

Legislating for Health and Human Rights: Model Law on Drug Use and HIV/AIDS

Treatment for drug dependence



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This model law resource consists of eight modules, addressing the following issues:

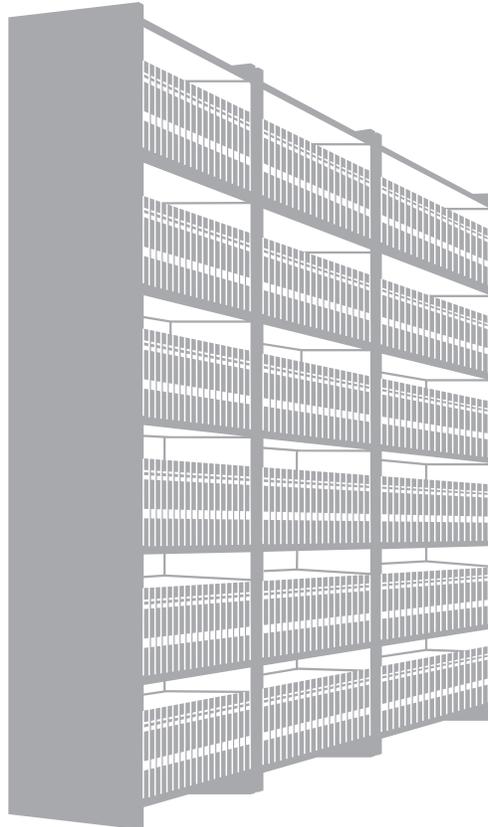
1. Criminal law issues
2. Treatment for drug dependence
3. Sterile syringe programs
4. Supervised drug consumption facilities
5. Prisons
6. Outreach and information
7. Stigma and discrimination
8. Heroin prescription programs

This module, and the other modules, are available in multiple languages on the website of the Canadian HIV/AIDS Legal Network at www.aidslaw.ca/drugpolicy.



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Legislating on Health and Human Rights: Model Law on Drug Use and HIV/AIDS Module 2: Treatment for drug dependence

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About the Canadian HIV/AIDS Legal Network

The Canadian HIV/AIDS Legal Network (www.aidslaw.ca) promotes the human rights of people living with and vulnerable to HIV/AIDS, in Canada and internationally, through research, legal and policy analysis, education, and community mobilization. The Legal Network is Canada's leading advocacy organization working on the legal and human rights issues raised by HIV/AIDS.

Introduction

UNAIDS (the Joint United Nations Programme on HIV/AIDS) suggests that approximately 30 percent of new HIV infections outside sub-Saharan Africa are due to contaminated injection equipment.¹ In eastern Europe and Central Asia, the use of contaminated injection equipment accounts for more than 80 percent of all HIV cases.² Yet, globally, less than five percent of people who inject drugs are estimated to have access to HIV prevention services,³ and even in regions where they account for the majority of HIV infections, people who use drugs are routinely excluded from HIV/AIDS care and treatment.

Many countries with injection-driven HIV/AIDS epidemics continue to emphasize criminal enforcement of drug laws over public health approaches, thereby missing or even hindering effective responses to HIV/AIDS. There is considerable evidence that numerous interventions to prevent HIV transmission and reduce other harms associated with injection drug use are feasible, effective as public health measures and cost-effective.⁴ Despite such evidence, millions of people around the world who use drugs do not have access to such services because of legal and social barriers.

International human rights law establishes an obligation on states to respect, protect and fulfill the right to the highest attainable standard of health of all persons, including those who use drugs. Other human rights are equally relevant in the context of the HIV/AIDS epidemic. When human rights are not promoted and protected, it is harder to prevent HIV transmission, and the impact of the epidemic on individuals and communities is worse. Consequently, UN member states have committed to

enact, strengthen or enforce, as appropriate, legislation, regulations and other measures to eliminate all forms of discrimination against and to ensure the full enjoyment of all human rights and fundamental freedoms by people living with HIV/AIDS and members of vulnerable groups⁵

¹ UNAIDS, *2006 Report on the Global AIDS Epidemic*, May 2006, p. 114. At www.unaids.org/en/HIV_data/2006GlobalReport/default.asp.

² UNAIDS, *2006 Report on the Global AIDS Epidemic*, p. 114.

³ United States Agency for International Development et al, *Coverage of selected services for HIV/AIDS prevention, care and support in low and middle income countries in 2003*, June 2004. At www.futuresgroup.com/Documents/CoverageSurveyReport.pdf.

⁴ See, for example, N. Hunt, *A review of the evidence-base for harm reduction approaches to drug use*, Forward Thinking on Drugs, 2003. At www.forward-thinking-on-drugs.org/review2-print.html.

⁵ *Declaration of Commitment on HIV/AIDS*, UN General Assembly, Res/S-26/2, 27 June 2001, para. 58. At www.un.org/ga/aids/docs/aress262.pdf.

UN member states have also committed to ensuring that a wide range of HIV prevention programs is available, including the provision of sterile injecting equipment and harm reduction efforts related to drug use.⁶

The widespread legal, social and political ramifications of the HIV/AIDS epidemic make it necessary to review and reform a broad range of laws. Some countries have adopted national HIV/AIDS laws, but these laws often ignore crucial policy issues, as well as human rights abuses that perpetuate the HIV epidemic. This is particularly true with respect to illegal drug use. HIV prevention, care and treatment services operate best within a clear legal framework that specifically protects the human rights of people who use drugs and enables harm reduction measures to mitigate the impact of HIV. A legislative framework can provide clarity and sustainability for such services. This is particularly important, given the often dominant approach of criminalizing illegal drug use and people who use drugs, which creates additional barriers to delivering health services. Law reform is not a complete solution to effectively addressing the HIV epidemic among people who use illegal drugs, but it is a necessary and often neglected step.

The model law project

In early 2005, the Legal Network established a project advisory committee and, in consultation with the committee, developed a plan to produce model law that would assist states in more effectively addressing the HIV epidemic (and other harms) among people who use drugs, based on evidence of proven health protection and promotion measures, and in accordance with states' human rights obligations.

Comprehensive consultations were conducted during the drafting of the model law. A draft version of the model law was reviewed by a group of legal experts, harm reduction advocates and government representatives from central and eastern Europe, and countries of the former Soviet Union, during a meeting in Vilnius, Lithuania (7–8 November 2005). The document was modified in line with this feedback and recommendations. In early 2006, the model law was circulated in electronic form to a large number of people and organizations, providing a further opportunity to modify and strengthen the resource. This final document has, therefore, benefited from the thinking of a wide range of experts in the fields of HIV/AIDS, human rights and drug policy.

About this resource

This model law resource is a detailed framework of legal provisions and accompanying commentary. It makes reference to examples of law from those jurisdictions that have attempted to establish a clear legal framework for addressing HIV/AIDS issues among people who use drugs.⁷ This resource also incorporates human rights principles and

⁶ *Declaration of Commitment on HIV/AIDS*, para. 52.

⁷ References to national legal instruments are included in order to demonstrate the feasibility of establishing progressive legal frameworks so that law reform in other jurisdictions can be informed by such examples.

obligations of states throughout the document. It is annotated in order to highlight critical issues and evidence that supports the measures proposed.

This model law resource is designed to inform and assist policy-makers and advocates as they approach the task of reforming or making laws to meet the legal challenges posed by the HIV epidemic among people who use drugs. The model law resource is not intended for any one country or set of countries. Rather, it is designed to be adaptable to the needs of any of a wide number of jurisdictions. In some instances, the model law presents different legislative options for implementing states' human rights obligations. It is hoped that this resource can be most useful for those countries where injection drug use is a significant factor driving the HIV epidemic, and particularly for developing countries and countries in transition where legislative drafting resources may be scarce.

The model law resource consists of eight modules, addressing the following issues:

- (1) Criminal law issues
- (2) Treatment for drug dependence
- (3) Sterile syringe programs
- (4) Supervised drug consumption facilities
- (5) Prisons
- (6) Outreach and information
- (7) Stigma and discrimination
- (8) Heroin prescription programs

Each of the eight modules in this series is a stand-alone document. Each module begins with the introduction that you are reading now; the text of the introduction is identical in all of the modules.

Following the introduction, each model provides a prefatory note, model statutory provisions and a list of selected resources. (Taken together, the model statutory provisions in all eight modules would form a model law addressing HIV/AIDS and drug use.)

The prefatory note presents a rationale for reforming laws and policies in the area covered by the module. This is followed by a discussion of the relevant UN conventions on drug control, and of states' human rights obligations in this area.

The section on model statutory provisions contains provisions that could be included in a model law on HIV/AIDS and drug use. The provisions are divided into chapters, articles, sections and subsections. The first chapter ("General Provisions") describes the purpose of that Part of the model law, and provides definitions for many of the terms included in the provisions.

These references do not imply that the actual practice in the jurisdictions cited represents "best practice." There is often a long way to go in ensuring that actual practice conforms to these legal undertakings.

Some of the provisions are accompanied by a commentary. The commentary provides additional information on, or rationale for, the provision in question. For some model statutory provisions, two options are presented; a note inserted into the text indicates either (a) that one or the other option should be selected, but not both; or (b) that one or the other option, or both options, can be selected. As well, some of the provisions have been labelled as “optional.” This means that these provisions may or may not be applicable, depending on the situation in the country.

The section on selected resources contains a short list of resources which the Legal Network considers to be particularly useful. There are two subsections: one on articles, reports and policy documents, and one on legal documents.

The model law resource is heavily footnoted. The notes provide additional information on the issues being addressed, as well as full references. If the same source is cited more than once in a module, the second and subsequent references to that source are somewhat abbreviated (usually just the name of the author, or organization, and the title of the article or report).

Module 2: Treatment for Drug Dependence

Module 2 contains a prefatory note which discusses the evidence in favour of reforming laws and policies related to treatment for drug dependence, in particular opioid substitution treatment (OST) and which describes relevant international laws and policies, including human rights obligations. This is followed by a section on model statutory provisions. Module 2 concludes with a list of recommended resources.

