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Policy of the Department for the Treatment of Substance Abuse - Ministry of Health

Regarding :Treatment of opioid addiction through psychosocial therapy and maintenance treatment (agonists and partial agonists such as: methadone, buprenorphine/buprenorphine/naloxone)

Medical Administration

Mental Health Division

Department for the Treatment of Substance Abuse

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Nothing in this policy document shall reduce or restrict the application of the provisions and/or requirements and/or exclusions appearing in the Supervision of Institutions for Drug Users Law 5753-1993 and its Regulations or in the Department for the Treatment of Substance Abuse operating manual, as updated from time to time.

Nothing in this policy document shall be seen as imposing any obligation on the Ministry of Health to provide treatments and/or services beyond its area of responsibility and which anyway are outside its budgetary framework, notwithstanding the great importance attached to providing these treatments or services.

1. Main aspects of the policy for treatment of opioid addiction at medical assessment maintenance treatment.

Based on the research and international up-to-date medical information and the opinion of various professional bodies around the world such as the world health organization (WHO), American Psychological Association (APA), the National Institute for Clinical Excellence (NICE) and the Substance Abuse and Mental Health Services Administration (SAMHSA), the Ministry of Health has determined that:

1.1 Prolonged drug treatment using an agonist (such as methadone), or partial agonist (such as buprenorphine or buprenorphine/naloxone combination treatment) is the safest and most effective method of treating patients suffering from the disease of chronic opioid addiction who wish to stop using opiates, and significantly reduces the direct and indirect harm caused by their addiction.

1.2 Higher retention rates exist amongst drug treatment program participants when compared to other treatment approaches**.**

1.3 The effectiveness of the treatment is manifested in obtaining control over drug consumption patterns until total abstinence is achieved, a reduction in the risk of contracting and spreading infectious diseases due to injection use and the damage caused by the criminal activity which accompanies the

use of street drugs.

1.4 Combining psychosocial therapy and rehabilitation with MAMT- medical assisted maintenance treatment has been shown to significantly improve the chances of cessation and total abstinence from the use of opiates and other street drugs. This combined approach to treatment significantly contributes to the patient's ability to function in different facets of life: work, family and social interaction and thus facilitates his return to the normal cycle of life.

1.5 Since drug addiction is a chronic illness, the patients suffering from it may require long term treatment, which in many cases may continue for the rest of their lives.

1.6 A multi-stage-differential and methodical system must be built which combines within it treatment paths tailored to match the condition, character and progress being made in the process by the patient. The treatment path should be adapted to the patient in a personal way so that it caters to both his drug treatment and social and rehabilitation needs.

1.7 The Center must hold organized follow-up meetings at least once every six months during which decisions shall be taken by a multi-professional team (comprising of physicians and psychosocial therapists), in cooperation with the patient, regarding the contents and duration of the treatment at each phase reached by him.

1.8 The medication (methadone/buprenorphine/suboxone) and its dosage should be chosen by the Center's physician having regard to its indications and contra-indications and after a clinical examination, laboratory tests and a detailed consideration of the case taking into account a number of factors such as the history of the patient's addiction and its severity, his motivation to participate in a treatment program and an assessment of the advantages of and risks entailed in each treatment, in collaboration with the patient.

1.9 The preferred drug for any patient turning to the Center for the first time or returning to treatment following a break, should be suboxone, since it is included in the national health basket, has minimal side effects, a good safety record and a reduced risk of being used in an adverse way.

1.10 In addition to drug and psychosocial therapy, each treatment framework also requires that health promotion instructions regularly be given by the Center's medical and nursing team in order to minimize harm and improve the patient's wellbeing. The Center may be assisted by external agencies, such as representatives of the local Health Bureaus and the Ministry's Public Health Department.

1.11 Methadone (Methadone Hydrochloride) Buprenorphine and suboxone (buprenorphine/naloxone), in a customized oral dosage, are the agonist/partial-agonist medications currently being recommended in Israel as an option for the MAMT of opioid addiction. The drug buprenorphine **should be prescribed for women during pregnancy and while breastfeeding who before their pregnancy were being treated with**

suboxone but were advised to discontinue taking it after becoming pregnant.

1.12 Agonistic methadone-based drug treatment should only be provided by public Centers which hold a medical or combined license under the Supervision of Institutions for Drug Users Law 1993 and its Regulations. The Centers must satisfy the requirements of the Law and Regulations and be accessible by public transport and to disabled people.

1.13 Buprenorphine/Suboxone-based drug treatment may be provided by physicians qualified to administer it at both public and private Centers, provided they hold a medical or combined license under the Supervision of Institutions for Drug Users Law , 1993 and its Regulations, 1994. In the private Centers too, patients should be encouraged to move to the medication suboxone in order to avoid diversion and harmful use.

1.14 In order to provide a treatment solution to persons living in regions located far away from the permanent Centers, mobile clinics shall be operated in the Eastern, Western and Upper Galilee and Negev regions. The treatment places shall be decided upon with the approval of the Department for the Treatment of Substance Abuse.

1.15 It is important that the Centers extend their reciprocal ties with front line medical institutions (HMOs and General Medical Centers and Mental Health Centers).

1.16 Research on alcohol and drug abuse and addiction and new methods of treating them, should be strengthened, and encouragement should be given to researchers in the areas of medicine, infectious diseases, epidemiology, the brain and biology on the one hand and social sciences on the other, to undertake research studies in this area.

2. Introduction

2.1 The disease of opiate/opioid addiction and the harm it causes

Addiction to opiates (heroin, morphine, codeine) and opioids (methadone, oxycontin, fentanyl and their derivatives) is a wide-scale chronic disease of the brain that has many negative repercussions for the addict, his relatives, the community and public health.

This addiction is typically accompanied by use of other psychoactive substances (poly-substance abuse), and patterns of criminality which hamper the treatment process and require a multipronged, unique response.

2.1.1 Definition of Addiction

2.1.1.1 Addiction is a chronic brain disease caused by neuro-plastic changes in the brain at the neural and molecular levels, some of which are reversible and some

irreversible, as a result of the use of various psychoactive substances.

2.1.1.2 The disease is characterized by recurring bio-psycho-social episodes exhibiting obsessive-compulsive behavior in searching after drugs, alcohol or other psychoactive substances and their use, despite the resultant negative consequences. Because of the tolerance phenomenon, an ever increasing quantity of the substance is required in order to achieve the desired effect. Stopping or reducing the dosage causes the onset of withdrawal symptoms.

2.1.2 Diagnosis of Dependence syndrome

2.1.2.1 In Israel the diagnosis is made by a physician according to the World Health Organization's International Classification of Diseases, ICD-10.

2.1.2.2 A definite diagnosis of dependence may only be made when 3 or more of the following criteria were exhibited or experienced some time during the last year:

2.1.2.2.1 A strong craving or obsessive compulsion to take the substance.

2.1.2.2.2 Difficulty in controlling the pattern of taking the substance in terms of starting the use, stopping it and the quantity consumed.

2.1.2.2.2.1 A situation of physiological withdrawal when use of the substance is suspended or reduced, as manifested in the typical withdrawal symptoms for the psychoactive substance in question or the alleviation or prevention of the withdrawal symptoms when it (or a similar substance) is used.

2.1.2.2.2.2 Evidence of development of tolerance, in a way that requires increasing the dosage of the psychoactive substance, in order to achieve results that were initially achieved by taking far lower dosages (examples of this can be found amongst opiate addicts who take a daily dose sufficient to induce dysfunction or death where tolerance has not developed).

2.1.2.2.2.3 Advanced abandonment of pleasures and other areas of interest due to the use of the psychoactive substance and an increase in the time which the person dedicates to

obtain the substance or its consumption, or in the time required to recover from its effects.

2.1.2.2.2.4 Persistent use despite clear evidence of its detrimental effects, such as liver damage caused by excessive drinking, periods of depression resulting from "heavy" use or impairment of cognitive function connected to drugs. It must be verified that the user was indeed aware of the nature and extent of the harm being done, or could be expected to have been aware of it.

2.1.3 Diagnosis of Harmful Use (Abuse)

Definition - This is a pattern of use of a psychoactive substance which is harmful to health. The damage may be physical (such as hepatitis contracted through self-injection of drugs) or mental (such as bouts of secondary depressive disorder engendered by heavy alcohol consumption).

2.1.4 Damage caused by Addiction and Harmful Use

2.1.4.1 An elevated risk of death and physical/mental morbidity caused by the disease, from infectious diseases

contracted by using contaminated needles (hepatitis B and C, HIV), liver diseases such as cirrhosis, poor nutrition and health habits (dental diseases, loss of teeth), suicidal tendencies, falls, accidents, injuries caused by violence, etc.

