

## **Opioid Addiction Treatment: An Overview**

Opioid Treatment Programs (OTPs) provide outpatient services to individuals who are addicted to opioid drugs, which include both natural opioids such as opium, morphine and codeine products, and pure, semi- or totally synthetic opioids such as heroin, oxycodone and hydrocodone. OTP services include dispensing of the clinically appropriate daily dose of an opiate agonist or partial opiate agonist drug, either methadone or buprenorphine, to prevent withdrawal from illicitly obtained opioids, prevent or minimize cravings for illicit opioid drugs, and prevent or minimize any euphoria or “high” if illicit opioids are used. OTP medications are accompanied by counseling, education, referral and other supportive services. Individuals in opioid addiction treatment may receive OTP services for short period or long periods of time depending on their individual needs, and the goal of treatment is to help the individual live a productive lifestyle on the lowest possible dose of medication and to eliminate the medication entirely if possible. In 2008, Indiana opioid treatment programs provided services to 12,898 persons<sup>1</sup>, and the numbers receiving this type of outpatient treatment in Indiana have increased more than three-fold since 1998, when data were first reported to State authorities.

As of November, 2008, an estimated 260,000 persons were receiving methadone maintenance treatment in the U.S., with over a fourth of the total treated in the States of New York and California. According to the SAMHSA DPT's Nick Reuter, as of the same month, only four States prohibited establishment of OTPs (North and South Dakota, Montana and Wyoming), and there were 1,201 OTPs operating in the other 46 States. Cost-benefit analyses have indicated savings of between \$4 and \$5 in health and social costs for every dollar spent on MMT in this country. When compared to the cost of incarcerating addicts in the U.S. (\$20,000 to \$40,000 per year), MMT cost ranges between \$13,000 and \$20,000 per year, usually paid by the patient. This overview is not intended to be "everything you wanted to know about..." opioid addiction treatment but will add to what your knowledge about this important recovery intervention.

### **Regulation of Opioid Addiction Treatment**

Because they use controlled substances to treat opioid addiction, OTPs are highly regulated, certified or registered by two federal agencies<sup>2</sup> and certified, licensed or approved by two State agencies<sup>3</sup>. The Indiana State agency responsible for certification and approval of OTPs, the Indiana Family and Social Services Administration (FSSA) Division of Mental Health and Addiction (DMHA), is guided by Indiana Administrative Code (440 IAC 4.4) and State law (IC 12-23-1-6 and 12-23-18) and serves as the State

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<sup>1</sup> Data from the Indianapolis Veterans Administration Hospital, which also provides opioid addiction treatment services, are not included in this number because this hospital is not regulated by the State and does not report data to the State.

<sup>2</sup> Certification is required by the U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment (CSAT) Division of Pharmacologic Therapy (DPT), and registration is required by the Department of Justice Drug Enforcement Administration.

<sup>3</sup> Both certification and approval are required by the Indiana Family and Social Services Administration Division of Mental Health and Addiction, and licensure is required by the Indiana Professional Licensing

Opioid Treatment Authority (SOTA) in its relationship to the federal government. The federal certification under 42 CFR Parts 8.11 and 12 requires behavioral health accreditation by an approved accrediting body such as the Joint Commission or CARF - the Commission on the Accreditation of Rehabilitation Facilities. Accreditation is generally granted and renewed for three-year periods, unless there are conditions on the accreditation which require resolution and a return monitoring visit. Before OTPs can provide services, they are required to obtain DMHA certification, DMHA SOTA approval, DEA registration and Indiana Professional Licensing Agency licensure and must remain in good standing with all these agencies to continue operation. Currently, IC 12-23-18 prohibits establishment of new Indiana OTPs, and at the present time, 14 OTPs have approval to provide services.

