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# Obtaining the Buprenorphine Waiver

## Overview

This 8-hour activity and complementary online assessment meets the Federal training requirement of the Drug Addiction Treatment Act of 2000 (DATA 2000). Completion will allow qualified clinicians to apply for a waiver to their Drug Enforcement Administration (DEA) license and thus to provide office-based treatment of opioid use disorder with buprenorphine.

Development of this training was supported by the Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services, U.S. Department of Health and Human Services.

## Educational Objectives

- Discuss the rationale and need for medication-assisted treatment of opioid use disorder.
- Apply the pharmacological characteristics of opioids in clinical practice.
- Describe buprenorphine protocols for all phases of treatment and for optimal patient-treatment matching.
- Describe the legislative and regulatory requirements of office-based opioid pharmacotherapy.
- Discuss treatment issues and management of opioid use disorder in adolescents, pregnant women, and patients with acute and/or chronic pain.

## Target Audience

- Physicians interested in completing the training requirement for CSAT certification to qualify for the waiver authority from the requirements of the Controlled Substances Act

- Nurse practitioners and physician assistants interested in using this activity to satisfy 8 hours of their required training
- Physicians interested in learning more about office-based prescribing of buprenorphine for the treatment of opioid use disorder

## **Accreditation and Designation Information**

The American Psychiatric Association (APA) is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The APA designates this enduring material for a maximum of 8 *AMA PRA Category 1 Credit*<sup>™</sup>. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

The APA is one of the DATA 2000 organizations that can provide the 8-hour training for physicians, nurse practitioners, and physician assistants needed to obtain the waiver to prescribe buprenorphine. This book-based learning and complementary online assessment has been designed to meet these training requirements.

## **How to Earn Credit**

Participants who wish to earn *AMA PRA Category 1 Credit*<sup>™</sup> or a certificate of participation may do so by completing all sections of the course, including the evaluation. A multiple-choice quiz is provided based on the content. A passing score of 80% must be achieved. Retakes are available for the test. After evaluating the program, course participants will be provided with an opportunity to claim hours of participation and print an official continuing medical education (CME) certificate (physicians) or certificate of participation (nonphysicians) showing the completion date and hours earned.

## **Instructions for Claiming CME Credit and Applying for a DEA Waiver**

1. Visit [www.psychiatry.org/buprenorphinetraining](http://www.psychiatry.org/buprenorphinetraining).
2. Click on the *Office-Based Buprenorphine Treatment of Opioid Use Disorder* “Credit Claim” link.
3. Enter the group ID from the inside cover of this book to unlock the activity in the APA Learning Center.

4. Complete the program requirements, including a 25-question online self-assessment. Participants must obtain a passing score of 80% or greater.
5. Complete the CME evaluation.
6. Print and retain your CME certificate.
7. Follow the instructions provided with the CME certificate to obtain a DEA waiver for buprenorphine prescribing.

# 1

## **Opioid Use Disorder in America**

### **History and Overview**

John A. Renner Jr., M.D.

**OPIOID USE DISORDER** (OUD) has been a serious problem in the United States since before the Civil War. In this chapter, I trace the evolution of this problem from the era of opium-laced patent medicines, through the problems with injectable morphine after the Civil War, to the heroin epidemics of the twentieth century, and finally to the current epidemic of opioid pharmaceutical misuse that began in the 1990s. I highlight the history of medical efforts to manage OUD and recurrent conflicts with a public policy approach that has emphasized criminal justice solutions to the problem. The introduction of office-based buprenorphine treatment is best understood as an effort to restore a medical treatment model and a more coherent public health approach to what has become an intractable medical, legal, and social problem.

## Historical Overview

### OPIOID USE DISORDER 1830–1899

In eighteenth-century America, opium extracts such as laudanum, which contained alcohol, and black drop opium, which contained no alcohol, were common ingredients in a wide range of prescriptions and patent medicines. These medications were used to treat food poisoning and other gastrointestinal problems and were valued for their sedating and calming effects.

