

# METHADONE FAQs

## *Is Methadone an effective treatment for opioid addiction (efficacy)?*

Benefits of Methadone Maintenance Therapy:

- Reduced/stopped use of injection drugs
- Reduced risk of overdose (OD)
- Reduced risk of acquiring or transmitting diseases such as HIV, HEP, infections, TB, STDs and other contagious diseases
- Reduced mortality – median death rate of opiate-dependent individuals using methadone is 30 percent of the rate of those not using methadone
- Reduced criminal activity and associated costs
- Improved family and employment stability
- Improved pregnancy outcomes
- Use has proved effective and safe for over 40 years
- Properly prescribed use is not intoxicating or sedating
- Effects do not interfere with ordinary activities
- Suppression of opioid withdrawal for 24-36 hours

Overall, Methadone treatment is extremely cost-effective. The degree of effectiveness is dependent on proper individual dosing, length of treatment, attention to other client issues and managing relapse.

Attachment #1 - Heroin Data (potency, cost, availability)

Attachment #2 - CIS Data, Heroin and Other Opiate Admissions, 2004-05 to 2008-09

## *Is Methadone used for pain treatment or addiction treatment?*

- Methadone is used in Pennsylvania for both addiction treatment and pain management.
- PA Department of Health's Division of Drug and Alcohol Program Licensure (DAPL) has regulatory oversight of methadone in addiction treatment centers in the commonwealth through 28 Pa. Code § 715.1 (Narcotic Treatment Program regulations) and through the appropriate licensing regulations at 28 Pa. Code §§ 709.21, 709.91, 704.1 and 705.21.
- Pennsylvania does not regulate pain management clinics.
- Methadone is an important medication for the treatment of opioid-use disorders and for chronic pain:
  - Well-studied, safe, and powerful medication when prescribed and consumed properly
  - Use in the treatment of drug addiction has been effective for 40 years
  - Use for the treatment of pain has increased in the last 5 to 10 years

- Dispensing via methadone clinics aids in confronting opioid addiction
  - Prescriptions through private physicians for chronic pain
- Federal officials and experts in epidemiology, pain management and addiction treatment at the Substance Abuse and Mental Health Services Administration's (SAMHSA) National Assessment of Methadone-Associated Mortality in 2003 acknowledged a correlation between the increased distribution of methadone through pharmacies for pain management with an increase in methadone-associated overdose deaths and reached a consensus that the increase in these deaths was not associated with addiction treatment in Narcotic Treatment Programs (NTP).

***How do patients obtain Methadone (Methadone Clinics vs. Private Physicians)?***

- Admission to a NTP program licensed and approved by DAPL for methadone maintenance services
- Intake process for new patients is outlined at 28 Pa. Code 715.9 – Intake
  - Prospective patient must verify his/her identify, including name, address, date of birth, emergency contact and other identifying data.
  - Prospective patient must be able to establish for the Narcotic Treatment physician at least a one year history of drug use and demonstrate current drug dependency.
  - Prospective patient must have a face-to-face meeting with the Narcotic Treatment Program physician for determination that individual is currently physiologically dependent upon a narcotic drug and has been physiologically dependent for at least one year prior to admission for maintenance treatment.
- NTP explains options and treatment regimen and patient responsibilities prior to admission (see 28 Pa. Code 715.9 for additional detail).
- National Institute on Drug Abuse (NIDA) notes that one year is generally the minimum for methadone maintenance treatment, and that some individuals benefit from treatment over several years.
- Methadone used in addiction treatment must be dispensed by an NTP which is certified by SAMHSA, registered with DEA and licensed and approved by DAPL. In addition, the procedure for dispensing methadone in an NTP is Directly Observed Treatment (DOT), where the clinician directly observes the client consuming the methadone. For pain management methadone is provided via prescription by a physician, and is consumed by the patient without any direct observation.
- Nationally, over 1200 NTPs in a large majority of the states have been certified by SAMHSA and registered with DEA:
  - Only a few states do not have NTPs.
  - Pennsylvania currently has 59 NTPs.
  - Over 15,000 patients receiving treatment in Pennsylvania NTPs.
- DAPL has no control or authority over pain management clinics that utilize methadone
  - Pain management clinics using methadone are not subject to 28 Pa. Code, Chapter 715.