Federal regulation of treatment of opioid addiction can be traced back to the Harrison Narcotic Act of 1914, before which time opioid addiction treatment was carried out in physicians' offices. For many years, Indiana relied on federal regulation<sup>4</sup>, State law and State addiction services certification rules to oversee Indiana OTPs. In 2008, Indiana Senate Enrolled Act 157 amended IC 12-23-18 and required DMHA to promulgate State OTP rules, both for program and facility oversight. As of July, 2009, the proposed rules, 440 IAC 10-3 and 4, are moving through the promulgation process, with an expected effective date of January, 2010. Among new requirements in the proposed rules are an annual facility inspection and specifications concerning OTP maintenance of SOTA approval, including daily attendance for patients who test positive on drug screens until illicit use ceases, staff-to-patient ratios for OTP counselors, nurses and physicians, and penalty provisions if an OTP fails to meet either SOTA approval or facility certification requirements or both. SEA 157 and the proposed rules also require OTPs to pay an annual per-patient fee based on DMHA's previous year cost of administering the rules' provisions.

Among the provisions of the pre-2008 version of IC 12-23-18 were those giving DMHA authority to conduct annual regulatory OTP audits; authority to establish an electronic central patient registry to facilitate OTP data reporting to the Governor and Legislative Council and to prevent patients from simultaneously enrolling in more than one Indiana OTP; authority to collect annual per-patient fees for patients who reside outside of Indiana; and a requirement for OTPs to submit and for DMHA to approve annual diversion control plans. These provisions remain effective.

### **Important Public Awareness and Education Efforts**

Because the prevalence of illicit use of both prescription and illegally obtained pain relievers, predominantly opioid drugs, remains at concerning levels<sup>5</sup>, and because many individuals continue to question the value of "using a drug to treat drug addiction," it is important that efforts continue to be made to increase the public's familiarity with opioid

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<sup>4</sup> Prior to SAMHSA, regulation was through the U.S. Food and Drug Administration (FDA).

<sup>5</sup> According to 2008 *Data Highlights* from the Indiana University School of Public and Environmental Affairs Center for Health Policy, prevalence of past-year non-medical use of prescription pain relievers is greater in Indiana (5.9%) than the U.S. (5%) and even higher among 12-17-year olds (7.9% in Indiana compared with 7% in the U.S.). Past-year use of the illegal drug heroin, although low, is estimated at .2% in Indiana and across the Nation.

addiction treatment, its purpose and effectiveness. There are many readily accessible sources of authoritative information, including the SAMHSA CSAT DPT at <http://dpt.samhsa.gov/>, the American Association for the Treatment of Opioid Dependence (AATOD) at <http://aatod.org/>, and the National Institute on Drug Abuse (NIDA) at <http://www.nida.nih.gov/> There are also a number of Indiana physicians who are extremely well informed about this mode of treatment, including the U.S. Department of Veterans' Affairs (VA) Hospital's Dr. Chris Suelzer and Midtown Mental Health Center Narcotic Treatment Program's Dr. Ryan Moe. On the national level, experts include Dr. Mary Jeanne Kreek of the Rockefeller University in New York City and Dr. Eugene Somoza of the University of Cincinnati, as well as Mark Parrino, the President of the New York City-based AATOD, and Nicholas Reuter and Todd Rosendale of SAMHSA CSAT DPT.

### **History of Opioid Addiction Treatment**

Opioids, used licitly to treat pain and illicitly for their euphoric qualities, are addictive, creating tolerance and resultant need to increase dosage to obtain the desired effect. In the United States, late 19<sup>th</sup> century opioid addiction largely resulted from medical use of opioids during the Civil War era<sup>6</sup>, when significant numbers of both veterans and middle- and upper-class women being treated for various symptoms became iatrogenically addicted. During this same period, European immigrants to the United States used opium, cocaine and heroin for non-medical purposes, resulting in incidents of crime, violence and disease in poor urban communities and causing public policy concerns.

During this period in history, opiate medications were not controlled by the government, and treatment of resulting opioid addiction in physician's offices was common. Times changed, and the Pure Food and Drug Act of 1906 required medicines containing opioids to state this on their labels. This was followed by the 1914 Harrison Narcotic Act, interpreted by law enforcement officials to prohibit use of opioids to treat opioid addiction. Nevertheless, faced with continuing problems associated with opioid addiction, between 1914 and 1920, many large cities operated outpatient treatment clinics which used morphine, heroin and/or cocaine to treat opioid addiction. As a result of pressure from law enforcement, which continued to see the patients as criminals, however, most of these clinics were closed by the early 1920s.

