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The People's Republic of China

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林女士：

《私營醫療機構條例草案》委員會

在二零一八年二月十三日《私營醫療機構條例草案》（《條例草案》）委員會會議上，有委員就於新規管制度下，為某些私營醫療機構而設的實務守則提出疑問。我現來函就此提供進一步資訊。

在新規管制度下，不同類型的私營醫療機構各有一套與其服務所涉風險相稱的規管標準（以實務守則的形式頒布），必須予以遵守。《條例草案》第102條賦權衞生署署長就該條列明的事宜，發出實務守則。衞生署和香港醫學專科學院已於二零一五年年中成立日間醫療機構標準項目督導委員會，為日間醫療中心訂定規管標準，以及就診所的規管標準提供建議。督導委員會及其轄下工作小組包括由香港醫學專科學院提名的專家，以及其他來自公私營界別的醫生和牙醫。香港醫學專科學院和衞生署已於二零一六年年底頒布一套適用於所有日間醫療中心的核心標準（只備英文本，連結：http://www.dh.gov.hk/english/main/main_orphf/files/CS_DPC.pdf），並已於二零一七年五月頒布一套就特定程序訂立的標準，適用於施行外科、麻醉

和鎮靜程序的日間醫療中心（只備英文本，連結：http://www.dh.gov.hk/english/main/main_orphf/files/Procedure_Specific_Standards_for_Surgery_and_Anaesthesia.pdf）。有關其他特定種類的程序（例如內窺鏡程序和血液透析）的標準，則仍在草擬中。

此外，我們參考現行的《根據〈診療所條例〉（第343章）註冊的診所實務守則》和海外司法管轄區的相關標準，擬備診所標準的草擬本。該標準的最新草擬本，可從以下連結取得：http://www.dh.gov.hk/english/main/main_orphf/files/Draft_Standards_for_Medical_Clinics.pdf（只備英文本）。

食物及衞生局局長

（李智龍 代行）

副本致： 衞生署（經辦人：封螢醫生）

二零一八年二月十五日

CORE STANDARDS

FOR

DAY PROCEDURE CENTRES

May 2017

Department of Health

Hong Kong Academy of Medicine

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Preface

This document is developed by the Project Steering Committee on Standards for Ambulatory Facilities (PSC) set up by the Department of Health and the Hong Kong Academy of Medicine (HKAM). It sets out the basic standards for the operation and management of day procedure centres, as defined in section I, that are essential for the safe delivery of medical services.

In December 2014 to March 2015, the Government of the Hong Kong Special Administrative Region conducted a public consultation on a proposed regulatory regime for private healthcare facilities (PHFs) based on the recommendations of the Steering Committee on Review of Regulation of Private Healthcare Facilities and its Working Groups set up under the Food and Health Bureau. Under the new regulatory regimen, there will be four types of PHFs subject to regulation, namely hospitals which are now regulated under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Chapter 165, Laws of Hong Kong), ambulatory facilities providing high-risk medical procedures ("day procedure centres"), medical clinics operated by incorporated bodies ("medical clinics") and health services establishments. A new legislation will be introduced to provide for the regulatory regime.

In preparation for the new regulatory regime, the PSC was formed in April 2015 to develop regulatory standards for ambulatory facilities, co-opting members from the medical faculties of local universities, private hospitals and practitioners' associations. Seven Task Forces are formed under the PSC by nomination of the HKAM and constituent Colleges, comprising members who practise in hospital and/or ambulatory settings and from both the public and private sectors. The PSC is tasked to develop a set of basic standards for all day procedure centres ("Core Standards") and additional standards for specific classes of medical procedures ("Procedure-specific Standards").

In developing the Core Standards, the PSC and the Task Forces have taken into account the legislation and regulatory standards of overseas jurisdictions with adaptation to local practice environment. The Core Standards should be read with the Procedure-specific Standards that are subsequently promulgated by the HKAM. The document is subject to review as and when necessary.

This document serves to provide guidance to the operators of the day procedure centres in anticipation of a new licensing system and to provide a framework for the medical and dental professionals within which they plan and organise their private practices. The Core Standards will be adopted as an essential part of the regulatory standards when the statutory licensing system is implemented.

I. Application of the Core Standards

"Day procedure centres" refer to premises where high-risk procedures are performed. High-risk medical procedures are defined by the following principles and criteria.

General Principles

1. Any procedure defined by ANY one of the following three factors will be regarded as high-risk medical procedure –

   a) Risk of procedures

   b) Risk of anaesthesia involved

   c) Patient's condition

2. Medical practitioners and dentists should take into account, in addition to the criteria for defining high-risk and hospital-only medical procedures, the age, body size and other physical conditions of the patient when deciding whether a medical procedure is high-risk and should be performed in ambulatory facility or in hospital.

3. Certain high-risk procedures should only be performed in hospital in view of their risks. Overall, high-risk medical procedures may be performed in ambulatory setting only if -

   a) the patient is discharged in the same calendar day of admission;

   b) the expected total duration of procedure and recovery requiring continuous confinement within the facility does not exceed 12 hours; and

   c) patient's condition is not Class 4 or worse (i.e. Class 4 or 5) by American Society of Anaesthesiologist (ASA) Physical Status Classification System[1].

