دائـــــرة الـــصـــحـــة
DEPARTMENT OF HEALTH

DOH STANDARD FOR THE MANAGEMENT OF NARCOTICS, PSYCHOTROPIC AND SEMI-CONTROLLED MEDICINAL PRODUCTS

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DEPARTMENT OF HEALTH

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This document should be read in conjunction with the UAE Federal Laws Number 8 (2019), Number 14 (1995), Ministerial Resolutions Number (888) for the year 2016 and Number (397) for the year 2019 and DOH regulations including:

- Federal Code of Ethics and Professional Conduct for Health Professionals;
- Health Regulator Manual, Chapter on Medical Products;
- DOH standards on the use of medicinal products, including but not limited to:
  - DOH Standard on Approved Products List,
  - DOH Standard on Pharmacovigilance.

1. Purpose

This standard establishes the minimum requirements that must be in place with respect to narcotic, psychotropic and semi-controlled medicinal products to:

1.1 Ensure their appropriate use;
1.2 Ensure their safe handling; and to
1.3 Limit their diversion for illicit use.

2. Scope

This standard applies to Healthcare Providers (facilities and professionals) and pharmaceutical facilities licensed by DOH to store, distribute, prescribe, dispense, administer and/or handle narcotics, psychotropic and semi-controlled medications and medicinal products in the Emirate of Abu Dhabi;

3. Definitions

3.1 Narcotic and psychotropic medicinal products are categorized into two groups according to UAE Federal Law of Medicinal Product, pharmacy and Pharmaceutical Facilities, Number (8) for the year 2019, and UAE Federal Law Number (14) for the year 1995, as follows:

3.1.1 **Narcotic & Psychotropic Substances (CD):** Medical and therapeutic products and others containing any active ingredient according to Federal Law Number (14) for the year 1995 and its amendments;

3.1.2 **Semi-Controlled Substances (SCD)**: Substances or drugs not listed under narcotic Psychotropic Substances, however they must be controlled inside the country, as their misuse may lead to harm of public health.

3.2 **Controlled Substances and Products**: Products and substances which medical and commercial circulation require controlling actions. Such products include:

1. Toxic substances and plants
2. Prohibited veterinary substances
3. Narcotic and psychotropic substances, whether in form of raw materials or incorporated in a medical product
4. Hazardous medical products

3.3 **Drug Discrepancy:** Any inconsistency or disparity between the physical amount of a narcotic, psychotropic or semi-controlled drug and the amount of medication recorded in the narcotic/ psychotropic drug register.

3.4 **Disposal:** An act or instance of disposing psychotropic and narcotic drugs which are deemed unusable, damaged, expired or are destined for destruction as identified by the healthcare professional.

3.5 **Demand and return voucher**: A DOH-issued voucher used by the persons in charge at individual facilities for documenting all transactions related to requesting or returning or replacing of any narcotics and any other related transactions (**Appendix 1**).

3.6 **Register**: A register of information on the narcotic and/or psychotropic or semi-controlled medicinal product listed, including but not limited to:

- Prescription reference number;

- Strength, dose, quantity, formulation and balance of the product;
- Name and license number of the prescribing physician;
- Name and license number of the dispensing pharmacist;
- Patient's name and address;
- Date issued;
- Source of the medicine;
- Receiving date;
- Invoice reference number.

There are three categories of registers, all issued by DOH against a fee:

3.6.1 **PH 17** – psychotropic drug register book for pharmaceutical facilities,
Used by pharmacists, and nurses at individual facilities to record transaction of SCD and CD drugs within pharmacy and drug stores (**Appendix 3**).

3.6.2 **PH 18** –Narcotic drug register book for wards and clinical departments,
Used by nursing staff (in charge) at individual facilities to document narcotic stock received from pharmacy and details of administration to patients (**Appendix 4**).

3.6.3 **PH 20** – Narcotic register for stores and pharmacies, used by pharmacist in charge at individual facilities to document Narcotic purchasing and dispensing **(Appendix 5).**

3.7 **Central Purchase Store:** DOH licensed medicine storehouse designated to receive, store (in its vault) and distribute narcotics for DOH licensed healthcare facilities in the Emirate of Abu Dhabi.