Prefatory Note

Rationale for reform

Research has shown that substance dependence, including injection drug use, is not a failure of will or of strength of character but a chronic, relapsing medical condition with a physiological and genetic basis that could affect any human being.⁸ The World Health Organization (WHO) notes that substance dependence is characterized by the strong desire to consume psychoactive substances, difficulties in controlling substance use, the continued use of psychoactive substances despite physical, mental and social problems associated with that use, increased tolerance over time, and sometimes withdrawal symptoms if the substance is abruptly unavailable.⁹ Drug dependence treatment plays a key role in reducing the risk of HIV transmission because of its capacity to diminish drug use in general, to reduce the frequency of injecting and to decrease the incidence of associated risk-taking behaviour.¹⁰

Drug dependence treatment can vary greatly in approach and duration, ranging from outpatient treatment programs that may last a few months to more comprehensive residential programs in which people who use drugs live in “therapeutic communities” or other institutional settings for longer periods. Research and practice taking place in many countries suggest that the most effective forms of drug dependence treatment integrate

⁸ WHO, *Neuroscience of Psychoactive Substance Use and Dependence*, 2004. At www.who.int/substance_abuse/publications/en/Neuroscience_E.pdf. See, also, WHO, *Management of substance dependence* (Fact Sheet), 2003 (at www.who.int/substance_abuse).

⁹ See ICD-10 diagnostic guidelines (at www.who.int/substance_abuse/terminology/definition1/en/). The DSM-IV definition of drug dependence is provided in American Psychiatric Association, *DSM-IV, Diagnostic and Statistical Manual of Mental Disorders, ed. 4*, 1994 (at <http://allpsych.com/disorders/substance/substancedependence.html>).

¹⁰ WHO, *Policy Brief: Reduction of HIV Transmission Through Drug-Dependence Treatment — Evidence for Action on HIV/AIDS and Injection Drug Use*, 2004. At www.who.int/hiv/pub/advocacy/en/drugdependencetreatmenten.pdf.

medical therapy with psychosocial care and support.¹¹ It is also important to note that certain populations may face unique challenges in accessing treatment. For example, in many settings, women who are dependent on illegal drugs may not seek treatment because of fear that their children will be taken from them or that they will face violence or other reprisal from their male partners.¹²

In developing and implementing effective drug dependence treatment programs, human rights must be respected and protected. These rights include the right of people who use drugs to enjoy the highest attainable standard of physical and mental health; patient rights, including confidentiality and the right to receive information regarding one's state of health; the right to informed consent to treatment and the right to withdraw from treatment; and the right to non-discrimination in health care and to be free from torture or other cruel, inhuman or degrading treatment. These considerations must inform the types of programs that are undertaken and the procedures and regulations that govern their operation.

One type of drug dependence treatment program that is an essential part of a comprehensive response to HIV/AIDS in countries with significant opioid addiction is opioid substitution treatment (OST), sometimes referred to as opiate replacement treatment. While it should be noted that opioid dependence is a complex condition and that no single treatment approach is necessarily optimal for all people, there is consistent evidence that OST is one of the most effective therapies for drug dependence.¹³ OST has been recognized by WHO and many national medical associations as an effective, safe and cost-effective means of managing opioid dependence and as an essential HIV/AIDS prevention measure.¹⁴ WHO has also included methadone and buprenorphine, both used in OST as alternatives to heroin or other opium derivatives, on its Model List of Essential Medicines.¹⁵

¹¹ See European Monitoring Centre for Drugs and Drug Addiction, *Legal aspects of substitution treatment: an insight into nine EU countries*. 2003, p. 19.

¹² U.S. National Institute on Drug Abuse, *NIDA InfoFacts: Treatment Methods for Women*, 1999 (with updates). At www.nida.nih.gov/infofacts/treatwomen.html.

¹³ WHO/UNODC/UNAIDS, *Position Paper: Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention*, 2004; European Monitoring Centre for Drugs and Drug Addiction, *Legal aspects of substitution treatment: an insight into nine EU countries*, p. 40.

¹⁴ WHO/UNODC/UNAIDS, *Position Paper: Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention*, p. 32. See, also, P.G. Barnett, "The cost-effectiveness of methadone maintenance as a healthcare intervention," *Addiction* 94(4) (1999): 479–488.

¹⁵ The Model List of Essential Medicines is meant to guide health policy-makers in knowing what medicines are necessary to ensure the health of their populations. See WHO, *WHO Model List of Essential Medicines*, revised March 2005 (at <http://mednet3.who.int/EMLib/index.aspx>). The entry states that "[b]oth buprenorphine and methadone are effective for the treatment of heroin dependence. However, methadone maintenance therapy at appropriate doses is the most effective in retaining patients in treatment and suppressing heroin use." Methadone and buprenorphine are included in that portion of the model list termed the "complementary list": this listing does not signify a partial or limited endorsement of methadone

OST seeks to reduce or eliminate use of illegal opioids by stabilizing people’s cravings for as long as is necessary to help them avoid previous patterns of substance use and associated harms. More specifically, OST offers individuals and communities the following short-term and long-term advantages:

Health benefits:

- OST helps to reduce the use of illegal opioids when administered in appropriate doses.¹⁶
- OST stabilizes the cravings of people who use opioids, thus promoting improved physical and emotional well-being.¹⁷
- OST provides the ability to control the quality and potency of opioid substitutes, thus mitigating the risk of overdose.¹⁸
- OST reduces the risk of transmission of HIV and other blood-borne diseases through sharing drug injection equipment since it is usually administered orally.¹⁹

or buprenorphine, but rather indicates that this therapy should be accompanied by specialized diagnostic or monitoring facilities, or specialist medical care or specialist training.

¹⁶ See, for example, S.R. Yancovitz et al, “A randomized trial of an interim methadone maintenance clinic,” *American Journal of Public Health*; 81 (1991): 1185–1112; J. Keen et al, “Does methadone maintenance treatment based on the new national guidelines work in a primary care setting?,” *British Journal of General Practice* 53(491) (2003): 461–467; V.P. Dole et al, “Long-term outcome of patients treated with methadone maintenance,” *Annals of the New York Academy of Science* 311 (1978): 181–9; V.P. Dole et al, “A medical treatment for diacetylmorphine (heroin) addiction: a clinical trial with methadone hydrochloride,” *Journal of the American Medical Association* 193 (1965): 646–50; W.H. McGlothlin et al, “Long-term follow-up of clients of high- and low-dose methadone programs,” *Archives of General Psychiatry* 38 (1981):1055–1063; D.D. Simpson et al, “Effectiveness of treatment for drug abuse: an overview of the DARP research program,” *Advances in Alcohol and Substance Abuse* 2 (1982): 7–29; E. Strain et al, “Dose-response effects of methadone in the treatment of opioid dependence,” *Annals of Internal Medicine* 119 (1993):23–27; R.L. Hubbard et al, *Drug Abuse Treatment: A National Study of Effectiveness* (University of North Carolina Press, 1998); E. Gottheil et al, “Diminished illicit drug use as a consequence of long term methadone maintenance program,” *Journal of Addictive Diseases* 12(4) (1993): 45; J.C. Ball et al, *The Effectiveness of Methadone Treatment*, 1991.

¹⁷ See WHO/UNODC/UNAIDS, *Position Paper: Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention*, p 14.

¹⁸ “Individuals with opioid dependence — who often inject drugs of unknown potency and quality and in conjunction with other substances — frequently experience overdose, with a high risk of death. Longitudinal studies suggest that approximately 2–3 percent of them die each year. The mortality rate for dependent heroin users is between six and 20 times the rate expected for those in the general population of the same age and gender.” WHO/UNODC/UNAIDS, *Position Paper: Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention*, p. 5.

¹⁹ For example, see A.S. Abdul-Quader et al, “Methadone maintenance and behavior by intravenous drug users that can transmit HIV,” *Contemporary Drug Problems* 14 (1987): 425–433; D.R. Gibson et al, “Effectiveness of methadone treatment in reducing HIV risk behavior and HIV seroconversion among injecting drug users,” *AIDS* 13(14) (1999):1807–1818; E. Drucker et al, “Measuring harm reduction: the effects of needle and syringe exchange programs and methadone maintenance on the ecology of HIV,” *AIDS* 12(suppl. A) (1998): 217–230; E. Wells, “Retention in methadone maintenance is associated with

- OST provides the opportunity to refer people who use drugs to other services, such as psychological support, diagnostic services, rehabilitation, HIV/AIDS counselling, and other care.²⁰
- OST decreases the death rate of people who use drugs by to one-third to one-quarter the rate of those people not receiving OST.²¹
- OST more effectively retains people who are opioid-dependent in treatment than placebo and detoxification alone.²²
- Pregnant women and their unborn children who receive OST have fewer complications in comparison with those who do not.²³

Social benefits:

- OST helps reduce criminal activity associated with obtaining an illegal substance.²⁴
- OST plays an important role in community-based approaches in that the treatment can be provided on an out-patient basis, achieving high rates of retention in treatment and increasing the time and opportunity for individuals to tackle major health, psychological, family, housing, employment, financial and legal issues while in contact with treatment services.²⁵

reductions in different HIV risk behaviours for women and men,” *American Journal of Drug and Alcohol Abuse* 22(4) (1996): 519; S. Vanichseni et al, “A controlled trial of methadone in a population of intravenous drug users in Bangkok: implications for prevention of HIV,” *International Journal of the Addictions* 26(12) (1991):1313–1320; L. Gowing et al, “Substitution treatment of injecting opioid users for prevention of HIV infection,” in *The Cochrane Database of Systematic Reviews*, Issue 4 (2004).

²⁰ WHO/UNODC/UNAIDS, *Position Paper: Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention*, p. 23.

²¹ WHO/UNODC/UNAIDS, *Position Paper: Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention*, p. 18.

²² WHO/UNODC/UNAIDS, *Position Paper: Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention*, p 18. See, also, R. Newman et al, “Double-blind comparison of methadone and placebo maintenance treatments of narcotic addicts in Hong Kong,” *Lancet* 8 (1979): 485–488; E. Strain et al, “Dose-response effects of methadone in the treatment of opioid dependence,” *Annals of Internal Medicine* 119 (1993): 23–27.

²³ WHO/UNODC/UNAIDS, *Position Paper: Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention*, p 18; J. McCarthy et al, “High-dose methadone maintenance in pregnancy: maternal and neonatal outcomes,” *American Journal of Obstetrics and Gynecology* 193 (2005): 606–610.

²⁴ See, for example, N. Hunt et al, “Patterns of criminal activity among methadone clients and current narcotics users not in treatment,” *Journal of Drug Issues* 14 (1984): 687–702; L. Gowing et al, *Australian National Council on Drugs Research Paper 3: Evidence supporting treatment: The effectiveness of interventions for illicit drug use*, 2001; J. Bell et al, “Changes in criminal activity after entering methadone maintenance,” *British Journal of Addiction* 87 (1992): 251–258.

²⁵ WHO/UNODC/UNAIDS, *Position Paper: Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention*, p. 18.

- OST reduces costs to the health, law enforcement, and criminal justice systems by helping people who use drugs to avoid lengthy hospital stays, criminal investigations and convictions, and imprisonment.²⁶
- OST promotes community integration and improved quality of life of people who use drugs and their families.