Crime associated with acquisition of illicit opioids continued to be reported in cities throughout the country<sup>7</sup>, however, and in 1929, federal funds were made available to establish two residential treatment facilities, one in Fort Worth, Texas, and one in Lexington, Kentucky. Although these programs, which operated between the mid-1920s and the mid-1970s, accepted voluntary patients, the large majority of their patients were serving sentences or committed through a federal court for a drug offense. Treatment consisted largely of decreasing doses of heroin and morphine, but because of the drugs' short duration of action, euphoric effects and increasing tolerance, administration was required several times a day, and patients were reliant on treatment staff and the program

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<sup>6</sup> Known as Soldiers' Disease at that time.

<sup>7</sup> Tip 43, "*Medicated-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*," is the source of this historical information.

to function. Outpatient care was not considered feasible due to the need for frequent administration of the treatment medication. Although these programs provided a full range of services and were well-staffed, they were described as 'prison-like,' and follow-up studies on released patients found high relapse rates.

By the mid-1960's, heroin-related mortality was the leading cause of death for young adults between 15 and 35 in New York City<sup>8</sup>, and associated increases in incidence of serum hepatitis and drug-related crime were a concern to society. Opioid addiction had continued to be treated with decreasing doses of heroin and morphine, but in the early 1960s, Rockefeller University researchers determined that use of a long-acting oral opiate agonist, methadone, was worth testing for its efficacy with opioid addicts. The research on the use of methadone for opioid addiction done at that time found that when administered methadone:

- Opioid addicts did not experience euphoric, tranquilizing or analgesic effects;
- At a dose between 80 and 120 mg/day, tolerance to the narcotic effects of all opioid drugs was held at a level high enough to block their euphoric and tranquilizing effects if the patient administered them by injection or smoking;
- There was no change in tolerance levels over time, and the methadone dose could be held constant indefinitely;
- Methadone was effective when administered orally and could be taken once a day without the use of injection needles;
- Methadone relieved the narcotic craving described by addicts as a major factor in relapse and continued illegal opioid use; and
- Methadone was medically safe and nontoxic, with minimal side effects which usually decreased as treatment continued.

Further studies between 1965 and 1970 found that these positive results persisted, and in 1970, the federal government commissioned two groups to provide policy and program recommendations for initiatives to respond to increasing heroin addiction in urban areas. A group led by the National Institute on Mental Health (NIMH) recommended that continued research was indicated to prove the effectiveness of methadone as a treatment for opioid addiction, while a group made up of treatment program directors and researchers in drug addiction treatment recommended that treatment availability be expanded, including treatment with methadone. The latter group's recommendations formed the basis for early 1970's decisions which have guided the development of opioid addiction treatment in the U.S/ through OTPs since that time.

### **Federal Regulation of Opioid Treatment Programs**

Federal regulation of the treatment of opioid addiction has its more recent origins in 1970, when Congress passed the Controlled Substances Act of 1970 (CSA), which requires all manufacturers, distributors and practitioners who prescribe, dispense, to administer controlled substances to register with the Drug Enforcement Administration (DEA). In 1971, the recommendation of the group advocating that opioid addiction treatment availability be expanded became federal policy under the leadership of Dr.

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<sup>8</sup> Ibid.

Jerome Jaffe, the Director of the Special Action Office for Drug Abuse Prevention. Dr. Jaffe set a goal of promulgating Food and Drug Administration (FDA) regulations that would govern the use of methadone to treat opioid addiction. In 1972, the FDA issued these regulations, which governed eligibility, evaluation procedures, dosages, take-home medications, frequency of patient visits, medical and psychiatric services, counseling, support services, and related details for methadone treatment programs. These regulations also restrict the use of methadone to treat opioid addiction to treatment programs governed by the regulations.