3.8 **Narcotic, psychotropic and semi controlled medicinal products person in charge:** An appropriately qualified and trained DOH licensed healthcare professional (physician or pharmacist) assigned by the facility to be responsible and accountable for narcotic and psychotropic medicinal products held within the facility (**Appendix 6**).

3.9 **Unified platform system:** an electronic system for prescribing and dispensing narcotic, psychotropic and semi-controlled medicinal products as per the Ministerial Decree 379 for the year (2019).

3.10 **Narcotic Forecast**: An estimation of the narcotic medicines requirements for the annual year.

4. Duties of Healthcare Providers

Healthcare and Pharmaceutical Facilities permitted to prescribe, or store, or distribute, or dispense and/or administer and manage narcotics, psychotropic and semi controlled medicinal products must:

4.1 Be licensed as either a Hospital (general or specialised), Day Surgery Care Centre, Pharmacy, Drug Store or other DOH-licensed healthcare entities;

4.2 Assign a repsonsible person in-charge of narcotic and psychotropic medicines in the facility to be either a licensed physician or pharmacist and submit the following documents on the TAMM portal on (https://www.tamm.abudhabi/ar-AE/):

4.2.1 Official letter from the facility medical director on approving the person in charge

4.2.2 Filled in "In-Charge" form (Appendix 6)

4.3 Set out in writing and implement Policies and Standard Operating Procedures (SOPs) to manage, monitor and report on prescribing, storing, distributing and dispensing and/or administering as well as disposing of narcotics, psychotropic and semi-controlled substances in accordance with this Standard and UAE Laws.

4.4 Facility Standard Operating Procedures (SOPs) must, as a minimum, set out detailed procedures for:
- 4.4.1 Prescribing, dispensing and administering narcotic and psychotropic medicinal products depending on the scope of practice permitted by its license;
- 4.4.2 The storage, security and access to narcotic and psychotropic medicinal products;
- 4.4.3 The distribution of narcotic and psychotropic medicinal products from, to and within the facility and patient care settings;
- 4.4.4 Return, disposal and destruction of narcotic and psychotropic medicinal products;
- 4.4.5 Reporting on sentinel events, adverse drugs reactions and medication errors in accordance with the relevant DOH Standards.
- 4.4.6 On the Specific roles, responsibilities and accountability of healthcare professionals; and;
- 4.4.7 Monitoring, tracking and reporting accurately and completely all Narcotics, psychotropic and semi-controlled medicinal products stored, prescribed, dispensed and/or administered, returned and disposed of in the format, by the means and within the time period set out in this Standard, and adhere to the following:
  - 4.4.7.1 Reconciling received, used and un-used narcotic and psychotropic medicinal products and reporting on discrepancies identified in accordance with Sections 10 and 11 of this Standard.

4.5 Submit a forecast on narcotic products to DOH before the first of January and before the first of June annually;

4.6 Submit monthly reports on the consumption of psychotropic and semi-controlled medicinal products and quarterly reports for Narcotics to cdreport@doh.gov.ae;

4.7 Notify DOH of any narcotics and psychotropic medicinal products to be disposed:

4.8 Ensure products that require disposal e.g. expired narcotic medications and empty ampoules are separated from the active stock:
- 4.8.1 Disposal of such products is to be executed under the supervision of DoH auditors;
- 4.8.2 Facilities should have a contract with an approved medical waste destruction company. The cost of disposal of narcotics and psychotropic medicinal products is the responsiblility of the facility;

4.9 Development and implementation of facility driven ongoing notification system, monitoring and investigation of any identified discrepancies;

4.10 Maintain, manage and make available for DOH audit, a list of all narcotic, psychotropic and semi-controlled medicinal products stored, prescribed, dispensed and/or administered, returned and disposed of, along with their records, by the facility through an official register;

4.11 Comply and cooperate with the DOH authorised auditors, as required for inspections and audits by DOH.

4.12 Healthcare Professionals: All licensed health professionals involved in management of narcotics and psychotropic medicinal products must:

4.12.1 Be privileged by their facility to manage narcotic and/or psychotropic medicinal products in accordance with the DOH Standard for Clinical Privileging Framework including: limiting their practice to the skills, competencies and the privileges granted within the particular facility with which they are associated and as per their scope of service.

