Government of Punjab
Department of Health and Family Welfare
(Health-6 Branch)

To

1. All Deputy Commissioners, Punjab.

2. All Civil Surgeons, Punjab.

No. 3|26|18-3H6/1285582/1-2
Dated: 31|7|2018

Subject: **Standard Operating Procedure for Private centers who are providing de-addictiontreatment services to persons with substance abuse.**

1. Objective:

The State Government notified The Punjab Substance Use Disorder Treatment & Counseling and Rehabilitation Centers Rules 2011 on 16/01/11. These rules were notified under NDPS act 1985 and for the first time a provision was made for grant of licenses to private de-addiction centers. The state of Punjab had taken several interlinked, multilevel, systematic and proactive steps to curb the menace of drug abuse including demand reduction and harm reduction. The State Govt asked the Department of Psychiatry, PGI Chandigarh to assist the State in its drug deaddiction programme particularly in supply and use of Buprenorphine–Naloxone Combination. Dr Debashish Basu and Dr Ajit Awasthi, Professors, Department of Psychiatry in PGI Chandigarh prepared Standard Treatment Guidelines for treatment of Opioid Dependence (OATOD). They have cautioned that use of OATOD is a double-edged sword.

It is to be noted that opioid agonists like buprenorphine etc. are themselves opioids, with all the psychoactive and addictive properties of abused opiates. If they are used properly, they can save and rebuild lives, however if used improperly,they can cause damage like any other opiate.Based on Treatment Guidelines prepared by PGI, to ensure a proper, balanced and rational use of Opioid Assisted treatment of drug dependence in

private sector and to evolve a state-wide uniform mechanism for Opioid assisted treatment of drug dependence, these guidelines have been prepared and are being circulated to Private de-addiction centers, Health authorities, drug administration and District authorities for guidance. A copy of opioid agonist guidelines prepared by PGI Chandigarh in 2014-15 is attached with this document for reference.

The main objective of this SOP is to ensure that OATOD is used for saving and rebuilding lives and prevent its misuse. It is to be remembered that the Opioid agonist drugs are available only in licensed deaddiction centers and are supplied by manufacturer directly to them bypassing the wholesale and retail chemists. If the misuse and other malpractices go unchecked, the entire philosophy of OATOD would be brought to disrepute causing more harm than benefit. It is therefore necessary to ensure judicious use of these drugs and balance the risk benefit ratio.

These guidelines will be reviewed from time to time with first review, planned to be held after three months. All stakeholders are requested to send their suggestions at mhppunjab@gmail.com .

Note: The guidelines prepared by PGI are quite comprehensive. Therefore, while it is recognized that the psychiatrist will decide the treatment plan depending upon history of patient, yet it is expected that these guidelines will not be ignored without justified reasons. Besides it is also expected that all the centers will comply with the Punjab Substance Disorder Treatment Counselling and Rehabilitation Centers Rules 2011 under which they have been granted license.

2 Registration:

i) Any new patient reporting to a private de-addiction center must be registered and a UID Number must be assigned to him/her.

ii) His Aadhaar number or mobile number must be linked to UID.

iii) Every private de-addiction center licensed by State Government must get its computerized patient registry system linked with the Central registry software system of Department of health & family

welfare, Govt of Punjab in order to ensure that the same patient does not get opioid medication from multiple sources.

iv) The Privacy of patient must be maintained, and data will be kept confidential.

v) Ultimately Biometric system of Patient attendance will be implemented in all Centers for better transparency.

3. Patient Assessment:

i) After registration, patient will be assessed by a counselor and psychiatrist.

ii) His/her drug use and previous treatment history will be assessed

iii) The user would be required to undertake urine screening test for opioid.

iv) Support services: Every patient suspected to be using heroin through intravenous route be mandatorily assessed for comorbities like HIV, Hepatitis C, Hepatitis B, TB, STI. If found positive the patient should be advised for adequate treatment and this information should be shared with Civil Surgeon of the concerned district.

v) Detailed norms for staff requirement for a drug de-addiction center have been stipulated in the Punjab Substance Use Disorder Treatment & Counselling & Rehabilitation Rules 2011. Rule No.14C (I) of 2011 rules may be referred for details of staff requirement for a substance disorder treatment center. As per NACO guidelines one Nursing Staff is required for a daily patient load up to 120. Additional regular Nursing staff should be provided if the daily patient load exceeds 120.