In 1974, the DEA was given authority by Congress to play a role in regulating methadone clinics. The Narcotic Addiction Treatment Act of 1974 (NATA), which amended the CSA of 1970, recognized the use of an opioid drug to treat opioid addiction, defined maintenance treatment of opioid addiction, required separate DEA registration by medical practitioners who dispensed opioid drugs to treat opioid addiction, and increased coordination between the Department of Health and Human Services and the DEA. The NATA also established the National Institute on Drug Abuse (NIDA) as an institute independent of the National Institute of Mental Health and split authority to regulate the treatment of opioid addiction between NIDA and the FDA, with NIDA responsible for determining appropriate standards for the public health aspects of drug treatment and the FDA given authority to determine the safety and effectiveness of drugs and the approval of new drugs for opioid addiction treatment. In 1980, NIDA and the FDA agreed to jointly develop methadone maintenance treatment regulations.

The Drug Addiction Treatment Act of 2000 (DATA) amended a part of the CSA mandating separate registration for practitioners who dispense opioids in addiction treatment, allowing physicians meeting certain qualifying criteria to dispense or prescribe Schedule III, IV or V controlled substances specifically approved by the FDA for medicated-assisted treatment (MAT). The 1972 FDA regulations governing treatment of opioid dependence, modified during the 1980's, were in effect until 2001, when responsibility for oversight of programs using methadone to treat opioid addiction was transferred to the SAMHSA CSAT DPT, which instituted a regulatory model using accreditation in place of the FDA's compliance orientation. Final SAMHSA regulations governing the use of methadone and another FDA-approved Schedule II drug, LAAM, to treat opioid addiction, 42 CFR Part 8, became effective May 18, 2001. In 2002, the DEA classified buprenorphine as a Schedule II drug and made it the first drug approved for treatment of opioid addiction in physicians' offices. Private-practicing physicians who are certified under a waiver obtained through the DPT may treat up to 100 patients at a time and have the capacity to refer patients for needed counseling and other ancillary services.

Today, only opioid treatment programs (OTPs) certified under 42 CFR Part 8 and registered by the DEA are allowed to utilize methadone, which is commonly prescribed for pain by physicians, in the treatment of opioid addiction. Methadone, a full agonist, may be more suitable to more highly-dependent patients to treat opioid addiction, although buprenorphine is also effective and is being increasingly used for this purpose in these programs. A proposed 2009 federal rule would modify the dispensing requirements

for approved buprenorphine products in OTPs, placing them under the same time-in-treatment requirements for unsupervised medication as are in place for methadone.

### **Best Practices in Opioid Treatment**

As stated above, in the early 1960s, Rockefeller University researchers determined that use of methadone to treat opioid addiction was highly effective, resulting in positive treatment outcomes for both the addict and society. Between 1972 and 2001, FDA-regulated programs all over the U.S. provided services to opioid addicts, which supported their return to healthy societal functioning and movement away from use of illegal drugs and accompanying crime. In 1997, a National Institutes of Health (NIH) consensus panel called for expansion of methadone maintenance treatment and identified barriers including the public's misperception of opioid addiction not as a disease but as a moral failing and overregulation of treatment limiting flexibility and responsiveness of treatment programs to individuals' needs. The panel recommended federal leadership to educate the public that opioid addiction is a medical disorder which can be treated effectively, increased access to methadone treatment for persons under legal supervision, increased funding for methadone maintenance treatment and reduction of unnecessary regulation. As stated earlier, FDA regulation of opioid treatment programs was transferred to the SAMHSA CSAT DPT in 2001.

In 2005, SAMHSA published its Treatment Improvement Protocol (TIP) 43, "Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs," which provides best-practice guidelines for opioid addiction treatment in opioid treatment programs based on the experience and knowledge of clinical, research and administrative experts.

### **Use of Methadone, Treatment Goals and Objectives**

Methadone is a long-acting synthetic opioid agonist medication in use since the 1960s to treat heroin and other opioid addiction. Methadone treatment is generally divided into two forms, maintenance and detoxification, and there are requirements for each in the federal regulations guiding treatment in opioid treatment programs, 42 CFR Part 8.

