

**STANDARDS  
FOR  
MEDICAL CLINICS**



**Department of Health**

## **Preface**

The draft Standards for Medical Clinic (“draft Standards”) are developed by the Department of Health, in consultation with relevant stakeholders, in preparation for the introduction of a new statutory licensing scheme proposed by the Private Healthcare Facilities Bill (“PHF Bill”). The PHF Bill was introduced into the Legislative Council in June 2017 and being scrutinized by the relevant Bills Committee. Upon the enactment of the Bill, the draft Standards will be adopted as a code of practice for clinics as defined by the Bill.

The draft Standards are primarily based on the existing Code of Practice For Clinics Registered Under The Medical Clinics Ordinance (Cap. 343) promulgated by the Department of Health (version January 2010) and relevant provisions of the PHF Bill. Reference was taken from other prevailing local and overseas regulatory and professional standards and guidelines where applicable, with a view to setting out the minimum standards for the safe provision of medical services in a clinic setting. The existing medical clinics registered under Cap. 343 and the Project Steering Committee on Standards for Ambulatory Facilities, established by the Department of Health and the Hong Kong Academy of Medicine with co-opted members from major professional associations, universities and private hospitals, were consulted on the draft Standards.

The draft Standards are applicable to all medical and dental clinics to be licensed as “clinic” under the new scheme, and comprise standards in respect of management, physical conditions, service delivery and care process, infection control, and resuscitation and contingency for a clinic. For a facility that is to be licensed as a day procedure centre (i.e. where scheduled medical procedure(s) as defined by the PHF Bill is/are to be performed), a different set of licensing standards will apply.

The draft Standards are subject to review when necessary. The finalized standards will be promulgated as code of practice, along with other licensing requirements, when the new scheme is implemented. For the latest developments in the legislative review, please visit the website of the Food and Health Bureau (<http://www.fhb.gov.hk>).

**Office for Regulation of Private Healthcare Facilities**  
**Department of Health**  
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## **Standards for Medical Clinics (“the clinic”)**

### **1. Management/Governance**

#### **1.1. Registration**

- 1.1.1. The clinic shall clearly display the current certificate of registration in a conspicuous place in the clinic.

#### **1.2. Chief Medical Executive**

- 1.2.1. There should be a Chief Medical Executive (CME), who is a registered medical practitioner at all times. If the clinic provides dental services, there should be a registered dentist in charge of the dental services of the clinic. The clinic should appoint a registered medical practitioner or registered dentist, respectively, to deputise the CME in the latter’s absence from duties.
- 1.2.2. The CME is held accountable for the day-to-day administration and medical management of the clinic. He is responsible for the adoption and implementation of policies and procedures concerning healthcare services in the clinic.
- 1.2.3. The CME ensures that the policies and procedures are consistent with the Code of Professional Conduct for the Guidance of Registered Medical Practitioners issued by the Medical Council of Hong Kong and/or the Code of Professional Discipline for the Guidance of Dental Practitioners in Hong Kong issued by the Dental Council of Hong Kong wherever applicable.
- 1.2.4. CME ensures that all healthcare professionals working in the clinic have the requisite qualifications, valid registration and practising certificates, and relevant training related to the healthcare services they provide.
- 1.2.5. A person must not serve at the same time as the CME of more than two clinics. Where a person is licensed to operate three or more clinics (“group of clinics”) at the same time, the licensee may appoint a single CME for the group of clinics if he has also established a Medical Advisory Committee (MAC) for the same and has appointed for each of the clinics a registered medical practitioner, or a registered dentist, to assist the CME in carrying out the day-to-day administration of the clinic. The responsibilities of the CME, as set out in this document, in respect of each clinic in the group rest with the CME.

### **1.3. Staff training and supervision**

- 1.3.1. Clinical assistants work under the supervision of the registered medical practitioner, dentist or nurse. Clinical assistants shall have received appropriate training relevant to their duties.
- 1.3.2. The clinic provides job orientation programme for new staff. Current operational manuals and clinical guidelines are easily accessible and available to staff for their reference.

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## **2. Physical Conditions**

### **2.1. Clinic management**

- 2.1.1. The physical design, size, layout and condition of the clinic are appropriate for the safe and effective delivery of services and the needs of its patients.
- 2.1.2. All buildings, furniture, furnishings, fittings and equipment of the clinic are maintained in good operational order.
- 2.1.3. The clinic is kept clean and hygienic. Ventilation, lighting and signage are adequate and appropriate.
- 2.1.4. The CME ensures that the construction and use of the clinic premises are in compliance with relevant ordinances and regulations of the Laws of Hong Kong.

### **2.2. Equipment and store**

- 2.2.1. The clinic has the necessary and appropriate equipment which are used as intended for their purposes, in good working order and properly maintained. Records of maintenance and servicing of medical equipment should be kept.
- 2.2.2. Staff involved in clinical care are appropriately trained including training in the safe and proper use of medical equipment present in the clinic.
- 2.2.3. Equipment intended for single use are not reused.

### **3. Service Delivery and Care Process**

#### **3.1. Patients' rights**

- 3.1.1. The clinic should establish written policies and procedures to protect the rights of its patients.
- 3.1.2. Patients have the right to know the name and post of staff providing services.
- 3.1.3. Patients have the right to be informed of the investigation, procedure and treatment planned for them, and give informed consent to any investigation, procedure and treatment.
- 3.1.4. There are measures and facilities to provide for privacy of patients where appropriate.
- 3.1.5. Patients have the right to access their own health records.