The administration of OST varies among countries. OST may be offered by general practice physicians, specially trained pharmacists, clinics devoted exclusively to OST, and drug rehabilitation facilities. Some jurisdictions successfully offer OST services in mobile vans,²⁷ and numerous countries have OST programs in correctional facilities.²⁸ Though OST has proven simple to administer in many settings and effective for both treatment of heroin dependence and reduction of harms related to injection, methadone and other opioid substitutes continue to be classified as illegal in some countries.²⁹

²⁶ P.G. Goldschmidt, “A cost-effectiveness model for evaluating health care programs: application to drug abuse treatment,” *Inquiry* 13 (1976): 29–47; National Institute on Drug Abuse [U.S.], *Principles of drug addiction treatment: a research based guide*, National Institutes of Health, Publication No. 00-4180, October 1999, pp. 21, 23–25 (at www.nida.nih.gov/PDF/PODAT/PODAT.pdf).

²⁷ See A. Vertser et al, *Methadone Guidelines*, Euro-Methworks, June 2000. At www.q4q.nl/methwork/guidelines/guidelinesuk/methadone%20guidelines%20english.pdf.

²⁸ The *WHO Guidelines on HIV Infection and AIDS in Prisons* recommend that “[p]risoners on methadone maintenance prior to imprisonment should be able to continue this treatment while in prison. In countries in which methadone maintenance is available to opiate-dependent individuals in the community, this treatment should also be available in prisons.” See WHO, *Guidelines on HIV Infection and AIDS in Prisons*, UNAIDS/99.47/E, 1993, Para. 23. The services offered in prison vary considerably, with some programs allowing people to begin methadone treatment in prison, others only allowing people to continue treatment in prison if they were on methadone prior to entering prison, and still others allowing for continuation of methadone treatment only for a limited period of time in prison. As well, in limited cases, substitution treatment can be an alternative to incarceration. See H. Stöver, *Study On Assistance To Drug Users in Prisons. European Monitoring Centre for Drugs and Drug Addiction*, EMCDDA/2001, 2001 (at www.archido.de/eldok/docs_en/stoever_habil_2000.htm), K. Dolan et al, “An International Review of Methadone Provision in Prisons,” *Addiction Research*; 4(1) (1996): 85–97; K. Dolan et al, “Methadone maintenance reduces injecting in prison,” *British Medical Journal* 312 (1996): 1162; A. Byrne, “Methadone treatment is widely accepted in prisons in New South Wales,” *British Medical Journal* 316(7146) (1998).

²⁹ See International Harm Reduction Development Program (IHRD), *Harm Reduction Developments 2005: Countries with Injection-Driven HIV Epidemics*, Open Society Institute, 2005. In the Russian Federation, federal law prohibits the treatment of drug dependence with medicines containing opioids. Under the national drug legislation, methadone is prohibited by virtue of its inclusion in List I. Buprenorphine is included in the less-restricted List II, but the use of substances in List II for the treatment of drug dependence is explicitly prohibited. See Government Regulation of 30.06.1996 N 681, and *O narkoticheskikh sredstvakh I psikhotropnih veshestvakh* (Federal Law on Narcotic Drugs and Psychotropic Substances,) of 08.01.1998 N 3-FZ (last amended 09.05.2005 N 45-FZ), art. 31.

International law and policy

Several international legal instruments are relevant to the right to drug dependence treatment. Governments have an interest in providing such treatment, including OST, not only on public health grounds, but also based on existing international obligations. The implementation of harm reduction measures such as OST and sterile syringe programs is not only permissible under the international drug control treaties, but is also consistent with, and required by, states' obligations under the international law of human rights.

United Nations declarations on drug use repeatedly call on member states to prioritize measures to reduce the demand for controlled drugs, including “early intervention, counselling, treatment, rehabilitation, relapse prevention, aftercare and social reintegration.”³⁰ Governments need to ensure that their national legislation and policies do not contribute to the spread of the HIV epidemic and other social and health-related harms associated with drug use. Furthermore, governments need to ensure that legislation and policies on drug control do not impede the provision of services, such as OST, that promote health among people who use drugs. The following section briefly outlines international law and policy in the area of narcotics, health and human rights that are relevant to states' obligations regarding drug dependence treatment, including OST.

UN conventions on drug control

Methadone is classified in the UN 1961 *Single Convention on Narcotic Drugs* as a Schedule I drug, a category of substances “subject to all measures of control applicable to drugs under this Convention.”³¹ However, many national authorities and UN experts have criticized or effectively ignored this classification. They have noted, rather, the distinguished record of methadone programs over decades of clinical experience and especially its crucial role in the response to HIV/AIDS, which could not have been foreseen when the Convention was adopted in 1961.³²

Article 4(c) of the 1961 Convention calls on states “to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of drugs.” As the term “medical” is not defined further in the Convention, this leaves scope for states bound by the treaty to determine that distribution, use and possession of methadone and other drugs used in OST serve a “medical

³⁰ See, for example, UN General Assembly, *Declaration on the Guiding Principles of Drug Demand Reduction*, Resolution II adopted by the Ad Hoc Committee of the Whole based on draft in A/S-20/4, c. V, s. A, at the UN General Assembly Session on the World Drug Problem, 8-10 June 1998.

³¹ *Single Convention on Narcotic Drugs*, 1961, UN, art. 2(1). At www.unodc.org/pdf/convention_1961_en.pdf. See, also, *Protocol Amending the Single Convention on Narcotic Drugs (Schedules)*, UN General Assembly, p. 41 (at http://www.incb.org/pdf/e/conv/convention_1961_en.pdf).

³² UN International Drug Control Programme (UNDCP), *Flexibility of Treaty Provisions as Regards Harm Reduction Approaches*, Decision 74/10, E/INCB/2002/W.13/SS.5, 30 September 2002.

purpose.” According to Article 30, a state may deem the prescription of a controlled substance (such as methadone) to be “necessary,” and would then have to regulate the prescription through the use of official forms, registration and other control measures. Thus, many policy-makers and practitioners regard substitution treatment as a legitimate form of treatment that corresponds to the obligation under Article 38 for states “to take all practicable measures for the prevention of abuse of drugs and for the early identification, treatment, education, aftercare, rehabilitation and social integration of the persons involved.”

The *1972 Protocol Amending the Single Convention on Narcotic Drugs* clarifies that in the narrow sense “treatment” includes “the process of withdrawal of the abused narcotic drugs, or where necessary that of inducing the abuser to restrict his intake of narcotic drugs to such minimum quantities as might be medically justified in the light of his personal condition.”³³ Flowing from this definition, the official commentary to the convention acknowledges that “medically justified maintenance programmes” come within the definition of “treatment” under Article 38.³⁴

Buprenorphine, another opioid substitute, is listed in Schedule III of the UN 1971 *Convention on Psychotropic Substances*,³⁵ which covers “[s]ubstances presenting a risk of abuse, posing a serious threat to public health which are of moderate or high therapeutic value.”³⁶ Article 9 provides that “parties shall require that substances in Schedules II, III and IV be supplied or dispensed for use by individuals pursuant to medical prescription only” Buprenorphine is used in OST in many countries.

The 1988 *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances* does not elaborate further in regard to substitution treatment.³⁷

³³ *Protocol Amending the Single Convention on Narcotic Drugs*.

³⁴ *Commentary on the Single Convention on Narcotic Drugs*, UN, 1973.

³⁵ *Convention on Psychotropic Substances*, 1971. UN General Assembly. At www.unodc.org/pdf/convention_1971_en.pdf.

³⁶ WHO, *WHO Expert Committee on Drug Dependence: thirty-third report*, 2002. “The Guidelines also provide guidance for selecting an appropriate schedule for psychotropic substances under the 1971 Convention, as follows: Schedule I: Substances whose liability to abuse constitutes an especially serious risk to public health and which have very limited, if any, therapeutic usefulness. Schedule II: Substances whose liability to abuse constitutes a substantial risk to public health and which have little to moderate therapeutic usefulness. Schedule III: Substances whose liability to abuse constitutes a substantial risk to public health and which have moderate to great therapeutic usefulness. Schedule IV: Substances whose liability to abuse constitutes a smaller but still significant risk to public health and which have a therapeutic usefulness from little to great” (p. 3). At www.unicri.it/min.san.bollettino/dati/915-en.pdf. See, also, European Legal Database, *Classification of controlled drug* (at <http://eldd.emcdda.europa.eu/index.cfm?fuseaction=public.Content&nNodeID=5622&sLanguageISO=EN>)

³⁷ *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances*, UN, 20 December 1988. At www.unodc.org/pdf/convention_1988_en.pdf.

In reviewing the various types of harm reduction programs with respect to international treaties, the UN International Drug Control Programme (UNDCP), located within the UN Office on Drugs and Crime, concluded in 2002 that,

In its more traditional approach substitution/maintenance treatment could hardly be perceived as contrary to the text or the spirit of the treaties. It is a commonly accepted addiction treatment, with several advantages and few drawbacks. Although results are mixed and dependent on many factors, its implementation along sound medical practice guidelines would not constitute a breach of treaty provisions.³⁸

The International Narcotics Control Board (INCB) has acknowledged the potential of harm reduction programs to contribute to a comprehensive drug demand reduction strategy. In its *Annual Report 2003*, the INCB recognized that “drug substitution and maintenance treatment ... does not constitute any breach of treaty provisions, whatever substance may be used for such treatment in line with established national sound medical practice As is the case with the concept of medical use, treatment is not treaty-defined.”³⁹

Human rights obligations

Under the UN Charter,⁴⁰ all member states have a binding treaty obligation “to take joint and separate action” to achieve the purpose of the UN, which includes promoting “solutions of international ... health problems” and “universal respect for, and observance of, human rights and fundamental freedoms for all” (Articles 55 and 56). The UN Charter also expressly states that, in the event of a conflict between a country’s obligations under the Charter and their obligations under any other international agreement, their obligations under the Charter prevail (Article 103). This means that countries cannot validly implement international drug control treaties in ways that contradict or undermine their obligations to solve health problems and to respect and promote human rights.

For more than fifty years, all UN member states have repeatedly reaffirmed and recognized their obligations under the *Universal Declaration of Human Rights*,⁴¹ which sets out in more detail the human rights obligations of UN member states under the UN

³⁸ UNDCP, *Flexibility of Treaty Provisions as Regards Harm Reduction Approaches*, para. 17. See also D. Wolfe et al, *Illicit drug policies and the global HIV epidemic: Effects of UN and national government approaches*, Open Society Institute, pp. 24–27.

³⁹ INCB, *Report for the International Narcotics Board 2003*, E/INCB/2003/1 Part II, p.37. At www.incb.org/incb/annual_report_2003.html.