4.12.2 Comply with the requirements of this standard including restrictions on prescribing, dispensing, administration and disposal of narcotics and psychotropic medicinal products.

5. Prescribing Narcotics and Psychotropic Medicinal Products

5.1 All narcotics and psychotropic medicinal products in both inpatient and outpatient settings must be prescribed electronically through the unified platform system as per **Appendices 6 & 7**.

5.2 Narcotic- Inpatient setting

5.2.1 Each dose shall be prescribed on a separate prescription by a DOH licensed physician;

5.2.2 As per Ministerial Decree Number (888) for the Year 2016, the validity of a narcotic or psychotropic medicinal prescription shall be no more than three days, counted from the day of issuing the prescription by the respective physician.

5.2.3 Empty narcotic ampoule must be discarded in the sharp containers as per the Ministerial Decree Number (4192) for the year of 2018 and the following procedures to be applied:

5.2.3.1 Documenting the disposal of empty narcotic ampoules by hand writing on the back of the narcotic prescription (Form PH11).

5.2.3.2 Signing on the back of the narcotic prescription (Form PH11) by the person in-charge and another witness from the healthcare professionals in the facility.

5.3 Narcotic-Outpatient setting

Prescribing narcotics must only be undertaken by:

5.3.1 Either a specialist or consultant (within their scope of specialty) may prescribe narcotics for a maximum duration of up to 30 days in the following the dosage forms; tablets, capsules and patches;

5.3.2 Refill prescriptions are NOT permitted for narcotic products;

5.3.3 The validity of a narcotic prescription shall be no more than three days, counted from the day the prescription was issued;

5.3.4 The prescription must be issued through the unified platform system.

5.3.5 Physicians are not allowed to prescribe for themselves or their relatives.

5.4 Psychotropic Medicinal Products

Prescribing psychotropic medicinal products must only be undertaken in accordance with Ministerial decree Number (888) for the year 2016:

5.4.1 A DOH licensed General Practitioner is only permitted to prescribe up to 3 days' supply of psychotropic medicines.

5.4.2 A DOH licensed Specialist is only permitted to prescribe up to 15 days' supply of psychotropic medicines.

5.4.3 A DOH licensed Consultant is only permitted to prescribe up to 30 days' supply of psychotropic medicines.

5.4.4 Refill prescriptions for specific psychotropic medicinal products listed in Ministerial Decree Number (253) for the year 2020, are permitted and may be issued only as per the following:
- 5.4.4.1 Specialist is eligible to prescribe an initial 30 days' supply with one refill (up to 60 days);
- 5.4.4.2 Consultant is eligible to prescribe an initial 30 days' supply with two refills (up to 90 days);
- 5.4.4.3 The validity of a psychotropic medicinal products prescription will be no more than three days from the date of issuing the prescription by the respective physician;
- 5.4.4.4 Beyond the three-day period, the validity of the refill is governed by the rules of the Unified Platform System.

5.4.5 Physicians are not allowed to prescribe for themselves or their relatives.

5.5 Semi-Controlled Medicinal Products

Prescribing semi-controlled medicinal products must be as follows:

5.5.1 General Practitioner is eligible to prescribe 30 days' supply with no refill;

5.5.2 Specialist is eligible to prescribe an initial 30 days' supply with one refill (up to 60 days);

5.5.3 Consultant is eligible to prescribe an initial 30 days' supply with two refills (up to 90 days);

5.5.4 In the event that a patient prefers an alternative pharmacy to dispense the refill, the patient can go to any licensed pharmacy in the country to dispense his/her medication through the unified platform system;

5.5.5 The validity of semi-controlled medicinal prescription shall be no more than three days from the date of issuing the prescription by the respective physician;

5.5.6 Physicians are not allowed to prescribe for themselves or their relatives till category two.

6. Storage of Narcotic, Psychotropic and Semi-Controlled Medicinal Products in Healthcare Facilities

6.1 Narcotics: Must be stored in an inpatient pharmacy setting or a medication room.

6.1.1 All medication rooms used to store narcotics must be approved by DOH;

6.1.2 Narcotic medicinal products, registers and prescription forms must be stored in a secure cabinet with the following features:
- 6.1.2.1 Steel cabinet with internal hinges;
- 6.1.2.2 Have a double locking system;
- 6.1.2.3 Cannot be moved because it is either fixed to a wall or floor or is part of an immovable system;
- 6.1.2.4 Is not accessible to the public.