2.1.4.2 Heightened risk of passing on infectious diseases.

2.1.4.3 Criminal activity (theft, robbery, burglary) to purchase the substance.

2.1.4.4 Engaging in prostitution to purchase the substance..

2.1.4.5 Severely impaired ability to interact with family and society unemployment and a lack of productivity, homelessness, violence, family breakdown, loss of parental competency, descent of other family members to use of drugs.

2.2 **Drugs used to treat opioid addiction**

MAMT for opioid addicts is based on the principle of providing agonistic or partial agonistic medication. The drugs currently being administered are: Methadone (Methadone Hydrochloride)[used in Public centers only], Buprenorphine, Suboxone (buprenorphine/naloxone combination treatment) for patients being treated both in Public and Private Centers

which hold the standard licenses from the Ministry of Health.

Methadone preparation:

A full agonist opioid which acts on receptor μ. It was first used to treat heroin addicts in the 1960's. Various studies have shown that methadone is effective in maintenance therapy and in reducing opioid dependence. It is also effective in reducing infectious disease morbidity and lowering mortality.
It is important to note, that caution should be exercised when using the drug since there have been many cases of overdose-induced death, especially after the dosage has been lowered or a period of total abstinence, and therefore the drug will only be prescribed in public Centers following which the patient's progress is monitored by regular medical checkups.

Buprenorphine:

A partial-agonist for receptor μ. The drug is used extensively in many western countries, including France, the U.S., England, Austria and Finland. Moreover, some of those countries supply the drug within the framework of Primary Health Care.

In Israel. the drug was first used in 2002, and is prescribed in Public health care facilities and in a limited number of private clinics which are required to meet the statutory licensing requirements for an institution treating drug

addicts and are closely monitored by the Ministry of Health.

In 2013 after the inclusion of suboxone in the National Health Technology Basket, patients who had hitherto been treated with Buprenorphine were now being prescribed Suboxone instead and the buprenorphine preparation is now given only to pregnant or breastfeeding addicted women.

Suboxone (buprenorphine/naloxone)

A mixed preparation which also includes naloxone in a ratio of 4:1, which acts as an antagonist to opioids. When taking the drug orally, the effect of the naloxone is not felt. Only if used in an adverse way through injection or inhalation does the naloxone begin to act and causes severe withdrawal symptoms, an attribute which deters the user and reduces the risk of abuse. For this reason, the preparation is primarily designated for ambulatory treatment since it drastically reduces harmful use.

Interactions between methadone/ buprenorphine and other medications

It is well known that many patients receiving MAMT take additional medications such as: antiretroviral drugs to treat AIDS and other infectious diseases or psychiatric drugs.
Below is a list of the most commonly used medications amongst this population(Drug/drug interactions):

Medication	Clinical significance for:	
	Methadone	Buprenorphine
AMOTRIPTYLINE	++	++
ATAZAVAVIR		++
BENZODIAZEPINES (ALPRAZOLAM, DIAZEPAM, TRIAZOLAM)	++	++
CIPROFLAXIN	?	
CITALOPRAM/ESCITALOPRAM	++	
ERYTHROMYCIN	?	
FLUCONAZOLE	++	?
FLUOXETINE	+	?
FLUVOXAMINE	++	+
INDINAVIR	+	?
KETOCONAZOLE	?	?
MOCLOBEMIDE	+	
OMEPRAZOLE	?	
RITONAVIR (avoid using in combination with atazanavir)	?	?
SERTRALINE	?	
Urine alkalisers e.g. sodium bicarbonate	+	
ZOPICLONE	++	+

Legend:

+ = Weak interaction

++ = Not powerful interaction

Department for the treatment of Substance Abuse
Ministry of Health
P.O.B 1176, Jerusalem 91010
Call.Habriut@moh.health.gov.il
Tel: *5400 **Fax**: 02-5655969

קול הבריאות *5400

המחלקה לטיפול בהתמכרויות

משרד הבריאות
ת.ד.1176 ירושלים 91010
דוא"ל Call.Habriut@moh.health.gov.il
טל: *5400 **פקס** 02-5655969

Where an interaction exists use should temporarily be suspended if possible, and if not the effect of the drugs should be monitored and the dosage adjusted accordingly.

There are 4 groups of interactions:

1. **Medications which enhance the depressive/calming effect** - These medications may increase the risk of overdose due to their effect of strengthening suppression of the central nervous system or raise the level of methadone /buprenorphine in the blood as a result of a fall in the degradation rate or the rate of evacuation in the urine.

Medication	Clinical significance for:	
	Methadone	Buprenorphine
CARBAMAZEPINE	++	
CIMETIDINE	+	?
DISULFIRAM (if used in conjunction with methadone formulations containing alcohol)	+	
HYPERICUM PERFORATUM (St. John's Wart)	+	?
MOCLOBEMIDE	+	
NEVIRAPINE	+	
NIFEDIPINE		?
PHENYTOIN	++	?
RIFAMPICIN	++	?
RIFABUTIN	++	++
Urine acidifiers e.g. ascorbic acid	+	+

2. **Withdrawal symptoms or side effects -** This group of medications may

cause low levels of methadone or buprenorphine in the blood, the appearance of withdrawal symptoms due to their rapid degradation or side effects through other mechanisms

3. **QTC prolongation**

This group of medications may exhibit contraindications or require additional caution when given together with methadone or buprenorphine due to their effect on the heart rate through QTC prolongation.

Medication	Clinical significance for:	
	Methadone	Buprenorphine
DOMPERIDONE	+	+
CITALOPRAM/ESCITALOPRAM	+	
ERYTHROMYCIN	?	?
THIORIDAZINE	+	?

4. **Interaction with other medications –** Methadone or buprenorphine may detrimentally effect interaction with additional medications in this group.

Medication	Clinical significance for:	
	Methadone	Buprenorphine
ATAZANAVIR (methadone may decrease serum levels)	++	
DESIPRAMINE (metabolism decreased leading to increased plasma levels of desipramine)	++	
NIFEDIPINE (methadone may inhibit metabolism)	++	
ZIDOVUDINE (metabolism is decreased leading to increased plasma levels of zidovudine. Symptoms of	++	

zidovudine toxicity can be misinterpreted as opioid withdrawal)		

2.3 Psychosocial therapy

A combination of psychosocial therapy and rehabilitation with medical treatment has been proved to significantly reduce use to the point of total abstinence, including opiates, substance street drugs and alcohol. The integrative treatment makes a significant contribution to enhancing the functional capacity of the patient in various aspects of life: work, family and social interaction and thus facilitates rehabilitation of patients suffering from disease addiction and has positive implications for the functioning of the family unit.

It is important to note that psychosocial therapy is mandatory according to both the Drug Label and Ministry of Health guidelines. The psychosocial therapy techniques are tailored to each patient personally and in accordance with the phases of the addiction disease.

Recommended methods

-CBT

-DBT

-Motivational Interviewing

It has especially been proven that group psychosocial therapy methods greatly contribute to the rehabilitation of patients undergoing prolonged drug treatment and it is important that each Center adopt a motivational

interview technique which may bring about a dramatic improvement in the patients' condition.

Special group sessions should be held for women, with the emphasis on sexual trauma therapy. **(PE, SE, and others).**

3. The target population and treatment goals

3.1 The target population

3.1.1 Those addicted to opiate/opioid substances who failed in two previous attempts to achieve complete withdrawal, from the age of 18 and above, who have expressed their desire to stop using street drugs.

3.2 Goals of the treatment

3.2.1 In the short and medium term:

3.2.1.1 Limiting the use of opiates/opioids to the point of complete abstinence.

3.2.1.2 Limiting the use of street drugs and other psychoactive substances, including alcohol, to the point of complete abstinence.

3.2.1.3 Integration within individual and group psychosocial therapy programs.

3.2.2 In the long term

3.2.2.1 Rehabilitation and return to normative, family and working life.

4. Admission to treatment (Admission committee and Admission criteria)

4.1 **Admission Committee** - A multidisciplinary admission committee shall operate in each Center comprising of at least two members, amongst them the Center's physician, a social worker, clinical psychologist or clinical criminologist.

4.2 **Admission Criteria** -

4.2.1 Age 18 and over.

4.2.2 At least one year history of opiate/opioid use (determined by urine tests, anamnesis and testimonies from members of family and community, etc.).

4.2.3 At least two failed detoxification attempts or unsuitability for detoxification for medical or psychosocial reasons.

4.2.4 Positive assessment regarding ability and basic preparedness to comply with the Center's demands and the rigors of the treatment program.

4.2.5 Undergoing of mandatory medical tests in accordance with Ministry of Health directives.

4.2.6 Absence of contraindications (according to E.C.G. and chest x-ray results) to the medication prescribed in the program.

