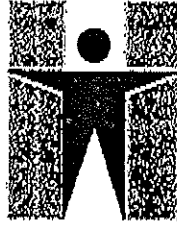


香港特別行政區政府  
衛生署  
私營醫療機構規管辦事處

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THE GOVERNMENT OF THE HONG KONG  
SPECIAL ADMINISTRATIVE REGION  
DEPARTMENT OF HEALTH  
OFFICE FOR REGULATION OF  
PRIVATE HEALTHCARE FACILITIES  
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*By post and by fax*  
(Fax no.: 2865 0943)

21 December 2016

Dr CHOI Kin  
President  
The Hong Kong Medical Association  
5th Floor, Duke of Windsor Social Service Building  
15 Hennessy Road  
Hong Kong

Dear Dr CHOI,

### Draft Standards for Medical Clinics

We are writing to consult the Hong Kong Medical Association on the enclosed draft Standards for Medical Clinics ("draft Standards"), which will be adopted as the regulatory standards for medical clinics under a statutory licensing scheme to be introduced as proposed in the Consultation Document on Regulation of Private Healthcare Facilities and its Consultation Report.

### Existing Regulatory Regime for Private Healthcare Facilities

2. At present, there are two ordinances providing for the statutory registration of private healthcare facilities (PHFs) providing medical services, namely the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap.165) and the Medical Clinics Ordinance (Cap.343). The latter provides for the registration of non-profit-sharing medical clinics while exempting consultation rooms of private medical practitioners and dentists, who are regulated by the Medical Council of Hong Kong and the Dental Council of Hong Kong under the Medical Registration Ordinance (Cap 161) and Dentists Registration Ordinance (Cap 156), respectively.

### Review of Regulation of Private Healthcare Facilities (PHFs)

3. To better safeguard public health and foster the sustainable development of our healthcare system, the Government established the Steering Committee on Review of Regulation of Private Healthcare Facilities (Steering Committee) in October 2012 to conduct a root-and-branch review on the regulation of PHFs. Based on the recommendations by the Steering Committee, the Food and Health Bureau conducted a public consultation on the

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Regulation of Private Healthcare Facilities from December 2014 to March 2015, proposing to replace the existing Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap.165) and the Medical Clinics Ordinance (Cap.343) by a single legislation for the licensing of three classes of PHFs, namely private hospitals, day procedure centres (where high-risk medical procedures or practices are performed), and medical clinics under the management of incorporated bodies. The consultation document and its report, which was released in April 2016, can be accessed at <http://www.hpdo.gov.hk/en/lhsdrelevantpapers.html>.

4. To take forward the proposals set out in the Consultation Document, we are working out the details of the new regulatory regime in collaboration with Government departments and stakeholders, with a view to introducing the relevant Bill to the Legislative Council in the 2016/17 legislative session. We are also working with the key stakeholders in the medical and dental professions to draw up regulatory standards for day procedure centres and medical clinics.

#### Draft Standards

5. Under the proposed regulatory regime, the three classes of PHFs will each be subject to a set of regulatory standards commensurate with the risk of the services they provide, with standards for private hospitals being the most stringent. The Project Steering Committee on Standards for Ambulatory Facilities was set up by the Department of Health and the Hong Kong Academy of Medicine in mid-2015, co-opting representatives from universities, private hospitals and professional associations, to draw up standards for day procedure centres and to also give advice on the standards for medical clinics.

6. DH has drawn up the draft Standards for Medical Clinics, taking reference from the existing "Code of Practice For Clinics Registered Under the Medical Clinics Ordinance (Cap. 343)". It covers five aspects, namely management / governance, physical conditions, service delivery and care process, infection control, and resuscitation and contingency. It is proposed that the finalized Standards will serve as the facility standards for the licensing of medical clinics when the new legislation comes into force.

#### Consultation on the Draft Standards

7. You are cordially invited to give us any comment and view that your association may have on the draft Standards. We will consolidate the comments collected in this consultation exercise for further deliberation by the Project Steering Committee before finalization and promulgation. Please send us your comments by post, by fax, or by email ([orphf.pds@dh.gov.hk](mailto:orphf.pds@dh.gov.hk)) **on or before 23 February 2017**. For enquiry, please feel free to contact the undersigned or Dr Darwin MAK at 3107 3257. Your participation and support to the standard-setting exercise are greatly appreciated.

Yours sincerely,



(Dr FUNG Ying)  
for Director of Health

c.c. Food and Health Bureau  
(Attn: Mr Michael LI, AS for Food and Health (Health)6)

Enclosure

**STANDARDS  
FOR  
MEDICAL CLINICS**

**August 2016**

## 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. Person-in-charge

- 1.2.1. There should be a Person-in-charge (PIC), 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 PIC in the latter's absence from duties.

- 1.2.2. The PIC is held accountable for the 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 PIC ensures that the policies and procedures are consistent with the Code of Professional Conduct 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. PIC 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.

#### 1.3. 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.

## 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 PIC 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 PIC 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 PIC 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 PIC 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 all 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 could be marked to indicate that price information will be available upon request.

### 3.7. Complaint handling

- 3.7.1. The PIC 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.



#### **4. Infection Control**

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

- 4.1.1. The PIC 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 PIC should report unusual clustering of communicable diseases to the Department of Health.
- 4.1.4. The PIC 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 processed and rendered sterile by appropriate procedures of sterilisation. 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 PIC should report any events of public health significance to the Department of Health as soon as practicable.
- 5.2. The PIC 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 PIC ensures that there are adequate precautions against the risk of fire.
- 5.4. The PIC ensures that there is an internal fire and emergency response plan incorporating evacuation procedures. Fire evacuation exercise is conducted at regular intervals and documented.