- No commonwealth agency regulates the operation of pain management clinics using methadone.

### ***How is Methadone regulated?***

- Entity must apply for and receive licensure and approval from DAPL, register with the Drug Enforcement Agency (DEA); and be certified by SAMHSA's Center for Substance Abuse Treatment (CSAT) prior to offering services as a Narcotic Treatment Program:
  - Application for approval must be made simultaneously to DAPL, DEA and CSAT.
  - DAPL and DEA coordinate initial inspections and work to provide notice of approval to CSAT simultaneously.
- State methadone regulations are included in 28 Pa. Code Chapter 715, Standards For Approval of a Narcotic Treatment Program.
- Act 63 of 1972 (71 P.S. §§ 1690.102 through 1690.112) "Pennsylvania Drug and Alcohol Abuse Control Act" with Reorganization Plan No. 2 of 1977 (which transfers from the Department of Public Welfare to the Governor's Council on Drug and Alcohol Abuse the functions, powers and duties relating to the regulation, supervision and licensing of drug and alcohol facilities) and Reorganization Plan No. 4 of 1981 (which transfers the functions, powers and duties relating to the regulation, supervision and licensing of drug and alcohol facilities from the Governor's Council on Drug and Alcohol Abuse to the Department of Health).
- Federal methadone regulations are included in 42 CFR Part 8, Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction.
- NTPs in Pennsylvania at a minimum undergo one annual licensing inspection and one methadone monitoring inspection by DAPL.

### ***What are the effects of Methadone diversion?***

- Published reports generated by the American Association for the Treatment of Opioid Dependence (AATOD), SAMHSA/CSAT, the Department of Justice Drug Intelligence Center report of November 2007 and the General Accounting Office's report of March 2009 all reached one general conclusion. The increase in methadone-associated mortality in the United States is directly related to the increasing use of methadone in the treatment of chronic pain and not to its use in treating chronic opioid addiction in the network of the nation's Narcotic Treatment Programs (NTPs).
- According to the United States Department of Justice's National Drug Intelligence Center November 16, 2007 Assessment: Methadone Diversion Abuse, Misuse and Use: Deaths Increasing at Alarming Rate, "*Most methadone deaths are the result of methadone diverted from hospitals, pharmacies, practitioners, pain management physicians and, to a much lesser extent, Narcotic Treatment Programs and used in combination with other drugs and/or alcohol.*"
- Participants at SAMHSA's 2007 Methadone-Associated Mortality Reassessment concurred that the circumstances of methadone-associated overdose deaths vary by state. Generally more of those who died had a prescription for methadone or obtained it through diversion rather than receiving methadone for addiction treatment in an NTP.