4.3 **Criteria for immediate admission**

The following applicants shall be admitted immediately without waiting in the following:

4.3.1 HIV carriers/AIDS patients.

4.3.2 Pregnant women.

4.3.3 Sex workers.

4.3.4 Patients being treated with methadone/ buprenorphine which they received in another institution - hospital, detention Center, prison, other clinic - as continuing treatment.

4.3.5 Homeless persons.

4.3.6 Persons who suffering from exceptional medical and/or psychosocial conditions were approved for immediate treatment by the Ministry of Health's Department for the Treatment of Substance Abuse.

4.3.7 Patients referred by the drug addicts syringe exchange program Units.

Where a concern exists of violent behavior on the part of a patient, a violence risk assesment must be carried out using questionnaires HCR 20 and PCLR-SV. A re-assessment must subsequently be made of the danger posed by the patient after his situation has stabilized.

4.4 Computerized registration

4.4.1 Each patient must complete a comprehensive registration process which shall be documented in the computerized system as approved by the Department for the Treatment of Substance Abuse.

4.4.2 During the first month following the patient's admission, an assessment must be made of the severity of his addiction using the ASI questionnaire; the questionnaire shall thereafter be filled out

once a year in order to monitor the patient's progress.

5. Guidelines for drug treatment and psychosocial therapy

5.1 Treatment principles

5.1.1 Patients are requested to stop using street and non-prescribed drugs with the help of medications and the clinical staff.

5.1.2 Randomal urine tests are performed to identify use of psychoactive substances.

5.1.3 The frequency of examinations is determined by the standing operating procedure regarding the taking and dispatch to the laboratory of urine samples, for the Substance Abuse Treatment Units (SOP 40.007).

5.1.4 Randomal alcohol detection tests which have been approved by the Department are carried out in each Center.

5.1.5 Patients must be integrated within the treatment program which has been Tailored for them addresses their medical, psychosocial, family and vocational problems.

5.1.6 Addicts suffering from a physical or mental illness shall be treated in collaboration with general practitioner treating psychiatrist.

5.1.7 Duration of treatment shall be determined in each case by medical indications and psychosocial considerations.

5.1.8 The Center's treatment program shall provide an appropriate solution for patients in each of the four phases of treatment, from the point of view of operating hours, intensity and contents.

5.1.9 The treatment program shall be devised in collaboration with the patient, subject to this policy and the standard operating procedures and directives of the Department.

5.1.10 Patients receiving prolonged drug treatment at one of the Centers shall be entitled to receive community care and other services from their local Welfare Offices based on cooperation and coordination between their professional workers and those employed by the Centers.

5.2 **Phases of treatment**

5.2.1 The acute phase - For those commencing treatment. This phase is comprehensive and intense and designed to reduce the use of opiates/opioids to the point of complete cessation and to reduce the use of street drugs and other psychoactive substances, in

conjunction with measures designed to stabilize the patient's medical, mental and social situation (social here meaning family, legal and other problems engendered by his addiction).

5.2.2 The stabilization phase - This is marked by the patient's stabilization in terms of medication dosage and abstinence from using street drugs and his cooperation with the treatment and the Center's rules. This phase is characterized by continued drug treatment and medical and psychosocial monitoring together with a reduction in the frequency of the patient's visits to the Center, depending on his needs and situation. Due to the manifold psychosocial problems which accompany the addiction disease, this stage can be protracted and for some patients may continue for the rest of their lives.

5.2.3 The advanced stabilization phase - During this stage an individual treatment program is devised together with the patient in accordance with his needs and the possibilities existing in the various systems at the time with the aim of advancing his integration into society in a normative way.

5.2.4 Completion of the treatment and transfer to the full rehabilitation track - The stage reached by a patient who steadfastly abstains from harmful use of street drugs and has for a long period of time been stable from a psychosocial standpoint. The method of treatment shall be decided upon jointly by the physician, the

social worker and the patient.

It should be noted that addiction is a chronic relapsing disorder of the brain and there may be a regression to earlier phases of treatment.

5.3 **Continuity of treatment**

5.3.1 Any applicant who has been treated with an agonist or partial agonist under the auspices of a recognized and licensed institution (such as a hospital, prison or other clinic) should be accepted by the Center without delay while maintaining continuity of his treatment.

5.3.2 In order not to undermine the patient's treatment, any treatment worker leaving his job at the Center must see to it that the patient's care is transferred to his replacement in an orderly fashion while making sure that his departure does not disrupt the continuity of treatment.

5.3.3 In compliance with the Patient's Rights Law 1996, the (medical, nursing and psychosocial) treatment staff of the Prolonged Drug Treatment Center, shall forward the requisite information to, and advise where necessary, the staff of general and psychiatric hospitals, detention centers and correctional facilities concerning the treatment of those addicts registered with

it.

5.3.4 Provision of the medical treatment is not an object in itself, but rather a tool for achieving treatment and rehabilitation goals, assisted by a multidisciplinary team.

5.4 Medical treatment

5.4.1 Admission examinations

5.4.1.1 Anyone applying to the Center must undergo the following examinations before being admitted: anamnesis, urine test for the detection of drugs, chest x-ray and E.C.G.

5.4.1.2 Where the physician in his judgment deems it necessary, the applicant shall be required to undergo further laboratory tests before being admitted.

5.4.1.3 Following commencement of the drug therapy and at least once a year thereafter, the patient shall be obliged to undergo blood tests to detect infectious diseases such as Hepatitis B and C and HIV and others.

5.4.2 Medical assessment

5.4.2.1 Once the drug treatment has begun and stabilized at a certain dosage, the physician shall make a comprehensive medical appraisal of the patient's physical and mental condition at least once a fortnight.

5.4.2.2 In order to complete the appraisal, it is recommended that the following auxiliary tests be carried out: a general urine test and for women of childbearing age a blood test to detection of pregnancy;(HIT) a biochemical blood test including chloride, glucose, urea, potassium, creatinin and sodium levels; a liver function test: bilirubin, direct and total; CGT, AST and ALT, and not less than once every six months.
It is important to note that undergoing these tests does not constitute a precondition for admittance to the Center.

5.4.3 Administering the drug – methadone

5.4.3.1 Other than on weekends and religious holidays, the prolonged drug treatment Centers give out individual doses of methadone each day in a drinkable form, under nursing and medical supervision.

5.4.3.2 In certain irregular situations, such as illnesses or psychosocial conditions which prevent the patient from

attending the Center, with the approval of the Center's physician, methadone doses may be given to a patient at home.

5.4.3.3 Where a patient being treated at a Center has been admitted to a general or psychiatric hospital, that Center shall inform the hospital of the medication and dosage he is receiving.

5.4.4 Dosage

5.4.4.1 Premise: The dosage of the agonist medication is one of the main factors influencing the patient's physical and mental condition and function, and especially his ability to refrain from using street drugs. Therefore, getting the dosage right for the patient's condition and its revision in accordance with medical and psychosocial indications throughout the treatment period is a medical and treatment task of the highest importance.

5.4.4.2 The dosage shall be determined in accordance with the patient's condition and the treating physician's discretion. The physician should consult with members of the multidisciplinary staff and to include in his deliberations information regarding the patient's psychosocial condition and how he is faring in terms of

his ability to function within the treatment framework provided by the Center.

5.4.4.3 The average dose of methadone (Methadone Hydrochloride) is 60-120 milligrams.

5.4.4.4 The dose will be increased following a medical examination and in accordance with the patient's condition. The drug-drug interaction (DDI) relationship including synergism, as happens for example when using antidepressants or treating tuberculosis and AIDS, must be taken into account.

5.4.4.5 Raising the dosage to above 120 milligrams requires authorization from the management of the Department for the Treatment of Substance Abuse empowered by the Director-General of the Ministry of Health as required under the Dangerous Drugs Ordinance.

5.4.4.6 A dosage in excess of 150 milligrams requires precautions to be taken, including tests to measure the level of methadone blood (desirable) and an EKG to rule out long QTC syndrome, which indicates a risk of cardiac failure.

5.4.4.7 In special cases, according to medical indications, the dose may be divided and given twice a day.

5.4.5 Administering the drug- buprenorphine/buprenorphine+naloxone (Suboxone)

5.4.6 The recommendation of the Department for the Treatment of Opioid Addiction is that, for all the reasons mentioned above, the preferred drug for treating the disease is suboxone.

5.4.6.1 The average dosage for buprenorphine is 12-16 milligrams a day. The starting dose is 2 milligrams a day and is only prescribed after objective withdrawal symptoms have begun to appear according to the score in the **Cows questionnaire** and the **Sows questionnaire** subjective indices (**see Exhibit 1+2**), (a score in the Cows questionnaire of over 12 and in the Sows questionnaire of over 16 being the threshold for commencement of treatment). The completed forms should be stored in the patient's personal file.

