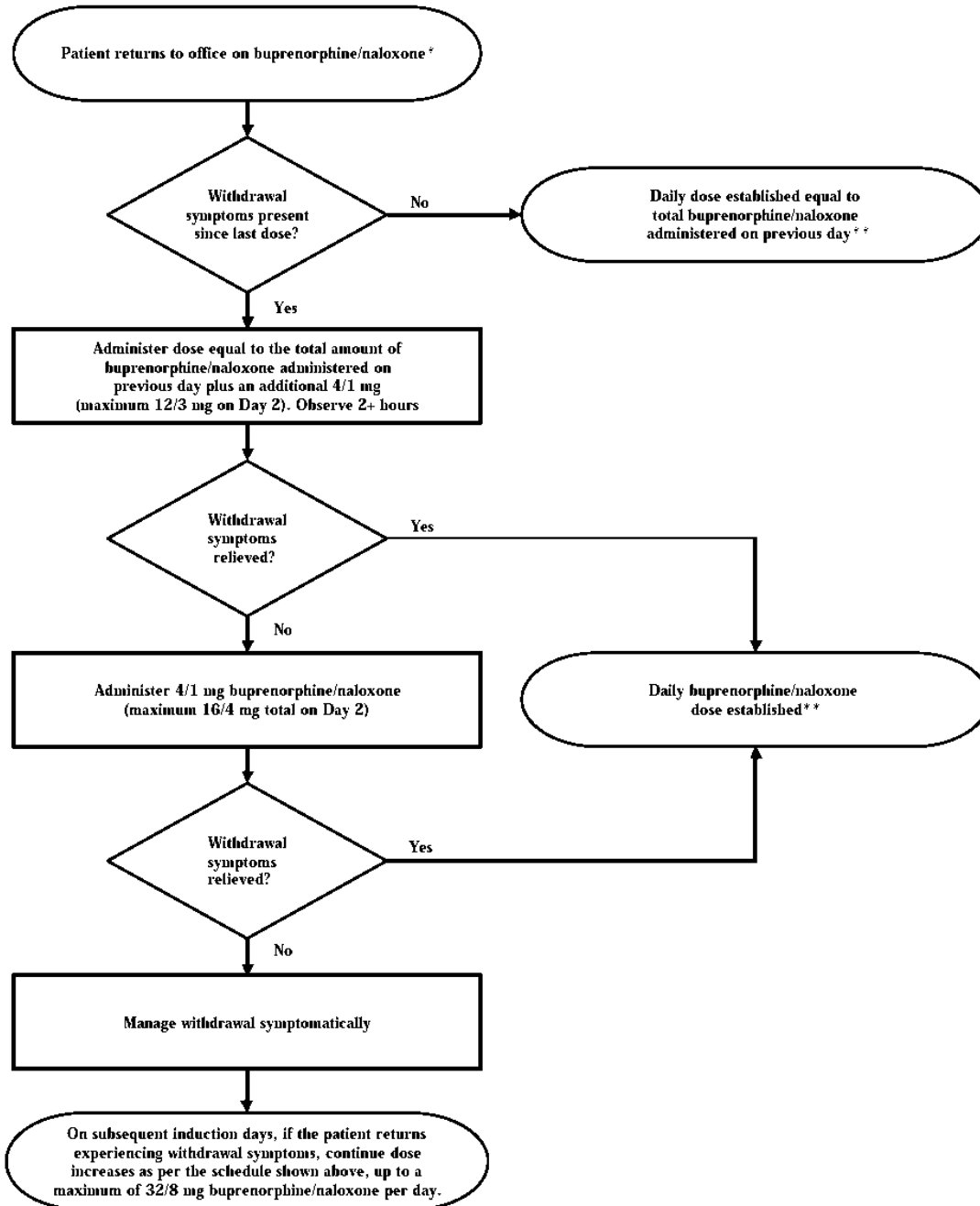


Figure 4-2

Induction Day 2 Forward



* If buprenorphine monotherapy was administered on Day 1, switch to buprenorphine/naloxone on Day 2 (for a patient who is not pregnant).