The first apparent opioid problem in the United States occurred in the early nineteenth century, when patent medicines laced with tincture of opium were readily available from apothecaries or door-to-door peddlers. Because the drugs were cheap, individuals with mild OUD had no problem maintaining medication supplies and had relatively little functional disability. The typical misuser of opioids at that time was a white, middle-class farm housewife who became addicted while self-medicating a wide range of physical and psychological ailments. Although some individuals were more impaired by their OUD, there was no association with criminal behavior. At worst, the individual with OUD was perceived as “sickly” or neurasthenic (Musto 1999). Physicians and the public associated the risk of problems with the lower social classes. These risks were noted, but they were thought to be minimal and to be balanced by the medicinal benefits of opium. Some physicians even claimed that opiates could improve the functioning of strong-willed individuals (Wood 1856).

Advances in technology in the early nineteenth century permitted the isolation of specific alkaloids from crude opium and led to the identification of morphine as a potent agent with significant physiological and psychological effects. Commercial morphine production began in the United States in 1832. The invention of the hypodermic syringe permitted the direct injection of this powerful and habit-forming substance and opened the door to both more effective pain treatment and increased risks for OUD.

A second and more visible group of individuals with OUD were Civil War veterans who became physiologically dependent on intramuscular morphine after being treated for combat injuries. By 1870, some physicians began to recognize the habit-forming risk of morphine injections, although injectable morphine was thought to present less of a dependence risk than oral opium preparations (Allbutt 1870). In the decades following the Civil War, it became common medical practice for physicians to give patients morphine as long-term therapy to manage chronic pain. This morphine dependence syndrome was called *soldier's disease*, a reflection of the origin of the disorder, the relatively acceptable social status of the patient, and the medical paradigm that informed society's understanding of the condition. During the late nineteenth century, rates of morphine dependence in the United States far exceeded those of other

Western industrialized nations. Although this was commonly attributed to the aftermath of Civil War injuries, other major European nations also experienced wars and extensive use of morphine without having comparable rates of OUD (Musto 1999). The reasons for the high levels of U.S. opium consumption and the unique vulnerability to OUD in this country have never been adequately explained.

In the United States, social attitudes regarding the long-term use of opiates began to shift with the increased immigration of Chinese laborers and growing public concern about the devastating effects of opium misuse in China. This change in attitudes, along with the growth of the Temperance Movement, led to a fear of OUD as a dangerous, foreign, “un-American” problem that needed to be eradicated. These attitudes led to a decline in the per capita consumption of crude opium, which was first noted in 1887. By the end of the nineteenth century, the conceptual paradigm for OUD had shifted from a medical model to a moral and criminal justice model—a conceptual ambiguity that continued throughout the twentieth century. Although the medical value of morphine was not questioned, physicians gradually came to recognize the dangers associated with overprescription of this drug. There was a perception that the risks of addiction were most prevalent in immigrant groups such as the Chinese and in the lower social classes. It was presumed that the social deterioration associated with chronic opiate use was a reflection of the user’s weak character and lack of morals. Very gradual dose reduction, or *detoxification*, was thought to be the cure, although it was recognized that successful treatment requires a high level of motivation. In Germany, there were reports of high relapse rates following attempts to wean patients from morphine, and it was hypothesized that regular use of morphine would induce predictable physiological changes that would make anyone an addict (Levinstein 1878). These observations contrasted with the dominant opinion in England and in the United States and supported the notion that the moral deterioration associated with OUD was a consequence of the disorder and not the cause.

## OPIOID USE DISORDER 1900–1914: MORPHINE MAINTENANCE CLINICS

By 1900, there were an estimated 250,000 individuals with OUD in the United States (Musto 1973, p. 5). In many cities, efforts to manage the problem medically shifted from the individual physician’s office to a system of morphine clinics, where groups of individuals with OUD were given daily morphine injections. In some cities, these clinics were administered by law enforcement authorities, a further reflection of the confusion between the medical and criminal justice paradigms. OUD was lumped together with alcoholism and syphilis as