5.4.6.2 The dose of the drug buprenorphine will be increased following a comprehensive medical examination by the Center's physician in accordance with the patient's condition.

5.4.6.3 Treatment with buprenorphine shall follow the Buprenorphine (Subutex) /Bup/Nalox(Suboxone) Treatment Protocol for use by Authorized Institutions (No. 40.008) + Exhibit 8.1 - Subutex Treatment Protocol.

5.4.6.4 Where a patient being treated at a Center has been admitted to a general or psychiatric hospital, the Center shall inform the hospital of the medication and dosage he is receiving.

5.4.6.5 As stated previously, when pregnant or breastfeeding, women are to move over to treatment with either methadone or buprenorphine, according to the physician's discretion.

5.5 **Psychosocial therapy**

5.5.1 Each patient shall be assigned a personal therapist who shall also serve as a case manager and shall be responsible for the inclusion and coordination of a range of solutions which are required under the treatment programs, even if they are not provided by him directly.

5.5.2 The forging of a personal bond and trust between the patient and his care provider are the basis for all psychosocial intervention.

The psychosocial therapy must address a variety of needs and issues such as coping with substance abuse, traumas, family problems, etc.

5.5.3 Each Center shall have a professional staff comprising of: social workers (and clinical psychologists and clinical criminologists) and a rehabilitation worker. Similarly, efforts shall be made to include professionals with different cultural backgrounds mirroring the existing range of cultures within the patient population, while ensuring the forms in the Center are culturally sensitive.

5.5.4 The personal treatment program should incorporate goals and intermediate objectives and be updated when necessary according to the patient's changing condition and at least once every three months.

5.5.5 The initial program shall commence from the day of admittance to treatment.

5.5.6 The intensity of the psychosocial therapy shall be commensurate with the phase of treatment and the patient's condition:

5.5.6.1 <u>During the acute phase</u>: At least one individual session a week, and participation in group sessions at least 3 times a week.

During the stabilization phase: At least one individual session a fortnight, and participation in group sessions at least once a week. Participating in the self-help group sessions is important (NA group 12 steps, MA).

5.5.6.2 During the advanced stabilization phase: Individual sessions according to need and not less than once a month and participation in group sessions once a month or according to need. Participating in the self-help group sessions is important.(NA Group 12 steps)

5.5.6.3 During the completion of treatment stage and/or following transfer to full rehabilitation track: Individual session at least once a week or more frequently if needed. In addition, participating in the self-help group sessions is important (NA group 12 steps, MA).

5.5.6.4 Should a crisis situation occur which requires assistance, the patient shall be entitled to as many additional sessions as his condition dictates.

5.5.7 The program shall be updated once every three months, or as shall be necessary, in consultation with the Center's physician.

5.5.8 In the case of patients whose drug treatment dosage has stabilized and who are working, a psychosocial therapy program shall be drawn up which does not impinge upon their work hours.

5.5.9 Psychosocial therapy is a solution for reducing and curtailing the use of street drugs, the types of intervention being tailored to the severity of the use, the types and quantities of substances being used simultaneously (poly-drug abuse including alcohol).

5.5.10 The psychosocial interventions are varied, individual, group, family and mediatory, and utilize a range of methods: cognitive and behavioral, such as: CBT (cognitive behavioral therapy), CT (contingency treatment) and DBT (dialectical behavioral therapy), advice on social problems, harm reduction, motivational (such as: motivational interview -MI) and psycho- education (health promotion and education) approaches, vocational training , 12-step groups, relapse prevention groups, trauma treatments, (PE,SE,EMDR), psychodrama, sand-play therapy) etc.

5.5.11 Training of care providers:

5.5.11.1 Each Center must provide psychosocial training to therapist and the treatment staff must therefore comprise of senior professional workers who are trained and experienced in the field.

5.5.11.2 Each Center must send representatives from its care providers to participate in continuing education programs, symposiums and designated courses which the Health Ministry's Department for the Treatment of Substance Abuse runs from time to time.

5.6 **Risk assessment**:

The addict population being treated in the Centers is largely made up of individuals who have criminal records and one of the main goals of the treatment is to keep them away from street drugs and reduce the risk of violent behavior towards themselves and those around them. Many patients come to the Centers from various institutions, including from prisons, and therefore a Dangerousness Risk assessment must be made of the degree of risk which they pose in order to correctly manage their case and reduce the danger to which members of staff and other patients are exposed.

As part of a broad clinical assessment, standard risk-assessment support tools should be used. We have chosen to use two of them:

HCR 20 **(see Exhibit 3)**

PCLR-SV **(see Exhibit 4)**

<u>The relevant population for Dangerousness risk assessment:</u>

1. **New patients** - upon being admitted to the Center. An attempt should be made to obtain all background material from the relevant institutions, including their crime record, probation officer reports, hospitalization summaries, etc. The assessment should also be reviewed once a year in order to gauge the basic and psychopathic indicators which increase risk and undermine the ability to achieve significant treatment results, as should the role played by treatment intervention in reducing the danger.

2. Patients returning to the Center after being released from prison.

3. Patients whose families or social services have reported violence directed against family members.

4. Patients whose behavior endangers others, including verbal and physical violence, where the cause of such behavior is unclear.

5. The risk assessment report should be prepared in conjunction with the ASI report in order to examine whether the degree of danger posed by a patient is linked to the severity of his addiction.

5.7 **Methadone/ buprenorphine/(Suboxone) assisted (detoxification) - medical guidelines**:

5.7.1 Gradual detoxification may be achieved with the help of methadone/buprenorphine/suboxone. As a rule, the dosage will be

lowered in the physician's discretion having regard to the patient's condition and in accordance with medical indications.

6. Treatment of special populations/situations

6.1 **Women**

Women tend to seek treatment less often than men due to their fear of a continuation of the pattern of victimization which they experienced during use. Against this background, women constitute a small subpopulation when compared with the general patient population, which requires special attention due to a propensity towards developing more severe medical and social complications, the concern for children and the fear of entanglement with the legal authorities regarding their custody.

We see that female addicts have often experienced sexual trauma and emotional abuse which is manifested in mental illness and post traumatic stress disorders.

Women may be treated together with men; however, their treatment must be tailored to meet their special needs, while developing group treatment programs and options specially designed for them addressing subjects such as: self-esteem enhancement, trauma, assertiveness training, healthy interpersonal relationships and correct parenting.

6.2 Pregnant women and treatment of newborns

The number of women using opiates/opioids has risen significantly in recent years and most of them are of childbearing age. While pregnancy can enhance the motivations to quit taking drugs, in the light of the significant medical risks for the mother and fetus posed by detoxification, it is recommended not to detoxify pregnant women but to opt for protracted drug treatment using methadone.

Because of the potential danger to the mother and fetus, it is strictly forbidden to treat pregnant women with a combined preparation of buprenorphine/naloxone (suboxone). Therefore, all pregnant patients who are taking suboxone within the framework of protracted drug treatment should immediately stop doing so and be given either buprenorphine or methadone instead, according to the physician's discretion, while closely monitoring her medical situation.
It is also forbidden to use the aforementioned combined(suboxone) preparation while breastfeeding.

Maintenance therapy during pregnancy has proved effective in improving the condition of the mother and fetus; for example: methadone reduces fetal exposure to poisoning and detoxification and therefore facilitates normal fetal development and reduces morbidity and mortality rates. The recommended option in most cases is methadone treatment. With regard to treatment with buprenorphine, the recommendation is that this preparation may only be used if the benefit outweighs the risk to the fetus and

therefore it may be used where the pregnant patient is already taking buprenorphine and does not wish to take methadone instead. In any other case in which the patient is determined to take buprenorphine, the following action must be taken:

1. The patient must be informed that there is still insufficient research evidence regarding the efficacy and potential risks to the fetus.

2. The patient's medical team must consult with a teratology clinic and document its recommendations in her medical file.

3. The patient's condition must be closely monitored and documented in her file.

4. The dosage of the drug must be tailored to suit the patient while taking special care during the third trimester (to reduce the dosage in preparation for the birth).

It is important to note, that while according to the current professional literature, use of buprenorphine during pregnancy is considered to be a sufficiently safe and effective treatment, the number of histories examined has not been large enough to reach any definite conclusions (Johnson et all, 2003).

Moreover, there are cases which indicate that infants of addicted mothers who were treated with buprenorphine during their pregnancy were born on the expected date of delivery and their birth-weight was normal (Lostono et al; 2002).

Female addicts tend to neglect their physical health and do not usually consult with a gynecologist until the later stages of their pregnancy, a factor which may increase the health risks to mother and fetus.

Where a patient is known to be pregnant, care must be taken to undertake the following actions:

6.2.1 Referral of the patient to a gynecologist as soon as possible for an assessment and to undergo the necessary examinations.