** Dose may be increased by 2/0.5–4/1 mg increments on subsequent days as needed for symptom relief. Target dose of 12/3–16/4 mg buprenorphine/naloxone per day by the end of the first week.

Figure 4-3

Stabilization Phase

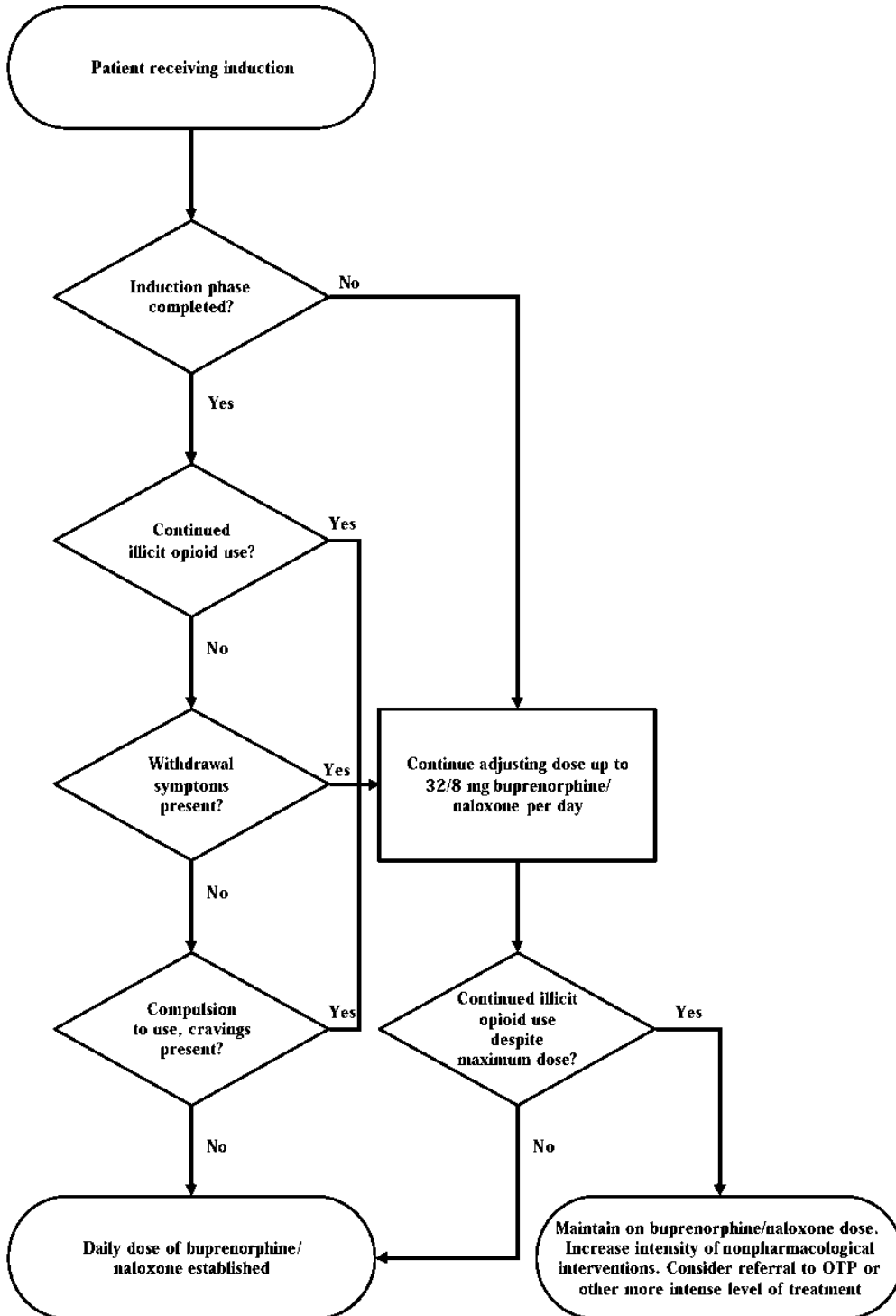