### *What are the mortality issues related to Methadone?*

- 2006 CDC researchers suggested that the increase in deaths involving methadone was related to physicians increasingly prescribing the drug for pain.
- Increase in deaths tracked the increase in methadone used for pain management rather than its use in NTPs.
- Methadone is life saving, yet it presents special challenges:
  - Some pharmacologic and pharmacokinetic properties of methadone can lead to harm if it is misused or used for nonmedical purposes.
  - Short duration of analgesic effect with methadone and significantly longer elimination half-life increase the risk for methadone toxicity (FDA web-site).
- Methadone can cause fatalities among individuals who have not developed any tolerance to opiates:
  - Deaths have occurred among children and adults who have accidentally taken methadone.
- Fatal intoxications have also been observed during the first weeks of treatment and adjustment of the methadone dose.
- Methadone associated deaths have continued to rise since the 2003 National Assessment meeting:
  - Methadone overdose deaths are real and substantial.
  - Deaths also have been escalating for other opioids such as oxycodone and hydrocodone.
- Several risk factors for methadone-related mortality have been identified:
  - Concomitant use of benzodiazepines, other opioids, and/or alcohol
  - Elevated risk of some patients for Torsades de Pointes (a cardiac rhythm disorder)
  - Inadequate or erroneous induction dosing and monitoring by physicians, primarily when prescribing methadone for pain
  - Drug poisoning that occurs as a result of diversion of the drug and its nonmedical use
  - A study by Zanis & Woody (1998) prospectively followed up 507 Methadone Maintenance Treatment (MMT) patients for 1 year. Among the 110 patients who were discharged 8.2 percent had died, while only 1 percent of the 397 patients who remained in MMT had died. Reasons for leaving treatment were either dropping out or discharged unfavorably from the program. There are several other studies that have documented increased death rates for opioid dependent patients who leave or are terminated from MMT.
- Federal officials and experts in epidemiology, pain management and addiction treatment at SAMHSA's National Assessment of Methadone-Associated Mortality in 2003 also acknowledged a correlation between the increased distribution of methadone through pharmacies for pain management with the increase in methadone associated overdose deaths and reached consensus that the increase in these deaths was not associated with addiction treatment in NTPs.

**Participants of a multidisciplinary group of more than 60 experts convened by SAMHSA in 2007 reported six overall findings:**

- Methadone associated deaths continue to rise, supported by medical examiner, toxicology, and other data sources.
- Males 35 and older had the highest rate of methadone associated deaths, approximately twice that of females.
- The reason for the majority of methadone associated deaths is often unknown; if known, it is largely the result of accidental exposures.
- Forms of methadone distribution continue to rise, with the greatest increases in distribution for the tablet form and going to pharmacies.
- Prescriptions for methadone have risen, although they are far lower than for other opioids.
- Circumstances of methadone associated deaths vary by state, suggesting a complex phenomenon.

***What are the services a person who is on methadone receives from a methadone clinic?***

- Daily methadone dose determined by the program physician:
  - Methadone is administered only in oral (liquid) form and dosing is observed by medical staff.
- Random urine drug screening occurs minimally once a month (does not include initial drug screen required for admission).
- Minimum of 2.5 hours of counseling per month
  - Additional counseling is provided based upon the clinical assessment and identified treatment needs.
- NTP must provide, either on-site or via referral agreements, a full range of health, social and rehabilitative services which included HIV education, employment services, adult education, behavioral health services and legal referrals.

***Why can't patients being treated with Methadone simply be transferred to treatment with buprenorphine?***

- Two buprenorphine products – Suboxone or Subutex
  - Suboxone is a combination of buprenorphine and Naloxone (opioid antagonist).
  - Subutex is buprenorphine without the antagonist.
- Patient methadone dose must be 30mg or less.
- Patient on higher dose needs to voluntarily taper over time to reach 30mg.
- Patient would experience withdrawal symptoms and increase risk for relapse. However, patient must first experience withdrawal symptoms before being inducted to Buprenorphine.

- Patient may not be appropriate for buprenorphine treatment:
  - Co-morbid dependence on benzodiazepines, alcohol or other central nervous system depressants
  - Untreated psychiatric issues
  - Chronic suicidal and/or homicidal ideation
  - Frequent relapses during previous treatment attempts
  - Unsuccessful past treatment episodes with buprenorphine
  - Significant medical complications
- Disadvantages of buprenorphine versus methadone maintenance:
  - Greater medication costs (Attachment #3)
  - Not pharmacologically suited for all patients due to chemistry, dose and the severity of an individual's addiction
  - Access - not enough physicians that have the DEA waiver to prescribe buprenorphine for addiction treatment:
    - Limited to 30 patients during first year
    - Limited to 100 patients after first year
    - 15,000 plus methadone maintenance patients in the commonwealth
    - No requirement for behavioral health counseling
    - Structured behavioral treatment experience for favorable outcome

***Why do some patients have problems transferring from one Methadone program to another?***

- 28 Pa. Code § 705.20 – Patient Transfers
  - Narcotic Treatment Program (NTP) must have written policy and procedures regarding patients' requests to transfer.
  - Transfer should be within seven days of the patient's request.
  - Transferee may be known to the NTP in their communities and may encounter difficulty with transfer due to previous unsatisfactory compliance issues.
  - NTP may be at its maximum capacity, and the patient may have to be added to a waiting list for admission.
  - Patient may be requesting transfer to an NTP which does not accept patient's funding source.
  - Patient would be able to transfer, but would be responsible for payment of services.