⁴⁰ *Charter of the United Nations*, UNTS 993 (entered into force 24 October 1945).

⁴¹ *Universal Declaration of Human Rights*, UN GA Resolution 217 A(III), UN GAOR, 3rd Session, 183rd plenary meeting, 71, UN Doc. A/910 (1948).

Charter. The *Universal Declaration* states that “everyone has the right to a standard of living adequate for health and well-being ... including medical care and necessary social services” (Article 25). The adoption and implementation of domestic legislation and policy on drug control needs to reflect these repeatedly stated obligations.

States that are parties to the *International Covenant on Economic, Social and Cultural Rights* (ICESCR)⁴² have recognized the right of every person to enjoy “the highest attainable standard of physical and mental health” (Article 12). They have a binding legal obligation to take steps to realize fully this right, including those steps “necessary for ... prevention, treatment and control of epidemic, endemic ... and other diseases” and “the creation of conditions which would assure to all medical services and medical attention in the event of sickness” (Article 12). In addition, the *International Covenant on Civil and Political Rights* (ICCPR)⁴³ states that every person has the inherent right to life (Article 6). The Human Rights Committee, the expert body charged with addressing states’ compliance with their obligations under the ICCPR, has explained that this right “should not be interpreted narrowly” and that governments must adopt positive, proactive measures to protect human life, including measures that can help reduce the spread of epidemics.⁴⁴

At the 1998 UN General Assembly Special Session on Drugs, UN member states declared that action against drugs requires “an integrated and balanced approach in full conformity with the purposes of the *Charter of the United Nations* and international law, and particularly with full respect for ... all human rights and fundamental freedoms.”⁴⁵ The UN’s position paper, *Preventing the Transmission of HIV Among Drug Abusers*, explicitly notes that the *Universal Declaration of Human Rights* and human rights principles are part of the foundation for HIV prevention efforts in this field.⁴⁶

UN documents, including the General Assembly’s unanimous 2001 *Declaration of Commitment on HIV/AIDS*, recognize the right of people who use drugs to a comprehensive range of HIV/AIDS prevention and treatment services, including access to sterile injecting equipment and to harm reduction services.⁴⁷ The UNAIDS policy paper, *Intensifying HIV Prevention*, which was approved by the UNAIDS Program

⁴² *International Covenant on Economic, Social and Cultural Rights* (ICESCR), 993 UNTS 3 (1966).

⁴³ *International Covenant on Civil and Political Rights*, (ICCPR), 999 UNTS 171 (1966).

⁴⁴ UN Human Rights Committee, The Right to Life (Art. 6), General comment 6, UN Doc. HRI/GEN/1/Rev.1, 6 (1982). Available via www.ohchr.org/english/bodies/hrc/comments.htm.

⁴⁵ UN General Assembly, Political Declaration, Resolution A/RES/S-20/2, UN GAOR, 20th Special Session, 9th plenary meeting, 10 June 1998.

⁴⁶ UN, *Preventing the Transmission of HIV Among Drug Abuser: A Position Paper of the UN system*, E/CN.7/2002/CRP.5, 12 March 2002. At www.cicad.oas.org/en/Resources/UNHIVaids.pdf.

⁴⁷ *Declaration of Commitment on HIV/AIDS*, UN General Assembly, UN doc. No. A/RES/S-26/2, 2 August 2001, para. 52.

Coordinating Board in 2005, makes explicit that the provision of drug substitution treatment is an important part of a comprehensive, integrated approach to preventing the spread of HIV among people who use drugs, and should be based on promoting, protecting and respecting human rights of people who use drugs.⁴⁸

The UN resolution, *Principles for the protection of persons with mental illness and the improvement of mental health care*, which emphasizes a number of human rights-based principles of care and treatment, is especially pertinent to the treatment of drug dependence.⁴⁹ It states that:

- All persons have the right to protection from torture, physical or other abuse or degrading treatment, and economic, sexual and other forms of exploitation.
- All treatment and care must respect the inherent dignity of the human person.
- No treatment shall be given to any patient without his or her informed consent.
- Everyone has the right to receive health care and treatment in accordance with the same standards as for other ill persons, and the right to be protected from harm, including unjustified medication, abuse by other patients or staff, or other acts causing mental distress or physical discomfort. Physical restraint or involuntary seclusion must not be used except in accordance with officially approved procedures and only when it is the only means available to prevent imminent harm.
- Everyone has a right to a fair hearing before an impartial tribunal before being declared incapacitated or incompetent to make decisions on his or her own behalf, in which proceedings everyone has the right to legal counsel. If declared incapacitated in this regard, a responsible representative should be appointed to assist in decision-making about treatment.

⁴⁸ UNAIDS, *Intensifying HIV prevention: UNAIDS policy position paper*, 2005, p. 34.

⁴⁹ UN General Assembly, *Principles for the protection of persons with mental illness and the improvement of mental health care*, GA resolution 46/119, adopted 17 December 1991. At www.unhchr.ch/html/menu3/b/68.htm.

Model Statutory Provisions

Chapter I. General Provisions

Article 1. Purpose of this Part

The purpose of this Part is to provide a legal framework for the provision of treatment programs for drug dependence, including opioid substitution treatment, by

- (a) encouraging the widespread availability and accessibility of said treatment;
- (b) protecting the human rights of those who receive treatment;
- (c) ensuring quality of care in the treatment provided; and
- (d) improving the physical and mental health of those people who seek treatment.

Article 2. Definitions

For the purposes of this Part, the following definitions are used:

“Opioid substitute” means any drug approved by the [relevant drug regulatory authority] for medical use in opioid substitution treatment, including but not limited to methadone and buprenorphine.

“Cruel, inhuman or degrading treatment or punishment” means any harsh or neglectful treatment that could damage a person’s physical or mental health, or any punishment intended to cause physical or mental pain or suffering, or to humiliate or degrade the person concerned.

“Dependence” means the criteria for dependence in the International Classification of Diseases (ICD-10) or the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) criteria.⁵⁰

“Dispensing pharmacist” means an accredited pharmacist who is licensed to dispense approved opioids.

“Drug dependence treatment” means a program with specific medical or psycho-social techniques aimed at managing or reducing a client’s dependence on one or more controlled substances, thereby improving the general health of the client. Such programs include opioid substitution treatment, residential or out-patient services, administration of medicines to reduce cravings or diminish an adverse impact of using controlled substances, psychiatric and psycho-social support services, and supervised support groups.

⁵⁰ The ICD-10 diagnostic guidelines can be found at www.who.int/substance_abuse/terminology/definition1/en/. The DSM-IV definition is provided in *DSM-IV, Diagnostic and Statistical Manual of Mental Disorders, ed. 4*. (Washington DC: American Psychiatric Association, 1994). At <http://allpsych.com/disorders/substance/substancedependence.html>.

“Health care” refers to services provided by health professionals in the formal health system for prevention or treatment of mental or physical diseases or conditions.

“Health practitioner” means a person entitled under the [relevant health law] to provide health services. Health practitioners include accredited physicians, registered nurses and other trained medical staff.

“Health insurance plan” means any health insurance policy or health benefit plan offered by a health insurer, as defined in [relevant legislation], including any health benefit plan offered or administered by the state or any state entity.

“Opioid substitution treatment” means the administration of an opioid substitute to a person with dependence on a pharmacologically related opioid, for achieving defined treatment aims,⁵¹ including maintenance treatment.

“Patient” means any individual enrolled in a drug dependence treatment program.

“Prescribing physician” means a physician who is licensed to prescribe approved opioids.

“Specialist opioid substitution clinic” means a facility licensed to provide opioid substitution treatment.

“Staff” of the drug dependence treatment program, includes the following persons:

- (a) the operator or manager of the program;
- (b) a person engaged by the operator or manager of the program to provide services at the facility, whether under a contract of employment or otherwise; and
- (c) a person engaged by the operator or manager of the program to provide voluntary assistance at the facility.

“Supervised consumption” means the consumption of a prescribed opioid substitute under observation at a specialist opioid substitution clinic, physician’s office, pharmacy, hospital or other medical facility.

“Take-away dose” means any prescribed dose of an opioid substitute for which supervised consumption by a health professional is not required.

“Torture” means any act by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person for such purposes as obtaining from the person or a third person information or a confession; punishing the person for an act he or she or a third person has committed or is suspected of having committed; or intimidating or coercing the person or a third person; or for any reason based on discrimination of any

⁵¹ Adapted from WHO/UNODC/UNAIDS, *Position Paper: Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention*, p. 12.

kind, when such pain or suffering is inflicted by, at the instigation of, or with the consent or acquiescence of, a public official or other person acting in an official capacity. It does not include pain or suffering arising only from, inherent in, or incidental to, lawful sanctions.⁵²

⁵² This definition is derived from art. 1 of the UN *Convention Against Torture, and Other Cruel, Inhuman or Degrading Treatment and Punishment*, 1984. Similar definitions have been incorporated into domestic legislation in various countries.

Chapter II. Patients' Rights

Article 3. The right to drug dependence treatment

The State shall guarantee access to drug dependence treatment for all who need it.

Article 4. Basic rights of patients

Every patient has the right:⁵³

- (a) to a full course of high-quality treatment and follow-up support to be provided in accordance with good clinical practice;
- (b) to treatment without discrimination;
- (c) to meaningful participation in determining his or her own treatment goals, which may include but are not limited to abstinence or changes in drug use that minimize the harms of dependence;
- (d) to meaningful participation in all treatment decisions, including when and how treatment is initiated and withdrawal from treatment;
- (e) to exercise his or her rights as a patient, including:
 - (i) reporting, without retribution, any instances of suspected abuse, neglect, or exploitation of patients in the program;
 - (ii) a grievance and appeal process, in accordance with national laws and regulations;
 - (iii) input into the policies and services of drug dependence treatment programs; and
 - (iv) voluntary withdrawal from treatment at any time.
- (f) to confidentiality of medical records and clinical test results; and
- (g) to be fully informed, including but not limited to the right to receive information on:
 - (i) his or her state of health;

⁵³ The rights listed in this article derive from a number of sources. Certain OST guidelines make specific mention of the rights of patients. Of particular mention are the Macedonian Ministry of Health *Guidelines and Protocol for the Administration of Methadone in the Treatment of Opiate Addiction*, October 2001, p. 21–22 (available via <http://www.ceehrn.org/index.php?ItemId=12518>); New Zealand Ministry of Health, *Opioid Substitution Treatment: New Zealand Practice Guidelines*, February 2003, p. 23 (available via www.moh.govt.nz); Ontario College of Physicians and Surgeons, *Methadone Maintenance Guidelines*, November 2005, pp. 6, 11 (available via www.cpso.on.ca/publications/methguidenov05.htm). More broadly, countries' health laws often contain provisions related to patients' rights which would be applicable to opioid substitution treatment. See, for example, *Basic Law of the Russian Federation on Public Healthcare* (Osnovi zakonodatelstva Rossiiskoi Federatsii ob Okhrane zdorov'ya grazhdan), 22 July 1993, N 5487-1, last amended on 31 December, 2005; *Law of Kyrgyz Republic On Public Healthcare* (Ob okhrane zdorov'ya grazhdan v Kyrgyzskoi Respublike), 9 January 2005, No 6. See, also, WHO Europe, *A Declaration on the Promotion of Patients' Rights in Europe*, ICP/HLE 121, 28, June 1994 (available via www.who.int/genomics/public/patientrights/en/). Documents on patients' rights for a variety of countries are also available via this site.