4. Initiating Opioid Assisted Treatment

Pre-requisites:

Following essential pre-requisites for starting Opioid assisted treatment of drug dependence as recommended by experts from PGI Chandigarh must be considered:

i) The first essential pre-requisite of starting any Opioid assisted treatment is Establishing Opioid Dependence. It should be further characterized about the exact type(s) of opioid, route of use, quantity typically consumed, the severity of dependence, and the adverse consequences of opioid dependence.

ii) Before initiation of Opioid assisted treatment, Patient should be asked to give his/her written informed consent. Copy enclosed (Annexure-A).

iii) The third essential pre-requisite is Considering Cautions and Contraindications for Opioid assisted treatment. This includes exploring concomitant use of other substances (especially other CNS depressants), and medical conditions that require caution before starting Opioid assisted treatment (e.g., bronchial asthma, severe respiratory or hepatic impairment, pheochromocytoma, inflammatory bowel disease, and hypothyroidism).

Minimum Facilities:

i) The facility should have a QUALIFIED PSYCHIATRIST to start, monitor and terminate Opioid assisted treatment. Only psychiatrists must start Opioid assisted treatment (after proper assessment and documentation and after meeting the other essential pre-requisites).

ii) The facility should have a Psychosocial Management Modality, which is mandatory along with Opioid assisted treatment. This may be, at the minimum, provision of a Counselor, and at best, a

multidisciplinary team of psychiatric social worker, psychologist, vocational instructor and psychiatric nurse. The point is that Opioid assisted treatment is not complete without concurrent psychosocial management.

iii) The facility should have A Valid and Accountable Set-Up within which Opioid assisted treatment can be carried out. This includes: -

- a designated de-addiction center or other valid treatment facilities,
- a valid and documented supply of the opioid agonist drug from the manufacturers, and
- a valid and documented system of dispensing of the opioid agonist drug to the opioid dependent patients.

5. Treatment in Indoor:

As per assessment of psychiatrist a patient may be admitted in indoor for detoxification and later on his long-term management may be done in OPD settings. Patients with severe withdrawal symptoms must be treated in indoor. Indoor management may be done with BNX or tramadol as per treatment plan decided by the psychiatrist.

The short-term treatment is for acute opioid withdrawal during detoxification phase. This is usually given for 7-14 days, where the dose of BNX is built up to 6-8 mg/day (occasionally up to 10-12 mg/day) and is tapered off without prolonging its use beyond this period after the acute withdrawal is over. This is the current standard of treatment for opioid withdrawal during detoxification phase. The dose of BNX can often be tapered off in 10-14 days in the inpatient setting. However, in certain circumstances (high-dose high-potency opioid dependence) it may be extended up to 3-4 weeks. It must not be extended beyond 4 weeks for detoxification purpose in any case.

6. OPD Based Opioid Assisted Treatment:

Where psychiatrist is of the view that OPD based opioid assisted treatment would suffice, the user shall be put on required doses of Buprenorphine- Naloxone combination (BNX).

Cautions:

(A) Based on the following cautionary notes, the psychiatrist shall decide the OPD based treatment:

i) Cases with Injecting opioid use (i.e., opioid use through parenteral routes by injection like IM, IV, SC, etc.) as the predominant route of use.

ii) In case of non-injecting opioid use, the predominant opioid should be either relatively pure white heroin ("Chita"), other varieties of heroin like impure street-variety brownish heroin ("smack"), pure opium, or other potent opioids.

iii) BNX for OPD Based Treatment Should Not Be Used for Any and All Cases of Opioid Use unless the opioid dependence is not established. For example, BNX treatment should not be prescribed in routine for low-potency opioids like poppy husk (bhukki, doda), low-quality opium, codeine cough syrups (Rexcoff etc.), propoxyphene capsules (Proxyvon, Spasmoproxyvon, "Neela", etc.) unless there are specific reasons for prescribing which should be documented in patient record.