### ***Why does MA pay for Methadone treatment?***

- Methadone treatment services are included in the Pennsylvania State Plan as a covered service under MA because they are effective in treating heroin and other opioid dependence.
  - Pennsylvania is among 43 states that provide methadone treatment under their Medicaid program as a treatment option for opioid dependence.

### ***How do MA patients on Methadone treatment overcome transportation barriers?***

- Medical Assistance Transportation Program (MATP) is designed to ensure that individuals can get to the medical services they need under the Medical Assistance (MA) program:
  - Federal rules require the mode of transportation must be the least costly appropriate mode.
  - MATP is county based, and each county administrator evaluates an individual's transportation needs and determines the most appropriate and least costly method.
  - Reimbursing mileage for people to transport themselves to medical services, including methadone maintenance, is often the least expensive way to ensure that they receive treatment.
- There are now 59 licensed and approved methadone maintenance providers in the Commonwealth of Pennsylvania.
- County MATP offices are responsible for ensuring that all transportation carriers have procedures for the prevention, detection and reporting of suspected fraud and abuse of all types, including any that may be related to methadone.
- DPW requires county MATP offices to report suspected fraud to the appropriate regional office of the Office of Inspector General, whose agents handle fraud prevention activities and fraud prosecutions and recoveries.

## **Attachment #1**

### Heroin Data (potency, cost, availability)

(Associated Press, 5-27-2010)

- Ultra-potent heroin is now available for \$10/bag.
- In the 1970s heroin was around 5 percent pure; now it is often 50 percent and as much as 80 percent pure.
- Greater potency allows more heroin users to snort or smoke heroin and achieve a sustained high. This is attractive for teens and suburbanites who don't want to risk HIV, HEP C or track marks. The effect is to open up heroin to a whole different group of users.
- Concern is that the high potency, low price and easy availability will widen the drug's appeal, much as crack did for cocaine decades ago.
- More of the heroin is coming from Mexico. Seizures at the border quadrupled from 2008-2009, from around 44 pounds to more than 190 pounds.

**Attachment #2 – Client Information System (CIS) Data, Heroin and Other Opiate Admissions, 2004-05 to 2008-09**

**Statewide Data**

**Under 18 - Paid by SCA**

|  | <b>2004-<br/>2005</b> | <b>2005-<br/>2006</b> | <b>2006-<br/>2007</b> | <b>2007-<br/>2008</b> | <b>2008-<br/>2009</b> |
|--|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Overall Admissions for clients (Under 18)            | 3,545                 | 3,200                 | 3,241                 | 3,061                 | 2,897                 |
| Heroin Admissions                                    | 96                    | 68                    | 43                    | 34                    | 62                    |
| Other Opiates/Synthetics Admissions                  | 74                    | 60                    | 75                    | 79                    | 114                   |
| <b>Percentage of Statewide Admissions (Under 18)</b> |                       |                       |                       |                       |                       |
| Heroin   | 2.71%                 | 2.13%                 | 1.33%                 | 1.11%                 | 2.14%                 |
| Other Opiates/Synthetics                             | 2.09%                 | 1.88%                 | 2.31%                 | 2.58%                 | 3.94%                 |