- (ii) his or her rights and obligations as a patient, as specified in this Part and in applicable law;
- (iii) the procedure for making a complaint about the services received through the program; and
- (iv) cost and payment conditions and the availability of medical insurance and other possible subsidies.

Article 5. Informed consent

- (1) Informed voluntary consent of a patient is a necessary preliminary condition for medical treatment or a preventive or diagnostic intervention.
- (2) The following are the elements required for consent to treatment:
 - (a) the consent must relate specifically to the treatment administered;
 - (b) the consent must be fully informed;
 - (c) the consent must be given voluntarily;
 - (d) the consent must be provided in writing; and
 - (e) the consent must not be obtained through misrepresentation or fraud.
- (3) A consent to treatment is fully informed if, before giving it:
 - (a) the person received the information about the matters set out in Section (4) that a reasonable person in the same circumstances would require in order to make a decision about the treatment; and
 - (b) the person received responses to his or her requests for additional information about those matters.
- (4) The matters referred to in Section (3) are:
 1. The nature of the treatment.
 2. The expected benefits of the treatment.
 3. The material risks of the treatment.
 4. The material side effects of the treatment.
 5. Alternative courses of action.
 6. The likely consequences of not having the treatment.⁵⁴

⁵⁴ This wording is derived from the *Health Care Consent Act*, 1996, Ontario [Canada], s.11. Provisions on consent to health care treatment are also found in the Law of Kyrgyz Republic *On Public Healthcare*, art. 74. See, also, the *Basic Law of the Russian Federation on Public Healthcare*, art. 32; Ontario College of Physicians and Surgeons, *Methadone Maintenance Guidelines*, pp. 10–11.

Article 6. Withdrawal from treatment

- (1) A patient shall have the right to withdraw voluntarily from treatment at any time.⁵⁵
- (2) The health practitioner shall fully inform the patient of the potential risks and benefits of withdrawal from treatment and shall work with the patient to ensure the patient's safety and comfort during the withdrawal process.⁵⁶
- (3) The health practitioner shall not discontinue services that are needed unless the patient requests the discontinuation, alternate services are arranged, or the patient is given a reasonable opportunity to arrange alternate services.⁵⁷
- (4) The withdrawal from treatment with an explanation of likely consequences shall be recorded or registered in medical documentation and signed by the patient and health practitioner.
- (5) Involuntary withdrawal from treatment shall be avoided except where compelling reasons exist. Regulations governing grounds for involuntary withdrawal shall be clearly communicated to patients at the outset of treatment.⁵⁸

Article 7. Confidentiality

- (1) The confidentiality of all health care information shall be respected. Records of the identity, diagnosis, prognosis or treatment of any patient which are created or obtained in the course of drug dependence treatment:
 - (a) are confidential;⁵⁹
 - (b) are not open to public inspection or disclosure;

⁵⁵ See the *Basic Law of the Russian Federation on Public Healthcare*, art. 33.

⁵⁶ Regulations should include non-mandatory guidelines for withdrawal doses. For examples, see S. Henry-Edwards et al, *Clinical guidelines and procedures for the use of methadone in the maintenance treatment of opioid dependence*, Australian Government Department of Health and Aging, August 2003, p. 5.

⁵⁷ This wording is derived from Ontario College of Physicians and Surgeons, *Methadone Maintenance Guidelines*, p. 38.

⁵⁸ Health Canada, *Best practices: methadone maintenance treatment*, 2002, p. 46. Regulations should include specific, limited criteria for involuntary withdrawal. These might include well-documented threats or violent behaviour toward staff or patients. See, also, Ontario College of Physicians and Surgeons, *Methadone Maintenance Guidelines*, p. 38.

⁵⁹ The OST Guidelines of the Czech Republic contain a special provision establishing that personal information should be used only in accordance with the existing legal framework regulating personal data. The provision to ensure confidentiality is included in a contract between patient and physician about the conditions of cooperation, and their rights and obligations. See Czech Republic Ministry of Health, *Czech Substitution Treatment Guidelines*, June 2000, adopted by a special Ministerial Decree in 2001.

- (c) shall not be shared with other individuals or agencies without the consent of the person to whom the record relates; and
 - (d) shall not be discoverable or admissible during legal proceedings.
- (2) No record referred to in Section (1) may be used to
- (a) initiate or substantiate any criminal charges against a patient; or
 - (b) act as grounds for conducting any investigation of a patient.
- (3) Program staff cannot be compelled under [relevant criminal procedure code] to provide evidence concerning the information that was entrusted to them or became known to them in this capacity.⁶⁰
- (4) All use of personal information of patients and program staff in research and evaluation shall be undertaken in conditions guaranteeing anonymity, and any such information shall also be governed by Section (2) of this article.

Commentary: Article 7

The requirement of confidentiality respects the right to privacy articulated under several international instruments.⁶¹ As well, many countries and institutions, such as hospitals, have legislation or guidelines concerning patients' rights, including the right to confidentiality.⁶² It is important in the context of opioid substitution treatment because people may be discouraged from seeking assessment or treatment, disclosing accurate information, or participating in research for fear that information about their health status, including HIV/AIDS status, may be released. In particular, they may fear that information regarding their drug dependence may be passed on to police.

Information regarding a person's health status should be made available to that person and, beyond him or her, only to those for whom knowledge of the person's status is absolutely necessary, such as a health practitioner where that information is relevant to the treatment being sought from that practitioner.⁶³ Ensuring confidentiality of health

⁶⁰ This wording is derived from Germany's *Code of Criminal Procedure*, s. 53, para. 1, no. 3b.

⁶¹ See, for instance, Article 12 of the *Universal Declaration of Human Rights*; Article 8(1) of the *European Convention for the Protection of Human Rights and Fundamental Freedoms*; Article 17(1) of the ICCPR.

⁶² See, for example, WHO Europe, *A Declaration on the Promotion of Patients' Rights in Europe*, p. 12; *Israel Patient's Rights Act 1996*, art. 19, 20 (at <http://waml.haifa.ac.il/index/reference/legislation/israel/israel1.htm>).

⁶³ In *Smith v. Jones* ([1999] 1 S.C.R. 455) at para. 74 et seq., the Supreme Court of Canada considered situations in which release of confidential health information to parties other than immediately concerned health-care professionals may be justified. Confidentiality may be breached when there exists a clear risk to an identifiable person or group of persons; the risk is that serious bodily harm or death may occur; the danger is imminent; and the proposed disclosure will minimally impair the right to privacy of the person involved.

status and all health-care information is critical to respecting the human rights of people who use drugs, including those who are dependent on drugs.

Article 8. Non-discrimination in health care

- (1) No health practitioner shall deny any person health care (which includes treatment for HIV) solely on the basis of actual or perceived drug dependence.
- (2) No health practitioner shall deny any person drug dependence treatment solely on the basis of actual or perceived infection with blood-borne or other diseases (including infection with HIV and diagnosis of AIDS).⁶⁴

Commentary: Article 8

Access to life-saving HIV treatment, already limited globally, is even more limited for people who use drugs. Even in regions where they account for the majority of HIV infections, people who use drugs are routinely excluded from HIV treatment.⁶⁵ Authorities often justify this exclusion by citing adherence problems and low motivation among people who use drugs. However, available research and treatment practice shows clearly that people who use drugs, including those who inject drugs, can adhere to antiretroviral (ARV) regimens as well as other people living with HIV.⁶⁶ Extensive experience and numerous studies have documented that HIV care tailored for people who use drugs is often highly successful.⁶⁷ There should be no categorical exclusion of such

⁶⁴ The European Parliament has called on Member States to “ensure that drug addicts have access to medical treatment and the necessary substitution therapies without discrimination.” See European Parliament resolution on the situation as regards fundamental rights in the European Union (2002) at para. 21.

⁶⁵ WHO, *Progress on global access to HIV antiretroviral therapy: a report on “3x5” and beyond*, March 2006, p. 8. The WHO report states that while an estimated 36 000 people who inject drugs were receiving ART by the end of 2005, more than 80 percent (30 000) were in Brazil. The remaining 6000 patients were distributed among 45 other countries. These figures suggest a large unmet need, particularly in eastern Europe and Central Asia, where people who inject drugs represent 70 percent of HIV cases but just 24 percent of patients currently on treatment. See, also, C. Aceijas et al., “Global overview of injecting drug use and HIV infection among injecting drug users,” *AIDS* 18(17) (2004): 2295–2303.

⁶⁶ E. Oppenheimer et al., *Treatment and care for drug users living with HIV/AIDS*, paper prepared for the UN Reference Group on treatment and care for drug users living with HIV/AIDS, Center for Research on Drugs and Health Behaviour, Imperial College, December 2003, pp. 5–9.