6.2.2 Referral of the patient to an MCHC for regular pregnancy monitoring.

6.2.3 Close monitoring by the Center's physician of the methadone/ buprenorphine dosage and adjusting it as the pregnancy progresses.

6.2.4 Examining the patient's social/family/welfare situation and the degree of risk to which she is exposed and finding appropriate solutions for her special situation (such as sheltered accommodation).

6.2.5 Encouraging the patient to register for childbirth in a hospital and to record the name of the hospital in her file.

6.2.6 Instructing the patient that upon arriving at the hospital she must expressly inform them that she is being treated at a methadone center, the dosage she is taking and the Center's contact details in order to coordinate her continued treatment and to prevent the newborn from suffering abstinence syndrome.

6.2.7 Consultation with the Center's medical team on any matter concerning the medical treatment of the mother and the newborn in order to prevent abstinence syndrome.

6.2.8 Informing the welfare officer where the mother is not cooperating with the treatment thereby exposing herself and possibly her unborn child to the risk of developing abstinence syndrome and thus bringing the child within the

definition of a "minor in need" who is accordingly entitled to protection under the Youth Care and Supervision Law, 1960.

6.2.9 Meeting the patient at least twice a week after she returns to treatment in the Center, including conducting medical examination, ascertain her condition and verify that she is properly taking care of the newborn.

6.2.10 Where a concern exists that the mother is undergoing a mental crisis following the birth, referring her for a situational assessment and to receive treatment and parenting guidance from a mental health clinic.

6.2.11 Where the mother is carrying infectious diseases such as: HIV, hepatitis B or C, referring her for advice to a specialist clinic.

6.2.12 Where the mother wishes to breastfeed, taking methadone does not constitute a contraindication; however, care must be taken to adjust the dosage to the lowest level possible. Where the mother is being treated with buprenorphine, the concentrations of the drug in the milk are low and therefore it does not pose a health risk and is even recommended in order to prevent neonatal abstinence syndrome. It is recommended that the Ministry of Health's Teratological Advice Unit be consulted regarding any query on this subject. The telephone numbers are as follows:

a. The National Center for Teratological Advice: 02-5082825
b. Medicinal Advice Assaf Harofeh: 08-9779309
c. Medicinal Advice Bellinson: 03-9376911
d. Rambam Poison Information Center: 04-8541900.

6.3 Pregnancy test

Female opiate addicts may sometimes not be aware that they are pregnant since monthly period loss/irregularity is common amongst this population. Therefore, each woman of childbearing age who is accepted for treatment should be encouraged to take an HIT pregnancy detection test, and to encourage her to take birth control pills.

6.4 Monitoring and keeping track of newborns

The situation of infants born to opiate addicts must be monitored in order to identify the onset of neonatal abstinence syndrome or irregular incidents. It is likewise important that such newborns be under the care of a developmental pediatrician for at least the first two years of their lives to ensure they are developing normally and if necessary to identify developmental problems.

Withdrawal symptoms generally appear within 48 hours of birth, although in rare cases they may only appear within one to two weeks from birth. Keeping track of how the infant is growing should preferably continue for at least a week in the hospital or in the community (MCHC). An assessment such as "Modified" should also preferably be used in order to evaluate the severity of the abstinence syndrome

According to the professional literature, the severity of neonatal abstinence syndrome is influenced by many variables and it is therefore difficult to predict its development. The severity of the syndrome appears not to be connected to the dosage of the maintenance medication and is likely to be less severe where the infant is in physical proximity to the mother rather than in an NICU.

The goal of the supportive care is to diminish environmental stimuli and the discomfort of the newborn, including for example through use of a pacifier, small, frequent meals and keeping the infant in physical proximity to his mother and rocking him as a sedative. Drug treatment will be required should any of the following symptoms occur: seizures, sleep disturbances, fever or weight loss (difficulty eating, diarrhea, vomiting, dehydration).

Treatment is based on the severity of the withdrawal symptoms and should be initiated when the score in the Finnegan assessment questionaire attached herewith is 9 or higher in two repeated examinations. The assessment in question may be reexamined following treatment in order to verify the improvement in his condition.

The center staff must stay in contact with the hospital medical team in order to help by providing information and support for the mother.

The Finnegan Scale for assessing neonatal abstinence syndrome (see Exhibit No. 5)

6.5 Parenting in the shadow of addiction

Substance abuse may impede parental competence and be the harbinger of the children's removal from their addicted parent and the transfer of custody to another party. The addict parent generally suffers from a plethora of risk factors, such as: mental morbidity, violence, criminality, a history of prior traumas, homelessness, poverty, social isolation and raising the child without a spouse and is either dependent upon the support of a third party, such as a grandparent, or daily foster care.

The addict parent cannot correctly understand simple situations and respond to them in an intelligent manner, a predicament which raises amongst others the risk of neglect, especially during the child's initial years and until he reaches school age.

The MAMT Treatment Center is usually the focal point in the addict's life, which he visits frequently and has meetings there with specialists in different treatment areas who are able to monitor his situation and serve as support and guidance framework, including with regard to parenting.

As soon as an addict being treated in the Center becomes a parent, the treatment staff must address the various aspects of being a parent and assess his capacity to function as a parent and where necessary must be in contact with the welfare officers in order to safeguard the wellbeing of the child.

6.6 Abortion

6.6.1 Where a pregnant woman who is being treated, wishes to terminate her pregnancy, she must be guided through this process, and the hospital where the abortion is to be performed must, with her consent, be informed that she is being treated with methadone/ buprenorphine/ suboxone, as well as the dosage which she is taking.

6.6.2 After an abortion or miscarriage, the patient's physical and emotional condition must be monitored and the dosage adjusted in accordance with her situation.

6.7 Psychiatric comorbidity

6.7.1 A high incidence of psychiatric comorbidity exists amongst MAMT Treatment Center patients. The combination of psychiatric morbidity and drug addiction exacerbates the severity of the addiction, leads to a less optimistic treatment prognosis, higher percentages of relapse into use of various street drugs, to repeated psychiatric inpatient care, an increase in the danger to others posed by the patient and the risk of suicide.

6.7.2 Psychiatric comorbidity patients harmfully use various drugs in a failed attempt at self-treatment, in order to cope with the psychiatric symptoms and their distress. It should be noted, that a higher incidence of psychological trauma exists amongst the addict population and when the psychological symptoms and drug abuse continue despite the treatment and optimal dosage, the trauma issue must be handled specifically through unique care methods or the patient must be referred to an institution which specializes in treating this kind of disorder.

6.7.3 In comorbidity cases, an examination must be carried out to determine whether drug addiction is secondary to a first psychiatric disorder, or vice versa, the mental symptoms are the result of substance abuse. Where the mental symptoms preceded the substance abuse, psychiatric heredity, continuation of mental symptoms or their intensification following a period of stability in prolonged drug therapy, it may be possible that the mental disorder is the dominant morbidity, in which case the treatment shall be adapted accordingly, while closely monitoring the patient's psychiatric condition or doing so in coordination with mental health clinics. In such a scenario, especially where a psychotic disorder exists,

the recommendation is to commence prolonged drug treatment as soon as possible with the aim of stabilizing the patient and not to choose the option of detoxification.

6.7.4 It must be examined whether or not the patient has contemplated suicide. If he has, then use should be made of a family member or another person prepared to lend support rather than give the patient drugs to take home, while closely monitoring the situation. In the event of a doubt, a psychiatrist should be consulted.

6.7.5 Upon admitting a patient into the Center, the physician must also make a comprehensive assessment of his mental state and should he be found to be suffering from a mental illness the physician should refer him to a mental health clinic for examination and treatment, while collaborating and remaining in continuous contact with the clinic in question.

6.7.6 Should the patient be diagnosed as suffering from a mental illness and the Center has a psychiatrist on its staff, then if the physician in his discretion so decides, the patient may be treated and his condition monitored at the Center.

7. Aging addicted populations (special populations)

An aging population amongst addicts in prolonged drug therapy programs is a growing phenomenon which may be attributed to the positive long-term results of the treatment.

In recent years the average age amongst this population stands at 50 and these patients constitute approximately half of all those receiving prolonged drug treatment. This

statistic compels us to address physical, emotional, psychological and cognitive aspects in a multi-systemic way. It is well known that this population is aging earlier than the regular population due to the effect of substance abuse over the years, traumas and a dangerous lifestyle.

Separate physical problems are: acute brittle bone disease with the accompanying danger of fractures, a fall in sex hormones, especially androgens in men, and early cognitive decline.