Figure 4-4

Detoxification From Short-Acting Opioids

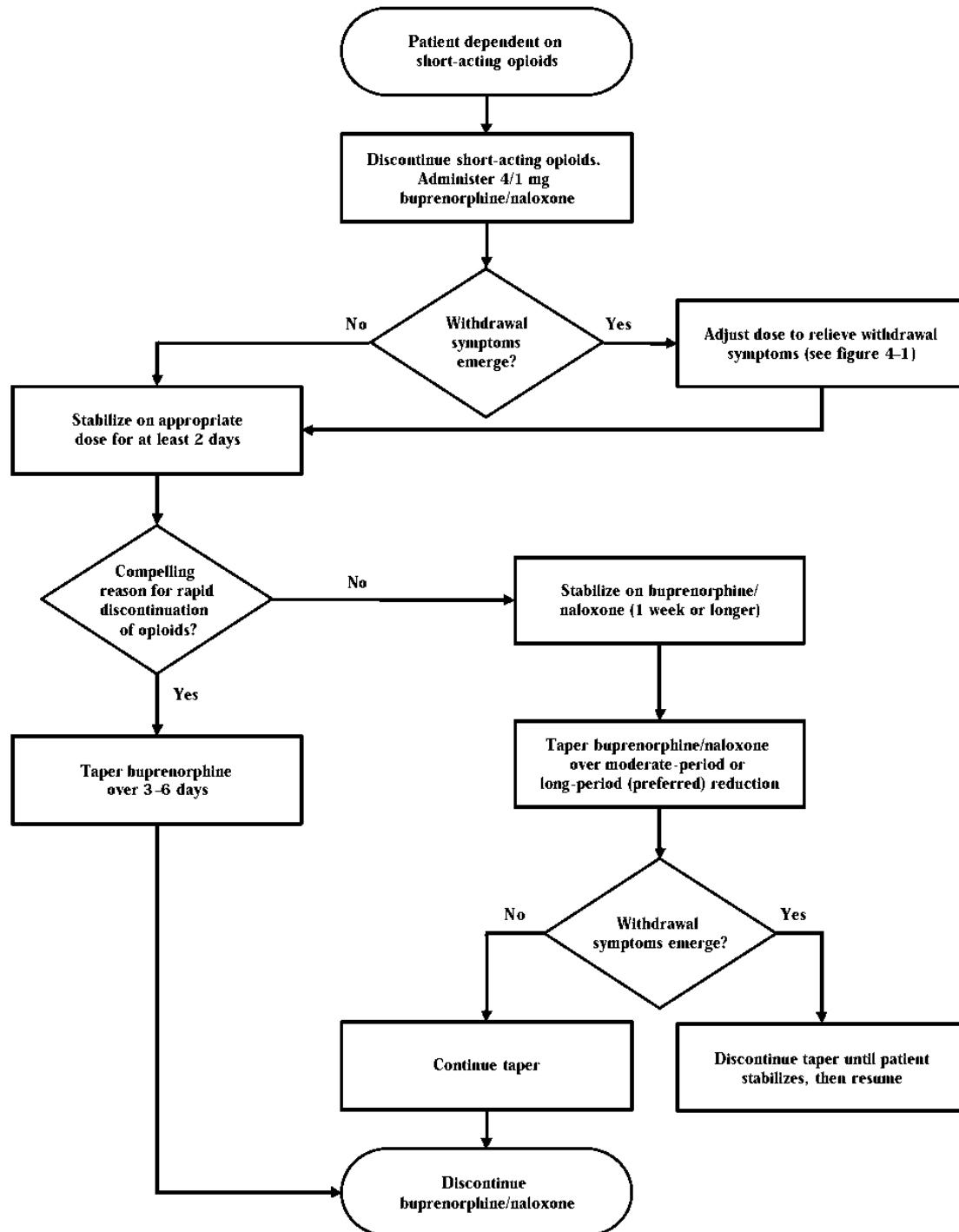
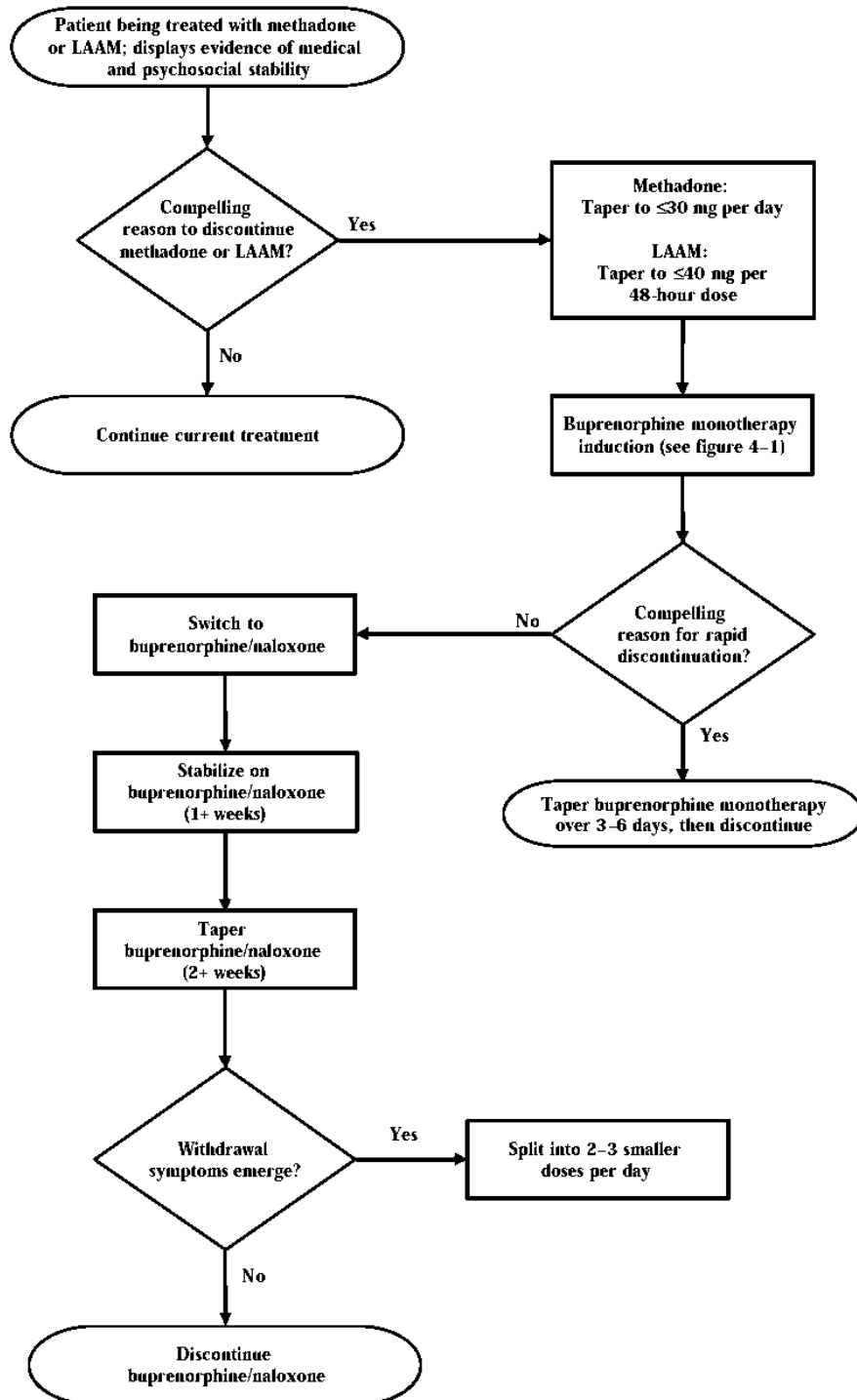