⁶⁷ Research confirms that simple and low-cost measures are available to provide tailored ARV programs to drug users that can make compliance equivalent to that of non-drug users. The best results on compliance of opioid-dependent drug users to ARV treatment regimens have been reported in settings where methadone or other opioid substitution therapy is readily available. Efforts aimed at helping clients cope with and manage their drug use may be an effective way to achieve and maintain high levels of adherence to HIV medications over time. See Open Society Institute, *Breaking Down Barriers: Lessons on Providing HIV Treatment to Injection Drug Users*, July 2004; N.C. Ware et al., “Adherence, stereotyping and unequal HIV treatment for active users of illegal drugs,” *Social Science and Medicine*, 51 (2005): 565–576; J.P. Moatti et al., “Adherence to HAART in French HIV-infected injecting drug users: the contribution of buprenorphine drug maintenance treatment,” *AIDS* 14(2) (2000): 151–155; A. Mocroft et al., “A comparison of exposure groups in the EuroSIDA study: starting highly active antiretroviral therapy

persons from any level of care. All patients who seek treatment and meet clinically appropriate treatment criteria should receive it, including people who use drugs.⁶⁸ States have a special obligation to prevent any discrimination on internationally prohibited grounds in the provision of health care and health services, especially with respect to the core obligations of the right to health.⁶⁹

Article 9. Prohibition on torture or cruel, inhuman or degrading treatment or punishment

Every health practitioner, or every person acting at the instigation of or with the consent or acquiescence of a health practitioner, who inflicts torture or cruel, inhuman or degrading treatment or punishment on any other person is guilty of an offence under [relevant criminal law] and liable to imprisonment for a term not exceeding [x].⁷⁰

Commentary: Article 9

There is an urgent need in many countries, particularly where individual use of controlled substances is highly criminalized, for legal protections of those seeking or undergoing treatment for drug dependence. Prohibitions against torture and other cruel, inhuman or degrading treatment or punishment are found in binding international treaties and conventions, international norms and many domestic constitutions.⁷¹ The European

(HAART), response to HAART and survival,” *Journal of Acquired Immune Deficiency Syndromes* 22(4) (1999): pp. 369–378; M.D. Stein et al, “Adherence to antiretroviral therapy among HIV-infected methadone patients: effect of ongoing illicit drug use,” *American Journal on Drug Alcohol Abuse*, 26 (2000): 195–205; M. Tyndall et al, “High rates of adherence to antiretroviral therapy among injection drug users in comprehensive support programs,” BC Centre for Excellence in HIV/AIDS, Vancouver, British Columbia, oral presentation at Canadian Association for HIV Research Conference, 2006, Québec; R. Therrien, “Implementation of modified directly observed antiretroviral therapy program in active intravenous cocaine users,” Centre Hospitalier Universitaire de Montréal, Montréal, oral presentation at Canadian Association for HIV Research Conference, 2006, Québec (abstracts available in *Canadian Journal of Infectious Diseases and Medical Microbiology* 17(Supplement A) (2006)).

⁶⁸ WHO, *HIV/AIDS Treatment and Care Protocol for Countries of the Commonwealth of Independent States*, 2004, pp. 33–38. Available via www.eurasiahealth.org/eng/health/resources/82082/.

⁶⁹ UN Committee on Economic, Social and Cultural Rights, The right to the highest attainable standard of physical and mental health, General Comment 14, UN Doc. E/C.12/2000/4 11, August 2000, paras. 18,19. Discrimination is also prohibited by art. 2 and 26 of the ICCPR. Art. 26 states: “All persons are equal before the law and are entitled without any discrimination to the equal protection of the law. In this respect, the law shall prohibit any discrimination and guarantee to all persons equal and effective protection against discrimination on any grounds such as race, color, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.” The UN Commission on Human Rights has frequently confirmed that “other status” in non-discrimination provisions in international human rights is to be interpreted to include health status, including HIV/AIDS.

⁷⁰ This definition is derived from the Canadian *Criminal Code* (R.S., 1985, c. C-46), s. 269.1. Similar wording is found in of the *Criminal Code* of Kyrgyz Republic of 01.10.1997 # 68, as amended of 15 November 2003, No 223, art. 305-1 (last amended 05.08.2005 N 122).

⁷¹ International treaties and conventions include the ICCPR, art. 7, the *European Convention for the Protection of Human Rights and Fundamental Freedoms*, art. 3, and the *Convention Against Torture and*

Court of Human Rights has interpreted torture to indicate deliberate inhuman treatment causing very serious and cruel suffering,⁷² while “degrading” and “inhuman” have been interpreted by the same court to indicate treatment or punishment which causes intense mental or physical suffering and humiliation beyond that which is associated with punishment in general.⁷³

In the context of drug dependence treatment, there exists the potential for abuse of patients who are likely to be in pain or severe mental distress and may be incapacitated by the symptoms of drug withdrawal or other problems. In several countries, human rights organizations and others have documented instances of “treatment” for drug dependence that are cruel, inhuman or degrading.⁷⁴ The denial of other medical treatment until a person has undergone drug dependence treatment has also been found by national courts to constitute cruel and unusual punishment.⁷⁵ Both international and national organizations have produced guidelines for drug dependence treatment. In some cases, they specifically address the combination of drug dependence treatment and HIV/AIDS prevention and treatment.⁷⁶

Other Cruel, Inhuman or Degrading Treatment or Punishment. Similar provisions may be found in widely accepted legal documents such as the UN *Standard Minimum Rules for the Treatment of Prisoners*, s. 31, and the UN *Universal Declaration on Human Rights*, art. 5. Though these sources of law are not binding, they have widespread influence and reflect international consensus on the matter. Domestic constitutions prohibiting cruel treatment or punishment include the *Canadian Charter of Rights and Freedoms*, s. 12, and the *U.S. Constitution (Eighth Amendment)*.

⁷² *Aydin v. Turkey* (1997), 23178/94 [1997] ECHR 75.

⁷³ *Soering v. The United Kingdom* (1998), 14038/88 [1989] ECHR 14.

⁷⁴ See, for example, Human Rights Watch, *Locked doors: the human rights of people living with HIV/AIDS in China*, 2003, pp. 42–48; Human Rights Watch, *Lessons not learned: human rights abuses and HIV/AIDS in the Russian Federation*, 2004, pp. 42–43.

⁷⁵ See, for example, *Domenech v. Goord* 20 A.D.3d 416; 797 N.Y.S.2d 313; 2005 N.Y. App. Div. In this case, a prisoner who was denied treatment for hepatitis C until he completed a drug dependence treatment program was found to have suffered cruel and unusual punishment.

⁷⁶ WHO, *HIV/AIDS Treatment and Care: WHO protocols for CIS countries*, Version 1, 2004, pp. 33–38 (at www.eurasiahealth.org/attaches/94/9435/WHO%20HIV%20Protocols%20for%20CIS%20En.pdf); [U.S.] National Institute on Drug Abuse, *Principles of drug addiction treatment: a research based guide*, National Institutes of Health, publication No. 00-4180, October 1999 (at www.nida.nih.gov/PDF/PODAT/PODAT.pdf).

Chapter III. Opioid Substitution Treatment

Article 10. Eligibility for opioid substitution treatment

- (1) The prescribing physician shall determine the patient's eligibility for opioid substitution treatment.
- (2) The determination of eligibility shall be based solely on:
 - (a) the presence of opioid dependence according to accepted medical definitions; and
 - (b) the patient's informed, voluntary consent.

Commentary: Article 10

Persons who are dependent on opioids have the same fundamental human right as all others to the highest attainable standard of health goods and services. Many countries have policies that make explicit the need for admission to OST programs to be as open as possible.⁷⁷ WHO and other UN agencies emphasize that since many people who use opioids come to OST programs at a moment of crisis, the ready availability of programs is crucial to stave off a worse crisis or to “take advantage of the motivation created by ... crises.”⁷⁸ OST should be available without discrimination based on age, sex, economic status, social circumstances or other similar criteria, including HIV status. Virtually no medical condition is a counter-indication for OST.⁷⁹ In fact, pregnancy and serious

⁷⁷ Health Canada notes: “Admission criteria should be as open as possible, given available resources, and should ensure timely access to methadone maintenance treatment.” See Health Canada, *Best practices: methadone maintenance treatment*, p 36. At www.hc-sc.gc.ca/ahc-asc/alt_formats/hecs-sesc/pdf/pubs/drugs-drogues/methadone-bp-mp/methadone-bp-mp_e.pdf. An Australian study traced for 2–3 years persons whose applications to a methadone treatment program had been rejected. It found that “the main consequence of an applicant not being approved was to substantially delay his/her entry to methadone treatment. At follow-up, most subjects were poorly integrated into society, and were either in treatment or still using illicit drugs.” See J. Bell et al, “Who should receive methadone maintenance?,” *British Journal of Addiction* 87 (1982): 689–694.

⁷⁸ WHO/UNODC/UNAIDS, *Position Paper: Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention*, p. 9.

⁷⁹ “Methadone should be available to any patient whom the physician believes is likely to benefit from it, and who voluntarily accepts it. There are no concomitant illnesses that preclude methadone, and it is irrational to demand of patients that they first ‘fail’ with other therapeutic approaches, survive a specified number of years of dependence or reach a certain age, or meet other arbitrary and unprecedented criteria for ‘eligibility.’” See R. Newman, *Methadone Treatment: Common Questions, A Common Answer*, Open Society Institute, 8 April 2003. At www.soros.org/initiatives/health/focus/ihrd/articles_publications/articles/methadone_20030408. The following conclusion was reached and reported in October 1994, by a special consensus conference convened under the auspices of the Minister of Health of Belgium. “There are no counter-indications [for methadone treatment] but related psychiatric conditions (alcoholism, multiple drug abuse, depression, psychosis) require diagnosis and appropriate care. Pregnancy is not a counter-indication.” See *Traitement de substitution à la méthadone: conférence de consensus* (Conclusion of the Belgian Consensus Conference on Methadone Treatment), October 1994.

health risks, such as HIV or hepatitis infection, are often indications for prioritizing treatment or relaxing admissibility criteria. Some countries run special programs for pregnant women and drug-using mothers with children.⁸⁰ A person should not be excluded from beginning OST on the basis of continued illegal drug use. In addition, the injecting of methadone or use of other drugs should not automatically be an indication for involuntary withdrawal of treatment.⁸¹ For those who are unable or unwilling to stop using drugs, treatment interventions should be directed at reduction of morbidity, disability and death caused by or associated with substance use.⁸² In such cases, opioid substitution treatment has a role to play in helping the individual to stabilize his or her consumption of drugs as opposed to complete elimination.

Article 11. Duration of treatment and dosage

- (1) The prescribing physician shall determine the appropriate dose of the prescribed opioid substitute in consultation with the patient and in accordance with best medical practice. The dosage shall aim to achieve an effective level of physical and psychological comfort while minimizing the likelihood of overdose.
- (2) The dosage should not be held out as a reward to the patient, nor withheld as a punishment of the patient.
- (3) The duration of treatment should be adequate to ensure the treatment effectiveness according to best medical practice.⁸³

⁸⁰ There are fewer complications for pregnant women and their unborn children who are in substitution maintenance treatment in comparison with those who are not in treatment. See WHO/UNODC/UNAIDS, *Position Paper: Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention*, pp. 15, 18, 26. Belgium, France and Ireland provide special programs for pregnant women and drug-using mothers with children. See European Monitoring Centre for Drugs and Drug Addiction, *Legal aspects of substitution treatment: an insight into nine EU countries*, p. 16.