The goals of methadone maintenance treatment include reduction in illegal opioid use and the crime, death and disease associated with addiction to opioids, which include natural, pure, semi- or totally synthetic forms. Natural opioids include opium, morphine and codeine products; pure forms include heroin; and semi- or totally synthetic forms include meperidine hydrochloride, propoxyphene hydrochloride, buprenorphine, methadone hydrochloride, oxycodone hydrochloride, dihydromorphone hydrochloride, fentanyl, and others, marketed under various names, including Dilaudid, Demorol, Methadone, Darvon, and Suboxone. The goal of methadone detoxification is to eliminate an individual's use of all opioids.

The principal behind methadone maintenance treatment is that persons who have used opioids for a considerable period of time (at least one year) and who become addicted may have modified their brain chemistry in a permanent or semi-permanent way, resulting in a need for an opioid agonist on a short- or long-term basis to function well.

Another principal is that some persons who become addicted to opioids had brain chemical deficits prior to their opioid addiction and that these chemical deficits and resultant compromised (to varying degrees) brain functioning are improved with regular use of an opioid agonist as a medication, again possibly on a long-term basis. Used as a regularly taken medication, at the appropriate dose, methadone eliminates an addict's craving for opioids, reduces or eliminates illicit drug use and allows individuals to function well, to either resume or accomplish productive living. At the appropriate dose, methadone does not cause euphoria, sedation or analgesia and has no adverse effects on motor skills, mental capacity or employability. Medication levels vary based on each individual's needs, and side effects, even from long-term (20-30 years) use, have been found to be few. In addition to the medication, individuals addicted to opioids and receiving treatment for opioid addiction benefit from varying amounts of counseling as they learn or relearn and practice productive living skills. Individuals addicted to opioids who additionally have a mental health disorder and individuals who have other physical health problems benefit from treatment for these conditions concurrently with treatment for opioid addiction.

### **Indiana Opioid Treatment and Regulatory Practices**

As mentioned earlier, in 2008, Indiana opioid addiction treatment programs (OTPs) provided services to 12,898 persons, and as of November, 2008, there are 15 OTPs in the State, 14 of which come under the oversight of DMHA. The 15<sup>th</sup> falls under the oversight of the federal government, is operated by the U.S. Veterans Administration (VA), and is located in Indianapolis on the campus of Indiana University-Purdue University Indianapolis (IUPUI). DMHA provides partial funding for three of the 14 OTPs under its oversight, those operated by community mental health centers, Midtown Community Mental Health Center in Indianapolis, Edgewater Systems for Balanced Living in Gary, and Porter-Starke Services in Valparaiso. The other 11 OTPs are operated by private companies. As of the date of this report, only one of the OTPs receives Medicaid reimbursement for qualified patients (Edgewater Systems for Balance Living), and the majority of OTP treatment costs are born by the patients themselves.

The SOTA (formerly the SMA, or State Methadone Authority) is a role established by SAMHSA, and in Indiana, it is filled by the FSSA DMHA. Indiana's SOTA is the Deputy Director for Addiction and Emergency Preparedness Services within DMHA, assisted by the Assistant Deputy Director for Opioid Addiction Treatment Services. The federal regulations governing establishment and operation of OTPs do not define how OTPs gain SOTA approval, nor do they preclude States from enacting regulations "necessary to carry out their responsibilities regarding opioid treatment". While some States have prohibited establishment of OTPs, many States have put more stringent State regulations in place.

Although federal regulations do not define what is required of States to grant approval of OTPs, SEA 157, enacted during the 2008 session of the Indiana General Assembly, prohibits establishment of new OTPs. Additionally, in addition to requiring annual OTP facility certification, SEA 157 requires that DMHA promulgate OTP rules regarding a number of program areas, including what drugs OTP patients are tested for, procedures to

follow when patients test positive for illicit drugs while in treatment, establishment of staff-to-patient ratios for treatment staff providing OTP services. SEA 157 also requires OTPs to pay an annual per-patient fee to DMHA to cover the costs of administering oversight of OTPs and gives DMHA authority to enforce the treatment and annual facility certification rules. OTP program oversight lies with the SOTA and in this capacity, the SOTA works closely with DMHA Certification and Licensure, which handles OTP addiction provider and facility certification responsibilities.

For more information, see the resources identified above or contact Louise Polansky at [Louise.Polansky@fssa.in.gov](mailto:Louise.Polansky@fssa.in.gov) or 317-232-7841.