6.1.3 Narcotic medicinal products stored outside the pharmacy must be placed in a double locked steel cabinet inside a secured medication room;

6.1.4 CCTV must be installed which clearly captures the secure area where the narcotics are stored.

6.2 Psychotropic and Semi-Controlled Medicinal Products: Must be stored in inpatient and outpatient pharmacy settings or a medication room (separate cabinets).

6.2.1 In a secure cabinet made of steel with a single locking system along with the respective registers;

6.2.2 Psychotropic and semi-controlled medicinal products stored outside the pharmacy must be placed in a single locked steel cabinet;

6.2.3 All psychotropic and semi-controlled medicinal product prescription forms must be kept within a secure cabinet that is not accessible to the public;

6.2.4 CCTV must be installed.

7. Record keeping

7.1 Healthcare facilities authorised to prescribe, dispense and/or administer and manage narcotics and psychotropic medicinal products in the Emirate of Abu Dhabi must keep a record of transactions relating to narcotics and psychotropic medicinal products in separate registers in accordance with the specifications provided in this standard.

7.2 Each entry into the respective register must be:

7.2.1 Accurate, contemporaneous and must include the prescription number and patient identifier where applicable e.g. outpatient and clinical areas;

7.2.2 Legible and clear and be entered into the register in a chronological order;

7.3 No erasing or crossing out from the register is allowed. In case of error in the entry, the information must be reentered on the following line.

7.4 Registers, invoices and prescription forms for all narcotic and psychotropic medicinal products must be kept on site for a minimum of five years after the date of the last entry; records for semi-controlled prescriptions to be kept in the pharmacy for at least two years from the last date of dispensing;

7.5 The stock levels and preparations of narcotic and psychotropic medicinal products recorded in the register must match the physical stock in dispensing areas;

7.6 Both inpatient and outpatient pharmacies must keep a record of contemporaneous specimen signatures of the prescribing physicians and nurses who order narcotic medicinal products.

7.7 All narcotic, psychotropic and semi controlled medicinal products must be recorded in their related registers in brand and generic names.

8. Return of drugs

8.1 The inpatient ward or clinical areas must return any non-reusable and/or expired stock of narcotic or psychotropic drugs (including empty used ampoules as per decree 68, 1995 for regulating the use, distribution and prescribing of medicines and narcotics medications) with corresponding narcotic prescription forms to the narcotic pharmacist in charge.

8.2 Upon return, the pharmacist must isolate the non-reusable and/or expired psychotropic or narcotic product and re-issue the exact amount and type of psychotropic or narcotic product to the inpatient ward or clinical areas if required for patient use;

8.3 Any expired/unusable narcotics products must be documented in the Register book and replaced by the pharmacy only upon verifying in the register and upon receipt of a written Store Demand and Return Voucher;

8.4 If the drugs cannot be replaced, the pharmacist-in-charge must sign them off the Narcotic register book for clinical sections and wards (section 3.5.2);

8.5 All transactions involving return of drugs must be documented by the pharmacist in charge as per section 3.5;

8.6 The Pharmacist-in-charge must contact the Central Purchase Store for the Emirate of Abu Dhabi regarding expired/unusable narcotic product, so that the concerned facilities may replace and/or dispose of the narcotic products in accordance with the established procedures;

8.7 Unwanted or expired narcotics, must be returned to the Central Purchase Store for destruction;

8.8 If a patient is admitted with his own narcotic, psychotropic and semi-controlled medicinal products, it must be registered in the designated register book and separated from the facility stock.

8.9 Should the patient be deceased, the medicinal products will be considered as non-reusable items and should be destroyed as per the approved procedure.