⁸¹ See Ontario College of Physicians and Surgeons, *Methadone Maintenance Guidelines*, p. 25. See, also, *Opioid Substitution Treatment: New Zealand Practice Guidelines*, p. 40: “Involuntary withdrawal has serious risks to the health of client and may well have implications for others, including the wider community. Flexibility and strategic thinking is encouraged rather than knee-jerk treatment termination approaches. An important outcome measure of OST is retention in treatment. Involuntary withdrawal should be a last resort and decisions relating to termination should be initiated only after careful consideration by the case management team and with input from a number of other sources.”

⁸² WHO/UNODC/UNAIDS, *Position Paper: Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention*, p. 9.

⁸³ A United Nations position paper notes of OST that “remaining in treatment for an adequate period of time is critical for treatment effectiveness” and that premature departure from OST programs has been associated with negative consequences, including relapse to harmful use of illegal drugs; see WHO/UNODC/UNAIDS, *Position Paper: Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention*, p. 9.

Commentary: Article 11

There are no established international standards for the optimal duration of OST or the dosages of opioid substitutes that are used. In determining duration of treatment and dosage, “best practice” experiences underline the importance of consulting with and listening to the patient and finding solutions that allow him or her to live without physical discomfort.

There is broad recognition that OST may need to be continued over a long period and should not, in any case, be thought of as having a predetermined duration.⁸⁴ After extensive study of methadone, for example, there is no evidence that controlled methadone consumption has negative health consequences. People who are dependent on opioids should be able to remain in OST programs as long as those programs are useful for them.

A key principle of OST best practice is that the adjustment of dosages, especially the reduction of the dose, should never be used as punishment or inducement for behavioural change.⁸⁵ The ideal dose is one that results in the absence of cravings without creating the ups and downs of euphoria and sedation.⁸⁶ This means that it is impossible to determine the ideal dose without thorough and unthreatening consultation with the person taking the opioid substitutes.⁸⁷ Persons following OST programs have the right to be part of the determination of the dose they receive. Clinical research has indicated that when consulted respectfully, OST program participants do not necessarily tend to seek higher

⁸⁴ Health Canada, *Best practices: methadone maintenance treatment*, notes: “It is not possible to determine an optimal duration of treatment for all individuals. The optimum duration is for each individual to continue receiving treatment for as long as they continue to benefit from it. Indefinite or lifetime maintenance on methadone is an option for some clients/patients” (p. 45).

⁸⁵ S. Maxwell and M. Shinderman, “Optimizing response to methadone maintenance treatment: use of higher-dose methadone,” *Journal of psychoactive drugs* 31 (1999): 95–102. The authors note that in the U.S., “[i]n the 1980s, practitioners were under a great deal of pressure to apply restrictive and punitive measures to addiction treatment. In MMT [methadone maintenance therapy] programs, contingency dosing and very low ceiling doses were attempted and shown to be of suboptimal efficacy. Numerous studies concluded that urine toxicology results positive for illicit opiates show robust inverse correlation to methadone dose There is a clear correlation between increased methadone dose and increased retention in treatment” (p. 97).

⁸⁶ H. Catania, *About methadone (2nd edition)* (New York: Drug Policy Alliance, 2003), p. 10.

⁸⁷ See, for example, Health Canada, *Best practices: methadone maintenance treatment*, which notes: “Given that individuals vary in how they respond to doses of methadone, programs should have a flexible, individualized policy on dosage. Each individual needs to be carefully assessed by a clinician who is experienced with treating opioid dependence, and the initial dose should be assessed on an individualized basis. Client/patient input should be taken into account in determining the dosage” (p. 42); see, also, S. Maxwell et al, “Optimizing response to methadone maintenance treatment: use of higher-dose methadone,” *Journal of psychoactive drugs* 31 (1999): 95–102, which demonstrates the reliability of self-assessment by OST clients of the effects of various doses.

or more intoxicating doses, but rather reliably seek to consume stabilizing levels of opioid substitutes.⁸⁸

Article 12. Eligibility for take-away doses

- (1) The determination of eligibility for take-away doses shall be based solely on:
 - (a) the clinical stability of the patient; and
 - (b) the patient's ability to comply with the procedures of the program.⁸⁹
- (2) The prescribing physician shall have discretion to initiate take-away doses to patients who do not meet the eligibility criteria in Section (1) where:
 - (a) the patient has a medical condition or disability that limits his or her mobility; or
 - (b) the distance the patient must travel to the clinic or other health care setting, or other circumstance, restricts the patient's ability to have his or her consumption supervised on each occasion.⁹⁰
- (3) The prescribing physician shall specify the procedures for take-away doses in writing and shall ensure that copies are provided to the patient and the dispensing pharmacist.⁹¹

Commentary: Article 12

Take-away doses are important in improving retention in treatment, reducing congregation at dispensing points and improving access to treatment by reducing travel

⁸⁸ See E. Robles et al, "Implementation of a clinic policy of client-regulated methadone dosing," *Journal of Substance Abuse Treatment* 20 (2001): 225–230, p. 226: "Not one patient continued to ask for increases in methadone after reaching clinical stabilization." In fact, the authors note, the opposite may cause concern: "When allowed to set their own dose of methadone, patients tend to maintain themselves at subtherapeutic doses." See, also, S. Maxwell et al, "Optimizing response to methadone maintenance treatment: use of higher-dose methadone" *Journal of psychoactive drugs* 31 (1999): 95–102.

⁸⁹ Health Canada suggests, "Programs should balance the advantages of ensuring compliance and having regular contact with clients/patients with the need for flexible, client/patient-centred treatment that takes into account the realities of clients'/patients' lives." Research has shown that flexible take-home doses are an important factor in patient retention. See Health Canada, *Best practices: methadone maintenance treatment*, pp. 44, 58. Regulations should specify how these requirements are to be judged. Examples of tools for assessment are listed in *Opioid substitution treatment: New Zealand practice guidelines*, p. 28. See, also, "Carry Policy" guidelines in Ontario College of Physicians and Surgeons, *Methadone Maintenance Guidelines*, pp. 18–21.

⁹⁰ This requirement is derived from Ontario College of Physicians and Surgeons, *Methadone Maintenance Guidelines*, pp. 30–37.

⁹¹ This requirement is derived from *Opioid substitution treatment: New Zealand practice guidelines*, p. 28.

difficulties.⁹² Medical practitioners are empowered with the flexibility to accommodate the needs of individual patients.

Dispensing treatment in take-away doses improves accessibility and enables patients to maintain autonomy over their personal lives. Maintaining relationships, employment and other personal obligations becomes easier. Take-away doses should be prescribed at the discretion of trained medical staff after undertaking a suitability assessment and appropriate patient education. Furthermore, take-away doses should never be withheld as a punishment. Risks associated with take-away doses (e.g., diversion, overdose) can be minimized by monitoring progress and reassessing their suitability over time.

Article 13. Withdrawal from Substitution Treatment

- (1) A patient shall have the right to voluntarily withdraw from treatment at any time.
- (2) The prescribing physician or another qualified health professional shall fully inform the patient of the potential risks and benefits of withdrawal from treatment and shall work with the patient to ensure the patient's safety and comfort during the withdrawal process.⁹³
- (3) The prescribing physician shall not discontinue services that are needed unless the patient requests the discontinuation, alternate services are arranged or the patient is given a reasonable opportunity to arrange alternate services.⁹⁴
- (4) The withdrawal from treatment with an explanation of likely consequences shall be recorded or registered in medical documentation and signed by the patient and health practitioner.
- (5) Involuntary withdrawal from treatment shall be avoided except where compelling reasons exist. Regulations governing grounds for involuntary withdrawal shall be clearly communicated to patients at the outset of treatment.⁹⁵

⁹² These advantages are reflected in New South Wales [Australia], *Guidelines for Prescribing Methadone for Unsupervised Administration Take-Away Doses*. At www.health.nsw.gov.au/public-health/dpb/publications/pdf/guidelines_takeaway.pdf.

⁹³ Regulations should include non-mandatory guidelines for withdrawal doses. For example, see S. Henry-Edwards et al, *Clinical guidelines and procedures for the use of methadone in the maintenance treatment of opioid dependence*, p. 5.

⁹⁴ This wording is derived from Ontario College of Physicians and Surgeons, *Methadone maintenance guidelines*, p. 25.

⁹⁵ Programs should adopt a problem-solving rather than a punitive approach when considering involuntary discharge of a patient. Ideally, patients should be retained in treatment for as long as they are benefiting from treatment. See Health Canada, *Best practices: methadone maintenance treatment*, p. 46. Regulations should include specific, limited criteria for involuntary withdrawal. These might include well-documented threats or violent behaviour toward staff or patients. See Ontario College of Physicians and Surgeons, *Methadone Maintenance Guidelines*, p. 26.

Optional: Article 14. Urine Drug Screening

The design and implementation of urine collection, testing and interpretation shall be carried out in a way that:

- (a) maximizes patient retention and other positive treatment outcomes and the safety of the patient;
- (b) respects the dignity of the patient;
- (c) minimizes the frequency of such screening, limiting it to tests needed to guide treatment;
- (d) recognizes the limitations of such screening, including false positives and false negatives; and
- (e) prohibits the use of results in a punitive manner.

Commentary: Article 14

Certain OST guidelines suggest that at least one urine drug screen must be collected, interpreted and documented prior to treatment initiation and that, thereafter, urine testing should be done on a fixed or random schedule.⁹⁶ Results of urine drug screens are frequently used to verify the patient's self-report of substance use and assess compliance with and response to treatment. However, some physicians consider urine testing to have limited clinical value, and prefer to establish a relationship of trust with their patients. From a human rights perspective, urine drug screening raises concerns regarding a patient's right to privacy. Less invasive screening methods such as mouth swab provide a viable alternative to urine testing. Where it is decided that urine drug screening will form part of the OST, why and how it will be done, and how the screening results will be used, should be clearly described to the patient when starting treatment. Urine drug screening should be performed in the least invasive manner possible.⁹⁷ Furthermore, it should be limited to those situations in which the prescribing physician considers it clinically necessary.

⁹⁶ See Ontario College of Physicians and Surgeons, *Methadone Maintenance Guidelines*, p. 28.

⁹⁷ New Zealand guidelines recommend, "If there is to be observation of the passage of urine there should be an appropriate environment for taking urine samples and staff of the appropriate gender should be involved"; see *Opioid substitution treatment: New Zealand practice guidelines*, at 31. Other commentators consider that observation is never necessary: "Urine specimens and other samples should only be taken in private, if at all, and their results should only be assessed in terms of treatment progress rather than being used punitively. Observed urination is undignified and unnecessary and should no longer be necessary now that other techniques are available, for example mouth swabs"; see The Methadone Alliance, *Service User's Charter*. Available via www.m-alliance.org.uk.