(B) As recommended by experts from PGI Chandigarh OPD based treatment must not be started in following conditions:

i) Without confirming and documenting opioid dependence.

ii) With concomitant use of high doses of sedative-hypnotics or alcohol.

iii) In those below 18 years of age.

iv) With known hypersensitivity to buprenorphine or naloxone

v) In the presence of severe respiratory or hepatic impairment, or in any circumstances where the CNS depressant effect of opioids may be accentuated

vi) Without obtaining informed consent and undertaking for Opioid agonist treatment.

7. Use of Buprenorphine- Naloxone (BNX)

Buprenorphine- Naloxone (BNX) combination can be given as a "Take-Home" dose, with the following ESSENTIAL CLAUSES:

i) The patient must be registered in Concerned De-addiction Center with some unique identification number by which he can be linked with a computerized database.

ii) The exact total number of Buprenorphine- Naloxone (BNX) tablets dispensed to the patient must be documented in (a) patient's treatment card (b) patient's case file and (c) dispensing register maintained by the nursing staff.

iii) The BNX tablets should be dispensed by pharmacist or nursing staff in the same place where the prescription is made, ideally in the same or adjacent room, or as close to it as possible

iv) Only the fixed-dose combination of sublingual Buprenorphine-Naloxone (BNX) must be used because of lower potential for diversion and injectable abuse. No other preparation of buprenorphine (e.g., plain sublingual buprenorphine, injectable buprenorphine, buprenorphine transdermal patch) must be used for this purpose.

v) To begin with, he/she should be given doses for 3-5 days. After three such consecutive visits, he/she can be given doses for 7 days in one visit.

vi) In case the patient asks for a take-home dose longer than 7 days, the doctor must be convinced about the genuineness and unavoidability of the situation (for example going out for a longer duration). This can be done by detailed questioning of the patient, inspection of supporting documents if any, and

confirmation from family members. The reason must be documented in the patient's case file, with corroborating facts.

vii) Even with this exception as above, the maximum duration for which take-home dose of BNX can be supplied is for two weeks (14 days) or maximum 100 tablets whichever is less.

viii) Para D at page No.7, 8 & 9 of PGI guidelines explain in detail as to how BNX has to be used for short term and long-term treatment of opioid dependence. It has also been stated that its dose has to be tapered off. As regards duration of the treatment, para 11, 12, 13 and 14 at page 16-17 of PGI guidelines may kindly be referred for more details. Psychiatrists may take holistic view and continue/prescribe treatment accordingly.

8. Use of Tramadol:

i) Tramadol can be used in OPD/Indoor settings.

ii) Tramadol must not be used for long-term therapy. It can only be used for short-term treatment of opioid withdrawal as a second-level option.

iii) The doses recommended are given in para 5 of page 13 of PGI Guidelines enclosed with this document.

9. Use of Naltrexone:

As per experts from PGI Chandigarh, it has been suggested that the following may be good indicators of attempting OPD based naltrexone therapy rather than Opioid assisted Treatment:

i) Shorter duration (less than one year) of opioid dependence.

ii) Patients who have not tried abstinence-based treatment or have relapsed after one attempt of abstinence-based therapy.

iii) High motivation

iv) Better social and occupational support

v) Higher levels of education; professionals; white-collared occupation

vi) Patients with co-morbid alcohol use disorders for whom treatment with anti-craving agents may be indicated

vii) Patients who express a desire for remaining free of any kind of opioids including Opioid Assisted Treatment.

10) Follow-up visits:

Assessment on first follow up visit must include Urine screening for Opioids, Clinical &Psycho-social follow-up (with filling of respective follow-up Performa) besides Buprenorphine-Naloxone dose titration,

After initiation of opioid assisted treatment and in specific cases as explained in Para 7 (vi) and (vii) above, doses up to 14 days can be given. In no case, he/she shall be given take home dose for more than 14 days or 100 tablets whichever is less.

11) Stabilization phase:

i) As per expert opinion it usually lasts for 3 months after initiation of opioid assisted treatment.

ii) During this phase, frequency of Clinical & Psycho-social follow-ups (with filling of respective follow-up Performa) and Urine screening should be once every 14 (fourteen) days. Further Buprenorphine-Naloxone dose dispensed during follow-up visits must not exceed 14 (fifteen) days &/or 100 (hundred) tablets (Whichever is applicable).