#### **3.2. Patient identification**

- 3.2.1 There are written policies and procedures for patient identification and appropriate verification processes to ensure that the correct patient receives the correct information, investigation, procedure or treatment.

#### **3.3. Medical records**

- 3.3.1. There is a written policy in place for the creation, management, handling, storage and destruction of healthcare records.
- 3.3.2. Medical records should include at least the following: unique identifier, patient's name, gender, date of birth, residential address, contact telephone number, drug allergy history, relevant consultation notes and investigation(s), treatment, and, where appropriate, sick leave and referral records.
- 3.3.3. All medical records are accurate, legible and up-to-date. All entries in the record should be dated and signed where appropriate. Medical records are maintained and retained for specified minimum period.
- 3.3.4. Patient records are confidential and kept secure. All stored personal data are protected from unauthorized access, alteration or loss. The staff handling personal data should be aware of the provisions of the Personal Data (Privacy) Ordinance (Cap. 486) and have due regard to their responsibilities under that Ordinance.

### **3.4. Drug management**

- 3.4.1. The CME ensures that the handling and supply of medicines at the clinic are in accordance with the requirements of the relevant legislation in Hong Kong and prevailing guidelines issued by relevant regulatory authorities including but not limited to the codes of professional conduct or discipline issued by the Medical Council of Hong Kong and/or the Dental Council of Hong Kong.
- 3.4.2. The clinic has mechanisms to ensure proper vaccine storage and handling, with reference to the Hong Kong Reference Framework for Preventive Care for Children in Primary Care Settings Module on Immunisation.
- 3.4.3. The CME should keep an up-to-date drug formulary. All medicines supplied should be registered pharmaceutical products in Hong Kong. Drug procurement documents should be kept appropriately for future reference and inspection.
- 3.4.4. All medicines are clearly labelled and stored appropriately. A system is in place to check the expiry dates of medicines. Expired medicines should not be used for dispensing or administration and should be disposed properly.
- 3.4.5. Medicines are dispensed under the supervision of a registered medical practitioner, dentist, or pharmacist. Staff responsible for dispensing and administering medicines should receive appropriate training. A system is in place to monitor the accuracy of dispensing and administration of medicines.

### **3.5. Laboratory specimen**

- 3.5.1. The CME should ensure there are mechanisms in place for proper handling of laboratory specimen.

### **3.6. Charges**

- 3.6.1. Patients should be informed of the charges of service whenever practicable. An up-to-date fee schedule covering major chargeable items, written in both Chinese and English, should be readily available for reference of patients at the reception office, cashier and where appropriate. If it is not possible to provide a fixed fee for a particular chargeable item, the fee could be presented in the form of a price range or a remark be inserted to indicate that price information will be available upon request.

### **3.7. Complaint handling**

- 3.7.1. The CME should implement a mechanism for handling all complaints made by patients or persons representing the patients. The mechanism consists of procedures for receiving, investigating, responding to the complainant and documentation, with a specified time frame.
- 3.7.2. Patients and their carers or representatives are provided with information about the procedure for making complaints and the process for managing and responding to any complaints.

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## **4. Infection Control**

### **4.1. Infection control measures**

- 4.1.1. The CME ensures that all staff of the clinic observe infection control and preventive measures, including but not limited to standard precautions of infections. Reference shall be made to relevant guidelines issued by international or local health authorities (e.g. the Centre for Health Protection of the Department of Health).
- 4.1.2. Appropriate and adequate stocks of personal protective equipment are available for use by staff.
- 4.1.3. The CME should report unusual clustering of communicable diseases to the Department of Health.
- 4.1.4. The CME should report any patient suspected or diagnosed to have a statutory notifiable disease in accordance to the Prevention and Control of Disease Ordinance (Cap. 599A) to the Centre for Health Protection of the Department of Health.

### **4.2. Cleaning, disinfection and sterilisation of medical equipment**

- 4.2.1. Reusable equipment and supplies used in invasive procedure are properly reprocessed by appropriate disinfection and sterilisation methods. Sterile equipment and supplies should be stored in a clean and dry area. There should be a system for regular checking of expiry of sterile supplies.
- 4.2.2. All sterilising equipment are regularly inspected and maintained with proper documentation. Relevant staff are appropriately trained in the use of the sterilising equipment.

### **4.3. Waste disposal**

- 4.3.1. Clinical and chemical wastes are handled properly and safely according to written policies and procedures promulgated by the Environmental Protection Department pursuant to the Waste Disposal Ordinance (Cap. 354) and its related regulations, including but not limited to Waste Disposal (Chemical Waste) (General) Regulation and Waste Disposal (Clinical Waste) (General) Regulation.
- 4.3.2. Radioactive waste are handled properly and safely according to the provisions of the Radiation Ordinance (Cap. 303) and the Radioactive Substances Licence issued by the Radiation Board in respect of the handling of the waste.

**5. Risk Management and Contingency**

- 5.1. The CME should report any events of public health significance to the Department of Health as soon as practicable.
- 5.2. The CME ensures that there are written policy and procedures for resuscitation of patients taking into account the range of services provided in the clinic. Resuscitation equipment are easily accessible and checked at regular interval.
- 5.3. The CME ensures that there are adequate precautions against the risk of fire.
- 5.4. The CME ensures that there is an internal fire and emergency response plan incorporating evacuation procedures. Fire evacuation exercise is conducted at regular intervals and documented.

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