**Over 18 - Paid by SCA**

|  | <b>2004-<br/>2005</b> | <b>2005-<br/>2006</b> | <b>2006-<br/>2007</b> | <b>2007-<br/>2008</b> | <b>2008-<br/>2009</b> |
|--|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| Overall Admissions for clients (18 and older)            | 56,485                | 57,516                | 52,652                | 50,504                | 50,257                |
| Heroin Admissions  | 11,964                | 12,642                | 10,664                | 10,019                | 10,498                |
| Other Opiates/Synthetics Admissions                      | 2,855                 | 3,062                 | 3,620                 | 3,587                 | 4,281                 |
| <b>Percentage of Statewide Admissions (18 and older)</b> |                       |                       |                       |                       |                       |
| Heroin   | 21.18%                | 21.98%                | 20.25%                | 19.84%                | 20.89%                |
| Other Opiates/Synthetics                                 | 5.05%                 | 5.32%                 | 6.88%                 | 7.10%                 | 8.52%                 |

**Attachment #3**

Fiscal Expenditure Comparison Methadone vs. Buprenorphine

METHADONE

SFY 08-09

Methadone SCA Total Expenditures - \$7,107,705.00

Methadone (total # of clients who received, per Case Management Resource Report [CMRR]) – 4,169

Average Expenditure per client - \$1704.89

SFY 07-08

Methadone SCA Total Expenditures - \$6,758,971.00

Methadone (total # of clients who received, per CMRR) – 3,921

Average Expenditure per client - \$1723.78

Average Daily Cost of Methadone

The *average* cost (bundled) is approximately \$100.00 *per week*, which includes the cost of the methadone, counseling, and urinalysis (when required). The cost of only Methadone is approximately \$1.00 per dose.

BUPRENORPHINE

SFY 08-09

Buprenorphine SCA Total Expenditures–Non-BDAP Funds - \$328,745.00

BDAP Funds - \$270,608.00

TOTAL - \$599,353.00

Total Clients - 406

Average Expenditure per client (BDAP Funds Only) - \$511.35

Average Expenditure per client (Total SCA Funds) - \$1476.24

Average Daily Cost of Buprenorphine (Reckitt-Benckiser)

2 mg - \$3.37/pill

8 mg - \$6.03/pill

***Buprenorphine Dosage***

It is very difficult to determine an average dose, since this medication is used in a variety of ways (detox, maintenance, pain management [not FDA approved for pain management]).

There is no difference for dosing between Suboxone and Subutex. The **active** ingredient for both is the same, with different formulations. Subutex should not be used in general for outpatient care, unless there is a specific contraindication, such as pregnancy. However, there are no hard and fast requirements in this regard, and the practitioner is free to decide.

***Buprenorphine Sample Dosing Information***

Sample Outpatient Detoxification Dosage

| <u>Dosage</u>                     | <u>Cost (2 mg - \$3.37, 8 mg - \$6.03)</u> |
|-----------------------------------|--|
| • Day 1- 6 mg, range is 4-8 mg    | approximately \$10.11                      |
| • Day 2- 8 mg, range is 4-12 mg   | approximately \$ 6.03                      |
| • Day 3 – 10 mg, range is 4-16 mg | approximately \$ 9.40                      |
| • Day 4 – 8 mg, range is 2-12- mg | approximately \$ 6.03                      |
| • Day 5 – 4 mg, range is 0-8 mg   | approximately \$ 6.74                      |
| • Day 6 – 0 mg, range is 0-4 mg   | \$ 0.00                                    |
| • Day 7 – 0 mg, range 0-2 mg      | \$ 0.00                                    |
| • Day 8 – 0 mg, range 0 mg        | \$ 0.00                                    |

Sample Inpatient Detoxification Dosage

7-Day Flexible

| <u>Dosage</u>     | <u>Cost (2 mg - \$3.37@, 8 mg - \$6.03@)</u> |
|-------------------|--|
| • Day 1 – 4-8 mg  | approximately \$ 7.67 avg.                   |
| • Day 2 – 4-8 mg  | approximately \$ 7.67 avg.                   |
| • Day 3 – 4-6 mg  | approximately \$ 8.43 avg.                   |
| • Day 4 – 0-4 mg  | approximately \$ 3.37 avg.                   |
| • Day 5 – 0-2 mg  | approximately \$ 1.69 avg.                   |
| • Day 6 – no dose | \$ 0.00                                      |