In addition, chronic hepatitis, obesity and the damaging effects of cigarette smoking. Since elderly people tend to break down medications at a slower rate, physicians should refrain from prescribing higher dosages, so that a dosage in excess of 150 milligrams Methadone or 8 milligrams Suboxone a day is not recommended.

It is important to cooperate with and consult a family physician to ensure the correct management of these cases.

7.1 Chronic use of street drugs and medications (poly-drug abuse)

7.1.1 Amongst patients in prolonged drug treatment programs it is common to find those who use additional street drugs and prescription drugs, in particular benzodiazepines, methylphenidate (Ritalin), opioid analgesics, etc. It is extremely important to encourage patients to stop using street drugs, while providing various treatment solutions, medicinal and psychosocial.

7.1.2 Where repeated attempts to stop using street drugs have failed:

7.1.2.1 The patient should undergo a psychiatric evaluation in order to rule out a underlying mental disorder which requires treatment.

7.1.2.2 The dosage being prescribed for the patient should be reviewed to make sure it is compatible with his physical and mental condition.

7.2 **Infectious diseases** (HIV, hepatitis B + C, Tuberculosis)

7.2.1 The population addicted to opiate medications, and in particular those who inject drugs are vulnerable to contracting various infectious diseases and therefore should undergo periodic testing in order to detect such diseases, and where HIV is detected it should be reported in accordance with the regulations, and in case HIV is detected action should be taken to raise awareness and explain and encourage referral to treatment programs for patients who carry and/or are sick with the viruses.

7.2.2 Since a high percentage of Prolonged Drug Treatment Center patients test positive for HBV, the acting physician should make sure that such patients are vaccinated against viral hepatitis A and hepatitis B.

Physicians should act in accordance with the instructions given in the following vaccination guide:

http://www.health.gov.il/PublicationsFiles/tadrich_Chisunim.pdf

The treatment team should take all the precautions necessary when treating patients suffering from various infectious diseases. The Director

of the Center must see to it that the members of the Center's medical team are vaccinated in accordance with the Ministry of Health vaccination guide for medical institution employees (Director General Circular: vaccination of Health Workers which replaced Circular No. 28/11 dated 16.11.11)

http://www.health.gov.il/hozer/mk07_2013.pdf

8. Patients' rights and treatment limitations

8.1 Introduction

8.1.1 Substance abuse victims constitute a challenging population which, as a group, presents perplexing and continuing treatment dilemmas. Most addicts require an adjustment period of six months or more, during which time the use of street drugs is likely to continue, while gradually decreasing with the help of the Center's treatment programs. Moreover, while the treatment framework must be consistent, stable and occasionally uncompromising, care providers are nonetheless obliged to treat patients fairly at all times and to honor their rights as citizens and patients (as required under the Patient's Rights Law, 5756-1996).

8.1.2 The accumulated experience in Israel and abroad has taught that in substance abuse victims treatment institutions in general and in the Prolonged maintenance Treatment Centers in particular, there is no alternative but to use sanctions as a tool for ensuring fair and professional treatment.

8.1.3 Generally speaking, every effort must be made to develop a system of treatment incentives and economic incentives (benefits).

8.2 **Patients' rights:**

8.2.1 Patients' rights and obligations shall be set out in a treatment contract with the Center, signed by the patient. Upon admitting a patient to the Center, the Center's management and staff undertake to provide him/her with proper treatment.

8.2.2 In any event, the patients' rights shall apply as stipulated in the Patient's Rights Law (1996), including confidentiality of the individual patient's details and affairs as provided in the Law, the Regulations and standard operating procedures decided upon by the Department for the Treatment of Substance Abuse.

8.2.3 To receive drug treatment using methadone/ buprenorphine/ suboxone, in accordance with the rules and standard operating procedures decided upon by the Department for the Treatment of Substance Abuse.

8.2.4 To receive a written copy of the treatment contract and if necessary verbal explanations, while ensuring its cultural accessibility.

8.2.5 To receive information and explanations as requested bythe Center's physician, in accordance with the Patient's Rights Law 1996, regarding his/her medical/psychological condition, the medications being administered to him/her, including the alternative medication, its side

effects and complications, as appear in physician's brochure.

8.2.6 To receive an answer within a reasonable time to questions put to the medical staff. The patient may also address his queries to the Director of the Center in accordance with reasonable arrangements to be decided upon in the Center and shall be entitled to receive an answer within a reasonable time in the spirit of SOP 40.010 "Handling of Complaints and Public Enquiries within the Department for the Treatment of Substance Abuse".

8.2.7 To fill a complaint directly to the Regional Supervisor or through supervisors to the Department for the Treatment of Substance Abuse.

8.3 Treatment limitations (framework rules)

8.3.1 Obligations

8.3.1.1 The following "framework" rules shall apply in each Center. The "framework" rules are uniform for all the Centers and constitute part of the treatment contract to be signed by the patient.

8.3.1.2 The patient must give a urine sample for the purpose of undertaking drug detection tests whenever asked to do so by the medical team.

8.3.1.3 The patient must adhere to the medication schedule drawn up in accordance with his individual treatment plan, based on his

condition and the guidelines and standard operating procedures of the Department for the Treatment of Substance Abuse.

8.3.1.4 The patient must comply with the instructions given to him by members of staff concerning the ongoing operation of the Center.

8.3.2 Prohibitions

8.3.2.1 Violence - Physical, including threats, against patients, members of staff or others, causing damage to property or equipment belonging to the Center or to individuals.

8.3.2.2 Sanctions - The management may ban a patient from entering the Center for a period of up to 3 months in response to an incident involving physical violence, while reporting it to the Police and referring him for inpatient detoxification. Where a termination of treatment is being considered, the decision shall only be implemented with the approval of the Center's physician.

8.3.2.3 In cases of special risk, continuation of treatment should be made conditional upon the patient being accompanied on visits to the Center by a relative or any other responsible person and the approval of the Center's Director.

8.3.2.4 Entering the Center with a firearm or other weapon is strictly prohibited and patients should not come to the Center with a

weapon in their possession.

8.3.2.5 Bringing drugs or medications to the Center is strictly prohibited.

8.3.2.6 Prolonged use of street drugs - Consistent evidence of opiate and street drug use, including alcohol and non-prescribed medications in a way indicative of persistent non-cooperation or a lack of potential to stop using street drugs and/or medications for a period of 3 years, may culminate in treatment being suspended, after the following steps have been taken: treatment interventions, including an examination of plasma methadone levels, intensifying the treatment, warnings and treatment transfers. **Provision of methadone/ buprenorphine/ suboxone to patients using street drugs or medications shall not be suspended unless continued use of methadone/ buprenorphine/ suboxone would exacerbate their condition.**

8.3.2.7 Prolonged use of opiate/opioid based street drugs - Where it has been determined that a patient who has been in a treatment program for 6 months does not have the potential for stabilization through methadone/ buprenorphine/ suboxone and that such treatment may even be injurious to his health, the Center may ask the Exceptions Committee for authorization to discontinue his treatment.

8.3.3 Imposition of treatment sanctions

8.3.3.1 Sanctions will be imposed gradually on an increasing scale of severity and contemporaneously with a process of providing treatment enhancements/enrichment.

8.3.3.2 Written Warnings shall be given by a staff member and copies of them shall be kept in the patient's personal file.

8.3.3.3 Cancellation of benefits - For example: cancellation/reduction in frequency of dispensing take home dosages.

8.3.3.4 Treatment transfer - The orderly transfer of the patient to another Center following approval by the Center's physician for a predefined period as coordinated with the management of the Center to which he is being transferred.

8.3.3.5 Expulsion - Denial of all treatments and services. Such a situation in fact requires the gradual and controlled reduction of the methadone dosage under medical supervision during a period of not less than 21 days. In case of suboxone a fast reduction is possible. The expulsion may only be carried out with the approval of the Center's physician; alternatively, the patient may be referred to a medical institution for inpatient detoxification. Expulsion is a drastic step which should only be taken in extreme cases according to a decision of the Center's management and for a period of not more than three months. A patient returning to treatment after a period of expulsion must go through the admission (intake) process again. It is important to note, that treatment may be terminated immediately in a case

involving physical violence against care providers or other patients.

8.3.4 Benefits (incentives)

8.3.4.1 Giving treatment doses which may be taken at home and reducing the number of visits to the Center.

8.3.4.2 Reduction in the patient's share of the Center's fees where test results show he has not used street drugs for a continuous period of at least half a year.

9. Provision of drug treatment and foreign travel

Stable patients may receive in most cases up to 21 individual doses of their medication to take with them when travelling abroad. For those staying abroad for longer periods, a request must be submitted to a medical institution in the country being visited which provides methadone/ buprenorphine/ suboxone treatment. The patient travelling abroad with the individual doses of methadone/ buprenorphine/ suboxone should be given a letter to take with him, in English and signed by a physician, confirming that he is undergoing treatment and the daily dosage which he requires. The letter shall state the name and form of the preparation, its concentration and the contents of the active substance. The giving of more than 21 doses shall require prior approval from the Department for the Treatment of Substance Abuse.