12) Maintenance phase:

i) After 3 months of Stabilization phase, those patients found stable on Clinical &Psycho-social follow-ups supplemented with

consecutive 3 negative urine screening results for illicit opioids will move to maintenance phase.

ii) Frequency of Clinical & Psycho-social follow-up should be once in a month till patient is into treatment.

iii) Further, Psychiatrist can prescribe Buprenorphine-Naloxone doses up to 14 (fourteen) days &/or 100 (hundred) tablets (whichever is less).

13) Clinical consideration for patients missing scheduled follow-up visits:

i) During Induction phase first and second follow-ups after 5 and 7 days respectively after the initiation of treatment, if patient misses scheduled follow-up visit, there is relaxation of 3 days beyond which Induction phase should be started again.

ii) Once patient is into Stabilization & Maintenance phase, missing scheduled Follow up should be dealt with as follows:

(a) Up to 5 days beyond the date of scheduled follow-up visit, patient should be deemed as stable patient with provision of dispensing of Buprenorphine-Naloxone dose for 14 days &/or 100 tablets (whichever is applicable).

(b) For 6 to 10 missed days beyond the date of scheduled follow-up visit, Buprenorphine-Naloxone dose dispensed must not exceed 7 days, followed by 14 follow ups.

(c) For more than 10 missed days beyond the date of scheduled follow up visit, induction phase must be started.

(d) For every missed follow up visit, urine screening will be mandatory on next visit.

14) Discontinuation phase:

Deciding criteria for discontinuation should be "Attainment of treatment goals"

Tapering off Buprenorphine-Naloxone may be done in Indoor or OPD setting and should be very gradual taking into consideration of patient's condition.

The typical duration of OATOD is a contentious issue. The decision regarding duration of treatment and treatment-completion (i.e., tapering of agonist maintenance medication to make patient opioid free) should only be arrived at in consultation with the patient and involves evidences that patient is stabilized, is leading an illicit opioid-free life and is socially and occupationally rehabilitated. Till such criteria are evident, the OATOD should continue, if required, for very long duration (running into years). However, there is evidence that unless a clear "goal for termination of OATOD is maintained, there is a risk that OATOD may become interminable, especially in government settings with free supply of the opioid medication. Thus, it is better to keep a "goalpost" in view, which may be flexible to an extent. The OST centers should not be reduced to dispensing of Buprenorphine-Naloxone medicine, otherwise the whole deaddiction programme will fall into disrepute.

With this background, and also keeping in view the National Policy on NDPS Act recommendation, it is recommended that OATOD should be terminated "preferably within one year but in no case later than two years." However, in exceptional cases, for cogent reasons select patients may need it for longer periods, perhaps for another year or so. In such cases, the exceptional need must be clearly documented in the case file.

Weaning off from buprenorphine can be difficult. Many patients find it difficult to completely discontinue buprenorphine, especially after prolonged use. In such cases, inpatient admission may be necessary for a short period (7-10 days) when detoxification is done using clonidine followed by induction on oral naltrexone for 6-12 months.

Para 11, 12 and 13 of page 17 of PGI guidelines may kindly be referred for more detail.

15) Monitoring and Evaluation:

Monthly Reports:

Every Private De-addiction center is required to submit monthly report at Civil Surgeon office of respective district, which includes details as per annexure-B.

The details of treatment i.e., frequency of visit, number of tablets per day and doses would be carefully recorded both in the register of the center as well as in the patient's card.

16) Misuse of Buprenorphine-naloxone (BNX):

Each patient registered in the Private deaddiction Clinic must have an individual case file along with consent form which would document their diagnosis (and how it was established), indications andPrivate Centers must be vigilant for any suspicious activity alerting to the possibility of diversion or abuse of BNX, such as:

i) Repeated requests for increased quantity of BNX in the absence of withdrawal.
ii) "Losing" OPD cards and asking for refill prescriptions.
iii) Proxy family members turning up instead of the patient for refills.
iv) Asking for prescriptions for long periods (beyond 7 days) without convincing circumstances or corroboration.
v) Appearing drowsy or under influence of opioids at follow-up visits, etc.