8.10 All expired/unusable narcotics must be returned to Abu Dhabi Central Purchase Store;

8.11 Unwanted or expired control and semi-controlled medicinal products, must be returned back to the source of purchase (Drug Supplier) or destroyed under the supervision of DOH audit/inspection team. When this takes place:
- 8.11.1 DOH must be informed (cdreport@doh.gov.ae); and
- 8.11.2 DOH auditors will witness the destruction of the of narcotics, psychotropic and semi-controlled drugs by the respective agent.

9. Narcotic Annual Forecast

9.1 DOH requires government and private facilities to plan their consumption of narcotic medicines and make an annual forecast. Healthcare facilities must be diligent when preparing their forecasts, as they will be liable to cover the cost of narcotics ordered on their behalf, whether consumed or not.

9.2 The narcotic forecasts from Abu Dhabi Government and Private sector must be sent to DOH (Drug and Medical Product Section (DMPR)) to ensure sufficient stock is available.
- 9.2.1 The responsible person must submit the annual forecast to DOH by June 1st of the preceding year (e.g. for 2022, the forecast must be received before June 1st 2021);
- 9.2.2 The annual forecast must be addressed on the organizations official letter head, signed and submitted to Drug and Medical Product Regulation section in DOH;
- 9.2.3 A revised forecast can be submitted if the facility requires any modification on the previous submitted forecast. This takes place on December 1st of the preceding year (e.g. for 2022, the revised forecast must be received before December 1st 2021);
- 9.2.4 The responsible person must communicate with DOH, if the facility wishes to increase or decrease the narcotic forecast to avoid any future shortages. This is an important process and delays in submitting or confirming the revised forecast could result in shortages for the facility.

9.3 Narcotic procurement
- 9.3.1 Healthcare facilities must procure their narcotic medicines from the Central Purchase Store;
- 9.3.2 A newly licensed facility applying to stock narcotics for the first time must apply to DoH by submitting the required documents as follow:

9.3.2.1 Responsible in charge person form (**Appendix 5**);
9.3.2.2 Narcotic forecast official letter;
9.3.2.3 Demand voucher.

9.3.3 The demand voucher **(Appendix 1)** must state clearly the items required, the quantity required, the annual forecast and total amount received in the current year-to-date.

9.3.4 This demand should be presented by the responsible person to the Central Purchase Store along with:
9.3.4.1 The empty ampoules (exchanged 1 for 1);
9.3.4.2 Copies of narcotic prescription forms (one per dose), and
9.3.4.3 Incident reports (**Appendix 8**) relating to any broken or missing ampoules.

9.3.5 The received narcotic is for use by the requesting facility only and must be registered in the assigned narcotic register book of the requesting facility. The received narcotic must **NOT** be given to or exchanged with a branch or a different facility.

10. Narcotics, Psychotropic and Semi-Controlled Drugs Discrepancies

10.1 Healthcare providers and professionals must fulfill the requirements of Section 4 and the person responsible in-charge will be responsible and accountable for reporting any discrepancies of narcotics, psychotropic or semi-controlled drugs and for:
10.1.1 Notifying DOH of any discrepancy that cannot be reconciled through the DOH Incident Report Form (**Appendix 8**) within 48 hours;

10.2 All professionals must be aware of their duty to inform the responsible person and where they discover a discrepancy for narcotics or psychotropic drugs the duty to:
10.2.1 Attempt to reconcile the discrepancy by the end of the shift;
10.2.2 Report and document all discrepancies discovered during their shift, to the responsible if it cannot be reconciled.

11. Transfer of Narcotics and Psychotropic Drugs between Private Facilities

11.1 The transfer of narcotics between private establishments is strictly prohibited;

11.2 The transfer of psychotropic and semi-controlled drugs is not permitted unless the facility obtains prior approval from DOH, after providing a sound justification for their transfer request.

12. Enforcement and Sanctions

12.1 Healthcare providers must comply with the requirements of this Standard.
12.2 DOH may impose sanctions in relation to any breach of requirements under this standard in accordance with the Complaints, Investigations, Regulatory Action and Sanctions Chapter, Regulator Manual.