10. Admission of tourist patients for limited periods

10.1 The International Convention and the law in Israel allow a person to bring with him when entering Israel up to 31 days' supply of methadone/ buprenorphine/ suboxone, subject to approval from the Ministry of Health's District Pharmacist. The tourist entering Israel must have with him an original letter from the official authorities (an official institution in which he is being treated abroad), stating his name, dosage of medication and passport number and authorizing him to leave his country of origin with a quantity of methadone/ buprenorphine/ suboxone which is for his personal needs as prescribed to him by a physician.

10.2 A foreign resident may be admitted for treatment in a Prolonged Drug Treatment Center, provided that he has with him a letter from the official authorities as aforesaid And he pays it to the treatment provider.

11. Reporting obligation

Under the Sanitation Ordinance, 1961 and Director General Circular No. 35/09, the Center's physician has an obligation to report

11.1 to the Institute of Road Safety concerning the patient's driving and under the Firearms Law, 1949 and Director General Circular 35/92 to the Department for Information and Evaluation at the Ministry of Health concerning the current or potential degree of danger involved in permitting the patient to carry a firearm.

11.2 Irregular incidents must be reported under Director General Circular 23/98 and the Ministry of Health - Department of Mental Health Services Practice Direction entitled "Documentation and Reporting of Incidents of Violence and

Abuse during Psychiatric Treatment".

11.3 Contagious infectious diseases, such as tuberculosis, HIV and hepatitis B and C, must be reported under section 12 of the Public Health Ordinance 1940.

12. Supervision

12.1 The activities of all Prolonged Drug Treatment Centers shall be monitored by a Supervision Unit operating under the auspices of the Ministry of Health's Department for the Treatment of Substance Abuse as required under the Supervision of Institutions Treating Drug Users Law, 1993 and its 1994 Regulations.

12.2 Before it can begin operating, each Center must obtain a license under, and while steadfastly adhering to all the criteria required by, the Supervision of Institutions Treating Drug Users Law, 1993 and its 1994 Regulations.

12.3 The supervisors are authorized under the Supervision of Institutions Treating Drug Users Law, 1993 and its 1994 Regulations to enter any Center without prior warning and inspect any relevant information concerning patients, including their names, files and all other relevant information pertaining to the treatment being administered to them.

12.4 The regional supervisors are responsible for investigating complaints from patients and the Director of the Center and his staff are obliged to fully cooperate with them regarding the investigation and handling of a complaint,

including by submitting any information required for that purpose.

12.5 The valid license for operating the institution, the name of the Regional Supervisor and the current telephone and fax numbers through which he may be reached, must be displayed in a prominent place within the Center.

12.6 The Director of the Center must immediately notify to Supervision Unit of any irregular incident, such as physical violence, medical or medicinal complications or the death of a patient, followed by the submission of a full written report on the incident within 24 hours.

12.7

Appendix A

The Center's staff

he Director - Responsible for the day to day running of the Center, implementation of the Ministry of Health's policy and the rules of the Center. Chairs general staff meetings, leads and instructs the Center's workers, develops new and unique projects for treating the victims of substance abuse. As stipulated in the Supervision of Treating Drug Users Law, 1993 and its 1994 Regulations, the Director can be: a psychiatrist or a physician with training in the treatment of drug addiction or a social worker, clinical criminologist or clinical psychologist.

Function and responsibilities

1.1 Devising the Center's treatment program and running the Center after obtaining a license from the Department for the Treatment of Substance Abuse as required under the Supervision of Institutions Treating Drug Users Law, 1993 and its 1994

Regulations.

1.2 Implementation of the Supervision Law and implementation of the directives and operating procedures of the Department for the Treatment of Substance Abuse pertaining to the work of the Center.

1.3 Registration, documentation and reporting as required by the Law and the operating procedures, policies and directives of the Department for the Treatment of Substance Abuse.

1.4 Implementation of the Patient's Rights Law, 1996 and other laws concerning the treatment of addicts.

1.5 Ensuring the provision of medications through a licensed pharmacist.

1.6 Ensuring that the license required under the Supervision of Institutions Treating Drug Users Law, 1993 and its 1994 Regulations in order to operate the Center is obtained before the Center begins to function.

1.7 Submission of periodical reports to the Department for the Treatment of Substance Abuse and its supervisors and all information required by them.

1.8 Recruitment of suitably qualified personnel to fill positions in the Center.

1.9 Responsibility for the terms of employment, professional advancement and training of the Center's staff in accordance with Department for the Treatment of Substance Abuse guidelines, while devising an annual staff training program with

the approval of the Center's supervisor.

1.10 Devising a work plan for each of the Center's employees (professional and administrative).

1.11 Convening regular staff meetings.

1.12 Dealing with various external bodies as the Center's representative in accordance with the Department for the Treatment of Substance Abuse requirements.

2. **Psychosocial worker -** A social worker, clinical psychologist or clinical criminologist. Each team shall have a rehabilitation specialist to coordinate the rehabilitation program and adjust it in conjunction with the relevant parties for the benefit of the Center's patients.

Function and responsibilities

2.1 Devising and managing a treatment program.

2.2 Providing psychotherapeutic care for individuals, groups, families, etc.

2.3 Opening and managing patients' psychosocial files.

2.4 Managing links with relevant external professional bodies: welfare bureaus, the National Insurance Institute, etc, as necessary.

2.5 Case management in collaboration with relevant professional bodies.

2.6 Participating in admission committee meetings, staff meetings, courses, conference and training sessions, as determined in the Center and by the Ministry.

2.7 Carrying out periodic assessments and updating the treatment program of the patients for which he is responsible.

2.8 Referring patients to community care programs after completion or suspension of treatment in the Center.

3. Nurse/paramedic - Subordinate professionally to the Center's physician to whom he reports on a regular basis.

4. Function and responsibilities

4.1 Providing professional nursing care when needed.

4.2 Ongoing and proper management of the dispensing room and providing continuous drug treatment in the Center during the hours decided upon by its management.

4.3 Assisting the physician, carrying out his instructions when requested by him to do so.

4.4 Maintaining contact with the Center's pharmacist.

4.5 Running health education programs in the Center.

4.6 Participation in treatment staff meetings, and when necessary in the meetings held by other committees, such as the admission committee and the diagnosis committee.

4.7 Taking urine samples from patients according to Protocol No. 40.007: "Taking urine samples and sending them to the laboratory for drug victims treatment centers".

4.8 Giving patients general personal hygiene instruction with the emphasis on preventing the spread of infectious diseases.

5. **Physician** - A psychiatrist or a physician trained in the field of substance abuse (one of the physicians in each Center shall be chosen as the physician in charge).

Function and responsibilities

5.1 Making a medical diagnosis during the process of admitting a patient to the Center.

5.2 Determining drug dosage according to the patient's condition and his professional judgment.

5.3 Giving medical advice to medical institutions outside the Center.

5.4 Consulting with infectious disease, mental health and other clinics regarding his patients' various illnesses.

5.5 Maintaining contact with hospital wards during patients' hospitalization.

5.6 Caring for the physical and mental wellbeing of the patients and when necessary sending them for laboratory tests and to medical facilities which are best suited for treating their condition.

5.7 Opening a medical file for each patient and keeping it up to date in accordance with the Patient's Rights Law, 1996.

5.8 Providing instruction to the Center's staff on medical and nursing issues.

5.9 Providing patients with medical guidance and monitoring their state of health during the period of treatment in the Center.

5.10 Examining each patient being treated at the Center at least once a month.

5.11 For each physician who works at the Center authorization shall be obtained for him to prescribe the medication suboxone from the Pharmaceutical Division for a period of more than one week and up to 28 days.

6. Function of the pharmacist

6.1 The pharmacist shall be responsible for all the logistics concerning the ordering, storage and release of narcotic medications (methadone/ buprenorphine).

6.2 The Center's pharmacist is responsible for ordering, storing, releasing and issuing the medication suboxone (buprenorphine/naloxone) for patients for a period of up to 28 days pursuant to section 15 of the Pharmacists Ordinance and the instructions of the Center's acting physician.

6.3 The pharmacist is responsible for supervising and controlling the work of the paramedics/nurses in issuing the medications methadone/ buprenorphine/suboxone.

6.4 The pharmacist is responsible for taking stock of the narcotic medications (methadone/ buprenorphine/ suboxone), sending quarterly reports to the Pharmaceutical Division and issuing requisitions.

6.5 The Center's pharmacist works in accordance with the instructions and operating procedures of the Ministry of Health's Pharmaceutical Division.