17) Record Maintenance:

Private de-addiction facilities must maintain meticulous and detailed records of opioid medications purchased from the manufacturers and supply or sale to the patients. They must maintain following registers:

i) Stock of Medicine:

Entry of each purchase of the opioid drugs in the Central Consumable Stock Register:(Separate Register/Pages for each medicine). Annexure -C

ii) Patient Register:

Separate page for each patient registered should be maintained. Annexure-D

18) Drug administration:

i) Food and drug administration shall obtain details of opioid medicines supplied to private de-addiction centers in the format attached at annexure-E.

ii) The information furnished by suppliers/manufacturers as above shall be tallied with the information received by civil surgeons from the centers directly as mentioned in para (i) and (ii) of para 15 –Record Maintenance above in the following format attached at annexure-F.

(B. Srinivasan)
Additional Secretary Health

Annexure-A

CONSENT FORM FOR INITIATION OF BUPRENORPHINE TREATMENT

I, _____ _____ consent to start tablet buprenorphine for oral substitution therapy.

I have been explained that Buprenorphine is being initiated as a part of the comprehensive treatment for opioid dependence. As an opioid agonist (action similar to heroin), buprenorphine maintenance treatment will substitute an illicit, medically unsafe, short acting opiate such as heroin with a medically safer long acting drug with similar effect. The agonist maintenance will eliminate drug hunger and the drug that I was using will not be able to produce the same effect as before, so that I do not experience any withdrawal symptoms and there will be no craving for the drug being abused. When combined with psychological interventions it will minimize dysfunction and help me to become productive. My attendance to group sessions will improve the chances of successful outcome.

I need to be honest regarding follow up visit, revealing any medication side-effects, craving for opioid use and psycho-social stressors. Even if I discontinue buprenorphine and relapse to opioid use, early treatment seeking within days is advisable.

In addition, I have been given to understand that

- The use of other drugs (such as alcohol, tranquillizers, sleeping pills, heroin or other opioids) may be dangerous in combination with buprenorphine, and can lead to overdose, breathing failure and death.
- My dose of buprenorphine may be withheld or reduced in the event that I present intoxicated with alcohol or other drugs.
- I would undergo a monthly urine testing or as frequent as deemed necessary by the treating doctor.

I understand that my treatment may be stopped without my consent for reasons such as:

- Violence, threatened violence, or verbal abuse towards other patients or staff,
- Failure to attend medical or counseling appointments,
- Frequently missing doses,
- Unlawful entry onto the premises,
- Diversion of buprenorphine doses,
- Engaging in unlawful activities such as drug dealing around the hospital.

I have fully understood the above-mentioned information. I am willing to start buprenorphine and follow the instructions explained to me.

Patient's Signature	Date and Time
Signature of family member & relationship to the patient	Date and Time
Signature of treating physician	Date and Time

Annexure-B

De Addiction Center name _____ **Month** _____

Number of new registrations in the reporting month	Number of follow up patients in the reporting month	Number of indoor patients in the reporting month	Stock details of Medicines in the reporting month

Annexure-C

Stock of Medicine Month _____

Date (1)	Name of Medicine (2)	Quantity in stock at end of previous day (3)	Total Quantity received from supplier (4)	Total quantity of medicine available for dispensing during the day (5)	Quantity dispensed/ consumed on the day			Quantity In stock at closure of the day (9)=(5-8)	Remarks
					In OPD (6)	Indoor (7)	Total (8)		

Annexure-D

Name of Patient:_____ UID_____

Contact details_____

Date of visit	Medicines issued	Details of medicine (potency etc)	Total quantity issued (write number of tablets in bracket)	Signatures of patient	Signature of In-charge

Annexure-E

It should be separately filled for each Medicine

Name of Medicine_____

Manufacturer/Distributor Firm	Name of de-addiction centers to which supplied.	Details of orders: (like order placed on date, quantity supplied, date of dispatch etc)

Annexure F

Name of center	Medicine	Supply received from supplier				Medicine consumed at the center during the month	Balance stock
		supplier-1	supplier-2	supplier-3	Total		
	Medicne-1						
	Medicine-2						
	Medicine-3						