- Day 7 – no dose \$ 0.00

7-Day Fixed

| <u>Dosage</u>  | <u>Cost (2 mg - \$3.37@, 8 mg - \$6.03@)</u> |
|----------------|--|
| • Day 1 – 8 mg | approximately \$ 6.03                        |
| • Day 2 – 6 mg | approximately \$10.11                        |
| • Day 3 – 4 mg | approximately \$ 6.74                        |
| • Day 4 – 4 mg | approximately \$ 6.74                        |
| • Day 5 – 2 mg | approximately \$ 3.37                        |
| • Day 6 – 2 mg | approximately \$ 3.37                        |
| • Day 7 – 0 mg | \$ 0.00                                      |

Sample **Induction** from short-acting opioids (morphine, oxycodone, hydrocodone, heroin, etc.)

- First Dose is 4 mg after moderate opioid withdrawal symptoms have developed.
- After 1-2 hours, if no precipitated withdrawal is observed following first dose, another 4 mg is permitted.
- An additional 4 mg may be given 2-4 hours after first dose.
- Usual first day dose is 8 mg.
- On day 2, if withdrawal symptoms are fully suppressed or no withdrawal symptoms have occurred between doses, 2-4 mg is the dose.
- On day 3, if withdrawal symptoms are fully suppressed or no withdrawal symptoms have occurred between doses, keep the dose the same as day 2. Otherwise, increase by 2-4 mg.
- After 3 days, when stability is achieved, or after a **target dose of 16 mg** or greater is achieved, continue on that dose for 3-7 days.
- Doses should be decreased by 2 mg at a time if intoxication (not withdrawal) occurs.
- **GOAL** – Induce treatment smoothly and suppress withdrawal as completely and rapidly as possible. Failure may lead to other substance abuse to alleviate withdrawal or to treatment dropout.

Sample **Induction** from long-acting opioids (OxyContin, MS Contin, Methadone, etc.)

- Not recommended that patients transfer from Methadone to Suboxone, but there are legitimate medical reasons why it may be appropriate.
- Patients transferring from Methadone to Suboxone may experience discomfort or dysphoria for up to 2 weeks and should be informed of this.
- Initially, it may be best to split the dosage between Methadone and Suboxone. Reduction of Methadone dose by <30 mg/day is normal but should be adjusted according to the patient’s current Methadone dose.

Sample Dose Adjustment/**Stabilization/Maintenance** Following Induction

- GOAL – reach maintenance dose within 1-2 weeks
- 3-7 Days to reach steady-state blood levels
- Following stabilization (2-3 Days), once-a-day dosing should be possible.
- Any dosage adjustment should be in 2-4 mg (increases) or 2 mg (decreases).
- Generally, **stabilization/maintenance occurs at 12-16 mg**. Due to patient variability, each patient should be dosed to clinical effect. Doses greater than 32 mg are not recommended.

Sample Dose **Reduction/Medical Withdrawal** Following Maintenance (Actual reduction rates should be determined for each patient)

| <u>Dosage</u>        | <u>Cost (2 mg - \$3.37@, 8 mg - \$6.03@)</u> |
|----------------------|--|
| • Days 1-4 – 16 mg   | approximately \$12.06/per day                |
| • Days 5-8 – 14 mg   | approximately \$16.14/per day                |
| • Days 9-12 – 12 mg  | approximately \$12.77/per day                |
| • Days 13-16 – 10 mg | approximately \$ 9.40/per day                |
| • Days 17-20 – 8 mg  | approximately \$ 6.03/per day                |
| • Days 21-24 – 6 mg  | approximately \$10.11/per day                |
| • Days 25-28 – 4 mg  | approximately \$ 6.74/per day                |
| • Days 29-32 – 2 mg  | approximately \$ 3.37/per day                |
| • Days 33-36 – 0 mg  | \$ 0.00                                      |