7. Responsibilities of the occupational therapist

7.1 Devising and implementing treatment intervention of occupational therapy as part of the professional team in the Center, including assessment and identification of rehabilitative potential through utilization of professional assessment tools, including construction of an occupational, theoretical, observational, etc. profile (in collaboration with a rehabilitative social worker or other professional member of staff).

7.2 Forwarding functional-occupational-cognitive assessments, when necessary, in order to devise a treatment-rehabilitation program.

7.3 Devising a rehabilitation program.

7.4 Deciding upon and implementing an individual occupation-based treatment program.

7.5 Instructing groups (possibly in collaboration with a rehabilitative social worker, or other professional member of staff).

7.6 Advising on, coordinating and representing the discipline as instructed by the Commissioner or a person authorized by him, within the treatment framework.

7.7 Initiating, planning and practicing new modus operandi and work methods.

7.8 Participating in interdisciplinary team meetings within the treatment frameworks, in order to coordinate and integrate the subjects within his area of expertise, in coordination with the Commissioner.

7.9 Participating in professional discussions, symposiums and seminars in order to be updated and for the purpose of professional enrichment.

7.10 Taking part in professional and interdisciplinary committees within the institution and outside of it at the behest of the responsible party and in coordination with the Commissioner.

7.11 Participating in the preparation of professional surveys, the drawing of conclusions and their implementation at work in coordination with the Commissioner.

7.12 Reporting to the Commissioner, verbally and in writing, and coordinating with him the activities within his area of specialization, in accordance with the work procedures and the unit report.

Exhibit No.1

1. SOWS - *Short Opiate Withdrawal Scale* Estimate

Instructions - Please mark X in the appropriate box if you have suffered one or more of the following symptoms during the last 24 hours:

Symptoms	0	1	2	3
Feeling sick				
Stomach cramps				
Muscle spasms				
Feelings of coldness/chills				
Heart pounding				
Muscle tension				
Aches and pains				
Yawning				
Runny eyes				
Insomnia/problems sleeping				

0 - None; 1 - Mild; 2 - Moderate; 3 - Severe

Ref: M.Gossop: "The development of a short opiate withdrawal scale SOWS" addictive Behaviors, 15: 487-490, 1990

Exhibit No.2

2. Clinical Opiate Withdrawal Scale COWS estimate

Name/name of clinic

Record of opioid withdrawal (induction form)

Name of patient _____ Date on which treatment commenced _____

Circle the number/description that best describes the symptoms exhibited by the patient. Only mark the symptoms connected to withdrawal

Parameter	Basic observation From first dose ___ Milligrams Time ____ Morning/afternoon	First dose, first observation _____ minutes after first dose	First dose, second observation (when necessary) minutes after the first dose
Resting Pulse Rate: **record beats per minute** *Measured after patient is sitting or lying down for one minute* 0 pulse rate 80 or below 1 pulse rate 81-100 2 pulse rate 101-120 4 pulse rate greater than 120	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4
Sweating: *During 30 minutes not accounted for by room*			

temperature or patient activity 0 no report of chills or flushing 1 subjective report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face 4 sweat streaming off face	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4
Restlessness: *observation during assessment* 0 able to sit still 1 reports difficulty sitting still, but is able to do so 3 frequent shifting or extraneous movement of legs/arms 5 unable to sit still for more than a few seconds	0 1 3 5	0 1 3 5	0 1 3 5
Tremor: *observation of outstretched hands* 0 no tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching	0 1 2 3 4	0 1 2 3 4	0 1 2 3 4
Pupil size 0 pupils pinned or normal size for room light			

1 pupils possibly larger than normal for room light 2 pupils moderately dilated 5 pupils so dilated that only the rim of the iris is visible	0 1 2 5	0 1 2 5	0 1 2 5
GI upset: *During last 30 minutes* 0 no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhea 5 multiple episodes of diarrhea or vomiting	0 1 2 3 5	0 1 2 3 5	0 1 2 3 5
Anxiety or irritability 0 none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable or anxious 4 patient so irritable or anxious that participation in the assessment is difficult	0 1 2 4	0 1 2 4	0 1 2 4
Bone or joint aches: *if patient was having pain previously, only the additional component attributed to opioid withdrawal is*			

scored 0 not present 1 mild/diffuse discomfort 2 patient reports severe diffuse aching of joints/muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort	0 1 2 4	0 1 2 4	0 1 2 4
Yawning: *observation during assessment* 0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute	0 1 2 4	0 1 2 4	0 1 2 4
Runny nose or tearing: *not accounted for by cold symptoms or allergy* 0 none present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks	0 1 2 4	0 1 2 4	0 1 2 4
Gooseflesh skin 0 skin is smooth	0 3 5	0 3 5	0 3 5

3 pylo-erection of skin can be felt or hairs standing up on arms 5 prominent pylo-erection			

Overall Score: _____ _____

_____

Being the total of the 11 parameters

- 5-12 = mild
- 13-24 = moderate
- 25-36 = moderately severe
- More than 36 = severe withdrawal

Dr. Wesson, Ling W. Clinical Opiate Withdrawal Scale (COWS), Journal of Psychoactive Drugs 2003 35(2): 253-259.

Exhibit No.3

3. Questionnaire *HCR-20*

Name: _____	**Date: _____**	**Patient code: _____**

	Historical Variables	Codes (0, 1, 2)
H1	Previous violence	
H2	Young age in first incident of violence	
H3	Unstable interpersonal relations	
H4	Employment problems	
H5	Drug abuse disorders	
H6	Significant mental disorder	
H7	Psychopathic	
H8	Early adjustment problems	
H9	Personality disorder	
H10	Previous monitoring/supervision failure	
Total Score of Historical Variables		**/20**

	Clinical Variables	Codes (0, 1, 2)
C1	Lack of understanding	

C2	Negative attitudes	
C3	Active symptoms of significant mental disorder	
C4	Impulsiveness	
C5	Unresponsive to treatment	
Total Score of Clinical Variables		**/10**

	Risk Management Variables **☐Internal ☐External**	**Codes (0, 1, 2)**
R1	Programs which cannot be implemented	
R2	Exposure to stress factors	
R3	Lack of personal support	
R4	Unresponsive to rehabilitation efforts	
R5	**Stress**	
Total Score of Risk Management		**/10**

HCR-20 Final Score	**/40**
Final Risk Evaluation	☐ Low Risk ☐ Medium Risk ☐ High Risk

Evaluator Name: _____ **Job Title** _____	**Signature:** _____ **Date:** _____

Exhibit No.4

4. Psychopathy Assessment Questionnaire PCLR-SV

Personality Trait	Score
Superficiality	0 1 2 X
Grandiose Sense of Self-Worth	0 1 2 X
Manipulative	0 1 2 X
Lack of Remorse	0 1 2 X
Lack of Empathy	0 1 2 X
Refusal to accept responsibility	0 1 2 X
Impulsivity	0 1 2 X
Poor Behavioral Control	0 1 2 X
Lack of goals	0 1 2 X
Irresponsibility	0 1 2 X
Antisocial behavior during adolescence	0 1 2 X
Antisocial behavior during adulthood	0 1 2 X

Exhibit No. 5

5. <u>Finnegan Scale for assessing neonatal abstinence syndrome</u>:

This scale is used to measure symptoms and monitor abstinence symptoms in infants born to opiate addicted mothers

Body system	**Signs and symptoms**	**Score**
Central Nervous System Disturbances	Excessive high-pitched crying	2
	Continuous high-pitched crying	3
	Sleeps < 1 hour after feeding	3
	Sleeps < 2 hours after feeding	2
	Sleeps < 3 hours after feeding	1
	Mild tremors	1
	Moderate tremors	2
	Mild tremors when undisturbed	3
	Moderate tremors when undisturbed	4
	Increased muscle tone	3
	Superficial wound (focus on area	

	of body) Myoclonic jerks Generalized convulsions	5
Metabolic/Vasomotor/Respiratory Disturbances	Hyperthermia (37.3-38.3C) Hyperthermia (> 38.3C) Frequent yawning > 3-4 times Mottling Nasal stuffiness Sneezing > 3-4 times Nasal flaring Respiratory rate > 60/min Respiratory rate > 60/min with retractions	1 2 1 1 1 2 1 2
Gastrointestinal Disturbances	Excessive sucking Poor feeding Regurgitation Projectile vomiting Loose stools Watery stools	1 2 2 3 2 3

Scoring instructions:

Infants whose average score in three repeat measurements exceeds 8 (for example: 9-7-9) or 12 or more in two repeat measurements, require treatment. The pause between each measurement should not exceed four hours.
(Ref: Finnegan L. Drug Dependence in Pregnancy. Castel House Publications, London (1980))