Optional: Article 15. Preventing the diversion of opioid substitutes used in opioid substitution treatment

- (1) A health practitioner may implement practices to minimize diversion of approved opioids into the hands of persons for whom they are not prescribed or otherwise not intended, including one or more of the following measures:
 - (a) periodic reinforcement with patients of detailed information on dosing, take-away policies, and procedures for dealing with diversion;
 - (b) requiring patients to present a unique identifier at the point of dispensation;⁹⁸
 - (c) supervised consumption; or
 - (d) separation of waiting and dispensing areas.⁹⁹

Commentary: Article 15

The unauthorized giving, lending or selling of opioid substitutes, such as methadone, is considered diversion of a controlled substance. Despite the fact that opioid substitutes can themselves be addictive and in most countries are classified as controlled substances even where they are authorized for medical use, many governments have concluded that the health benefits of OST programs far outweigh any security risks.¹⁰⁰ There is also the concern that overly restrictive policies may reduce treatment retention and increase mortality by increasing the population of untreated opioid users. Governments need to ensure national legislation and policies aimed at preventing diversion do not contribute to the spread of the HIV epidemic and other social and health related harms associated with drug use by impeding access to treatment or making adherence to treatment overly complicated. In implementing measures to reduce the risk of diversion, the human rights of patients must be respected and protected, particularly the right to confidentiality and the right to receive an adequate dose.

Optional: Article 16. Central treatment list

- (1) Where a physician intends to prescribe an approved opioid for the first time to a patient, the prescribing physician shall not issue a prescription for the approved opioid until he or she assigns a unique identifier to the patient and notifies the [responsible public health authority] of that unique identifier.

⁹⁸ A unique identifier could, for example, be constructed from letters from the person's name together with his or her date of birth. The unique identifier should not contain the person's name or address.

⁹⁹ The above practices are listed in United States Institute of Medicine, *Federal regulation of methadone treatment* (Washington: National Academy Press, 1990), p. 115.

¹⁰⁰ United States Institute of Medicine, *Federal regulation of methadone treatment*, p. 115; Ontario College of Physicians and Surgeons, *Methadone Maintenance Guidelines*, p. 31.

- (2) The [responsible public health authority] shall maintain a central treatment list which shall contain the information notified to it under Section (1).¹⁰¹
- (3) Where a notification is made to the [responsible public health authority] in accordance with Section (1), the [responsible public health authority] shall inform the prescribing physician as to whether the patient has previously been included in the central treatment list.
- (4) The confidentiality of all providers and patients shall be respected.¹⁰² Any information obtained by the [responsible public health authority] or any other body that would identify patients shall be regulated so as to preserve the right to confidentiality.

Commentary: Article 16

Where it is deemed necessary to implement a monitoring system, such as a central treatment list, aimed at preventing the diversion of controlled substances used in drug dependence treatment, including OST, two important concerns must be highlighted. First, the development and implementation of a monitoring system must be undertaken in light of international human rights law. In particular, a patient's right to confidentiality must be protected in the development and operation of a monitoring system. Second, it is imperative that the management of a monitoring system be undertaken by the appropriate public health authority, as opposed to, for example, a law enforcement body.¹⁰³

¹⁰¹ Experts note, "The registration/accreditation of treatment providers and registration of those receiving treatment, are useful approaches to ensure the quality of service and to minimize the risk of prescribed medications being diverted into illicit channels"; see WHO/UNODC/UNAIDS, *Position Paper: Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention*, p 28. In Europe, "[c]ontrol of prescribing and dispensing substitutes is achieved mainly by means of central registration (countries that legally demand registration are Austria, Finland, France for methadone, Ireland, Spain) and/or through special prescription forms for doctors (France, Ireland). Registration can also be used for evaluation purposes"; see European Monitoring Centre for Drugs and Drug Addiction, *Legal aspects of substitution treatment: an insight into nine EU countries*, p. 16.

¹⁰² According to the Lithuanian OST Guidelines, the Vilnius Narcological Centre maintains a register of patients receiving OST and is responsible for guaranteeing the confidentiality of patient's health care information in accordance with the law on mental health. See Lithuanian Ministry of Health, *Confirmation of the Application Procedure of Substitution Therapy to Opioid Addicts*, December 1997. See, also, Czech Republic Ministry of Health, *Czech Substitution Treatment Guidelines*, June 2000.

¹⁰³ For example, in Ireland, the Central Treatment List was established under Statutory Instrument No. 225 (Minister for Health and Children 1998) following the *Report of the Methadone Treatment Services Review Group 1998*. The list is administered by the Drug Treatment Centre Board on behalf of the Health Service Executive and is a complete register of all patients receiving methadone in Ireland.

Optional: Article 17. Reporting to public health authority

- (1) A dispensing pharmacist or prescribing physician shall forward to the [responsible public health authority] at prescribed intervals:
 - (a) in respect of each supply of an authorized opioid:
 - (i) the prescription on which the supply of the approved opioid was made; and
 - (ii) a statement which confirms the unique identifier of the person to whom the prescription was issued.
 - (b) particulars of each supply of an approved opioid made to a prescribing physician.
- (2) The [responsible public health authority] shall maintain a record of all information received under Section (1).¹⁰⁴

Commentary: Article 17

Where it is deemed necessary to implement a monitoring system, such as requiring a dispensing pharmacist or prescribing physician to report to a public health authority, aimed at preventing the diversion of controlled substances used in drug dependence treatment, including OST, the health authority must make sure that all available measures are undertaken to ensure the information is kept confidential and not used for inappropriate purposes. The information should be gathered according to unique identifiers given to participants of methadone programs.

¹⁰⁴ The language in the above sections dealing with Central Treatment List is adapted from Ireland's *Misuse of drugs (supervision of prescription and supply of methadone) regulations*, 1988, ss. 3–10, 21. See, also, European Monitoring Centre for Drugs and Drug Addiction, *Legal aspects of substitution treatment: an insight into nine EU countries*, p. 16.

Chapter IV. Health Insurance Plans

Article 18. Coverage of drug dependence treatment by health insurance plan

Any person who is entitled to coverage for prescribed medication or health services under [relevant health insurance legislation] is entitled to coverage for such drug dependence treatment services or medications as are required for the person's maintenance, care, diagnosis and treatment in accordance with this Act.

Commentary: Article 18

This article is designed to ensure coverage of drug dependence treatment within public and private health care insurance schemes. Health insurance plans should be comprehensive. They should cover the entire continuum of clinically effective and appropriate services provided by licensed professionals and should provide benefits analogous to those covering other illnesses.¹⁰⁵ In some situations, health insurance plans will not provide coverage for drug dependence treatment. In other situations, where such coverage is provided, insurance policies may impose higher payments, deductibles and more restrictive limitations on access.¹⁰⁶ As noted above, everyone has a right to the highest attainable standard of health without risk of discrimination. If a person has been determined to be eligible for coverage under a particular health insurance plan, permitting less favourable coverage for medication prescribed for treatment of a particular condition, such as drug dependence, amounts to discrimination.

¹⁰⁵ This wording is derived from *An Act Relating to Health Insurance for Mental Health and Substance Abuse Disorders, Act No. 25 of 1997, Vermont (U.S.A.)*, s. (b).

¹⁰⁶ See [U.S.] National Mental Health Association, *Substance Abuse Insurance Parity: A guide for advocates*, Spring 2002, p. 1.

Selected Resources

This section provides a list of resources that the Legal Network considers to be particularly relevant.

Articles, reports and policy documents

Barnett, P.G. “The cost-effectiveness of methadone maintenance as a healthcare intervention.” *Addiction* 94(4) (1999): 479–488.

British Institute of International and Comparative Law. *Draft fourth framework convention on risk management*. 2003. At www.senlisCouncil.net/documents/BIICL_HR_Framework#search=%22Draft%20fourth%20framework%20convention%22.

Council of the European Union. *Recommendation on the prevention and reduction of health-related harm associated with drug dependence* of 18 June 2003. 2003/488/EC.

Czech Republic Ministry of Health. *Czech Substitution Treatment Guidelines*, June 2000.

European Parliament. *Recommendation to the Council and the European Council on the EU drugs strategy (2005-2012)*. A6-0067/2004, 15 December 2004.

Health Canada. *Best practices: Methadone Maintenance Treatment*, 2002.

Henry-Edwards, S. et al. *Clinical Guidelines and Procedures for the Use of Methadone in the Maintenance Treatment of Opioid Dependence*. Australian Government Department of Health and Aging, 2003.

Macedonia Ministry of Health. *Guidelines and Protocol for the Administration of Methadone in the Treatment of Opiate Addiction*, October 2001.

Mattick, R. P. et al. “Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence.” *The Cochrane Database of Systematic Reviews* (Issue 2) (2003).

Mattick R et al. “Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence.” In *The Cochrane Library*, Issue 4, 2002.

New Zealand Ministry of Health. *Opioid Substitution Treatment: New Zealand Practice Guidelines*, February 2003.

The College of Physicians and Surgeons of Ontario. *Methadone Maintenance Guidelines*, 2005 [Canada].

Ward J et al (ed). *Methadone Maintenance Treatment and Other Opioid Replacement Therapies*, 1998.

WHO/UNODC/UNAIDS. Position Paper: Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention, 2004.

WHO. *Policy Brief: Reduction of HIV Transmission Through Drug-Dependence Treatment — Evidence for Action on HIV/AIDS and Injection Drug Use*, 2004.

WHO. *WHO Model List of Essential Medicines*, revised March 2005.

Legal documents

Decree of the Verhovna Rada of Ukraine On Recommendations of the Parliament trials on Socio-economic problems of HIV/AIDS, drug abuse and alcoholism in Ukraine and means of their solving of 3 February, 2004, No 1426-IV [Ukraine].

Decree-Law No. 183/2001 of 21 June 2001 [Portugal].

Federal Act of the Russian Federation on narcotic drugs and psychotropic substances (O narkoticheskikh sredstvakh i psikhotropnih veshchestvakh), 8 January 1998 [Russian Federation].

Law of Ukraine on prevention of Acquired Immunodeficiency Syndrome [AIDS] and social protection of the population (Pro zapobigannia zakhvoriuvanniu na sindrom nabutogo imunodefitsitu (SNID) ta sotsial'niy zakhist naseleattia), N 1972-XII of 12.12.1991, amended 03.03.1998 No 155/98-BP [Ukraine].

Public Health Service Act, 42 U.S.C. 290ee-3 [US].

Seyed Mahmood Hashemi Sharoudi, Head of the Judiciary. *Executive Order to All Judicial Authorities Nationwide*, 24 January 2005. Ref 1-83-14434. [Islamic Republic of Iran].

The US Federal Alcohol/Drug Confidentiality Regulations, 42 C.F.R. Part 2: Confidentiality of alcohol and drug abuse patient records [US].



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