Figure 4-5

Discontinuation of OAT Using Buprenorphine



D. History and physical assessment prior to induction:

The physical assessment must be supported by a comprehensive and accurate clinical history. The history should encompass the types of opioids abused and the history of usage. The provider should review first use, illicit vs. licit use, frequency and amounts, routes of administration, and recent use. The provider should consider tolerance and withdrawal, relapse frequency, and history of non-opioid substance use disorders. Psychiatric and medical histories should be components of the overall history.

The physical assessment should evaluate the patient's sensorium and mental status. The medical provider should assess for dilated pupils (opioid withdrawal), constricted pupils (opioid intoxication), unstable vital signs, possible pregnancy, and medical conditions such as chronic pain, renal insufficiency, hepatitis, and HIV/AIDS. The provider should assess the patient for needle marks, cellulitis or dermal abscesses. Laboratory testing should be based on clinical history and the physical examination. Certain high risk medical illnesses should mandate specific laboratory tests. (American Academy of Addiction Psychiatry, 2008)

E. Laboratory studies prior to induction and post-induction:

The ordered laboratory studies should be based on the findings of the history and physical. The examiner should order pregnancy testing on all women of child-bearing years with noted exceptions (i.e., hysterectomy, history of tubal ligation).

Urine drug testing enhances treatment outcomes in patients receiving buprenorphine treatment. Urine drug testing is an integral part of on-going evaluation and treatment planning. The provider should consider mechanisms to maintain the validity of the results. In-office buprenorphine practice policies should cover in-office vs. off-site collection, random vs. scheduled, and observed vs. non-observed. Urine drug testing can allow for the monitoring of co-occurring substance use disorders. (American Academy of Addiction Psychiatry, 2008)

Practice and prescribing should be based on the patient needs and FDA and State guidelines.

- F. Each behavioral health recipient has the right to participate in decisions regarding his or her behavioral health care, including the right to refuse treatment. It is important for persons seeking behavioral health services to agree to those services and be made aware of the service options and alternatives available to them as well as specific risks and benefits associated with these services. Providers shall reference [ADHS/DBHS Provider Manual Section 3.11, General and Informed Consent to Treatment](#) for additional guidance.

G. Storage of records

The patient record is:

1. Maintained on the premises of the behavioral health agency at which the patient is admitted until the patient is discharged;
2. Available and accessible to staff members who provide behavioral health services to the patient;
3. Retained after a patient's discharge:
 - a. For a patient who is an adult, for 7 years after the date of the patient's discharge, unless otherwise provided by law or this chapter ([9 A.A.C.20, Article 211 A](#));
 - b. For a patient who is a child, for 7 years after the date of discharge or for at least 3 years after the date of the patient's 18th birthday, whichever is a longer period of time; and
 - c. Disposed of in a manner that protects patient confidentiality.
4. Storage of Buprenorphine in the physician's office must include being stored under locked conditions and include record keeping tracking information on who received Buprenorphine and the quantity of drug dispensed.

Pade (2008) reported the following:

“DEA record keeping requirements for office-based opioid therapy go beyond the Schedule III record keeping requirements. According to DEA: Practitioners must keep records (including an inventory that accounts for amounts received and amounts dispensed) for all controlled substances dispensed, including Subutex and Suboxone ([21 CFR Section 1304.03\[c\]](#)). In some cases, patients return to the prescribing physician with their filled Subutex or Suboxone prescriptions so that the practitioner can monitor the induction process. While it is acceptable for the patient to return to the practitioner with their filled prescription supplies, practitioners shall not store and dispense controlled substances that are the result of filled patient prescriptions.”

Practitioners must keep records for controlled substances prescribed and dispensed to patients for maintenance or detoxification treatment ([21 CFR Section 1304.03\[c\]](#)). Many practitioners comply with this requirement by creating a log that identifies the patient (an ID number may be used instead of name), the name of the drug prescribed or dispensed, as well as the strength and quantity and date of issuance or dispensing. Some physicians comply with this requirement by keeping a copy of the prescription in the patient record.

Alternatively, DEA suggests that practitioners could keep separate records for controlled substances prescribed and dispensed for maintenance or detoxification treatment to facilitate the record reviews during physician inspections for DATA compliance. This way, DEA will only review those records related to controlled substances prescribed and dispensed for maintenance or detoxification treatment for physicians maintaining separate records.”

H. Storage of buprenorphine in the patient's home

It is best to store the medication in a location other than where vitamins, aspirin or other over-the-counter medications are stored to avoid any confusion.

Buprenorphine must be stored in a location that is safe and kept away from children or pets. If buprenorphine is taken by a family member or a person by mistake he or she should be evaluated by a physician immediately.

I. Special Treatment Populations

The physician should take special considerations when prescribing in the populations below:

1. Pregnant women
2. Adolescents
3. Geriatric Population
4. Persons suffering from pain
5. Persons with a comorbidities (e.g. Hepatitis, HIV, TB, etc)
6. High risk psychiatric patients with suicidal ideation and impaired judgment
7. Under the jurisdiction of the criminal justice system
8. Persons who have a concurrent alcohol or other substance abuse disorders

J. Opioid Withdrawal Protocols

The physician should consider the use of objective opiate withdrawal assessment instruments (e.g., Clinical Opiate Withdrawal Scale (COWS)).

Training and Supervision Recommendations

Per DATA 2000, training that meets the requirement for a waiver may be provided by the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Academy of Addiction Medicine, the American Psychiatric Association, the American Society of Addiction Medicine, and other organizations that the Secretary of the Department of Health and Human Services determines are appropriate for this purpose. DATA-qualifying training must include not less than eight hours of instruction on the treatment and management of opioid-addicted patients.

Also, as part of training in the treatment of opioid addiction, physicians should at a minimum be a licensed physician to practice medicine in the state of Arizona and obtain some knowledge about the basic principles of brief intervention in case of relapse. Physicians considering providing opioid addiction care should ensure that they are capable and capable of providing psychosocial services. In fact, DATA 2000 stipulates that when physicians submit notification to SAMHSA to obtain the required waiver to practice opioid addiction treatment outside the outpatient treatment program setting, they must attest to their capacity to refer such patients for appropriate counseling and other non-pharmacological therapies.

Anticipated Outcomes

Maintenance of Office of Behavioral Health Licensing license:

- A. Measured by office inspections conducted by Office of Behavioral Health Licensing.

Avoidance of Critical Events within the office practice:

- A. Measured by critical incidence reporting by T/RBHA to ADHS/DBHS.

Resources:

American Academy of Addiction Psychiatry (AAAP)

www.aaap.org/buprenorphine/buprenorphine.html

Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction: A Treatment Improvement Protocol (TIP) 40

http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf

SAMHSA Buprenorphine Information Center at:

<http://buprenorphine.samhsa.gov>

Suboxone manufacturer's web page at:

<http://www.suboxone.com>

ADHS/DBHS Practice Protocol Buprenorphine Guidance Protocol Desktop Guide

- ❖ Key elements to remember about this best practice:
 - Establishing a maintenance dosage of medications
 - Regulatory issues related to buprenorphine
 - Licensed physicians must be capable and comfortable with opioid addiction

- ❖ Benefits of using this best practice:
 - Understanding the practice associated with buprenorphine
 - Intended to make opioid addiction treatment more available
 - Intended to place the treatment of opioid dependency into mainstream medical practice