[1] ASA Physical Status Classification System :
Class 1 – normal healthy patient
Class 2 – mild systemic disease
Class 3 – severe systemic disease – stable
Class 3 – severe systemic disease – unstable (acute exacerbation)
Class 4 – severe systemic disease that is a constant threat to life
Class 5 – moribund patient who is not expected to survive without the operation

The following high-risk procedures should only be performed in hospitals:

a) Administration of chemotherapy (cytotoxic) into body cavity or deep-seated organ

b) Image-guided core biopsy of deep-seated organ

c) Transarterial catheterisation or deep venous catheterisation

d) Continuous venous-venous haemofiltration / haemodiafiltration

e) Organ transplant [except corneal transplant] or complicated transplant procedures

f) Bronchoscopy or pleuroscopy

g) Therapeutic gastrointestinal endoscopy on children aged under 12 years old

h) Injection of sclerosing / embolisation agents into vascular / lymphatic compartment of deep-seated head and neck region

Risk of Procedures

4. High-risk surgical procedures include the following procedures –

a) Creation of surgical wound to allow access to major body cavity or viscus[2] (including access to central large joints) [except peripheral joints distal to knee and elbow (i.e. ankle and below, and wrist and below)]

b) Removal of tissue and/or fluid of a total volume of 500ml or above [except suprapubic tap]

c) Removal of tissue and/or fluid of any volume from deep seated organ in children aged under 12 years old

d) Removal of any volume of fluid and/or tissue from thoracic cavity [except diagnostic pleural tapping]

e) Insertion of any prosthesis [except prosthesis in ENT cavity, dental prosthesis and implants, facial implants, extra-ocular prosthesis and implants, intrauterine or vaginal prosthesis, bulking agents of urethra, prostatic urethral stent, urethral slings, testicular prosthesis]

[2] Not including needle injection into joint cavity, intraocular injection with fine needle by ophthalmologists and injection of Botox

f) Any core biopsy [except core biopsy of (1) superficial tissue (such as skin, prostate, breast and uterus) but excluding thyroid or salivary glands; (2) superficial muscle; or (3) peripheral muscle]

g) Any biopsy of deep-seated organ

h) Lumbar puncture

i) Transplant of any cell, tissue and organ (including autograft, allograft, xenograft and processed tissue or blood products[3]) or skin flap (including face lift) [except skin graft less than 1% of total body surface area, conjunctival autograft and transplant procedures which primarily involve dental-alveolar region]

j) Termination of pregnancy*

k) Dilation and curettage

l) Circumcision with use of skin sutures in paediatric patients

5. High-risk endoscopic procedures include the following –

a) Endoscopic procedures requiring image guidance (such as endoscopic retrograde cholangiopancreatography (ERCP))

b) Endoscopic procedures involving invasion of a sterile cavity (such as arthroscopy, laparoscopy and hysteroscopy) [except cystoscopy[4]] or gastrointestinal tract

c) Therapeutic endoscopic procedures (such as endoscopic resection) [except minor therapeutic procedures (such as removal of foreign body)]

d) Bronchoscopy or pleuroscopy

[3] Include platelet-rich plasma (PRP)

[4] Cystoscopy does not include therapeutic cystoscopic procedures such as cystoscopic insertion of ureteric catheter or stent, endoscopic urethral dilatation or urethrotomy, cystoscopic removal of stone or foreign body or polyp, cystoscopic injections/diathermy/cautery or haemostasis, cystoscopic lithotripsy.

* Under the section 47A of the Offences Against the Person Ordinance (Cap 212), any treatment for the termination of pregnancy must be carried out in a hospital or clinic maintained by the Government or declared by the Director of Health by notice published in the Gazette to be an approved hospital or clinic, except in the situation that two registered medical practitioners are of the opinion that the termination is immediately necessary to save the life or to prevent grave permanent injury to the physical or mental health of the pregnant woman.

6. High-risk dental procedures include the following –

   Maxillofacial surgical procedures that extend beyond dento-alveolar process, including but not limited to –

   a) Maxillary osteotomies and mandibular osteotomies including angle reduction

   b) Open reduction and fixation of complex maxillofacial fracture

   c) Surgical treatment of diagnosed malignancies

   d) Surgical treatment of complex haemangioma

   e) Surgery involving major salivary glands

   f) Open surgery of temporomandibular joint except arthrocentesis and arthroscopy

   g) Harvesting of autogenous bone from outside the oral cavity

   h) Primary cleft lip and palate surgery

7. The following procedures are also classified as high-risk –

   a) Administration of chemotherapy (cytotoxic) through parenteral routes regardless of therapeutic indication

   b) Image-guided core biopsy [except (1) superficial tissue (such as skin, prostate, breast and uterus) but excluding thyroid or salivary glands; (2) superficial muscle; or (3) peripheral muscle], or image-guided biopsy of deep seated organ

   c) Haemodialysis

   d) Transarterial catheterisation or deep venous catheterisation

   e) Extracorporeal shock wave lithotripsy (ESWL) requiring image guidance

   f) Injection of sclerosing/embolisation agents into vascular/lymphatic compartment of deep-seated head and neck region

Scope of High-risk Anaesthetic Procedures[5]

8. A procedure is considered to be high-risk if it involves any of the following modes of anaesthesia or sedation:

   a) General anaesthesia

   b) Neuroaxial blocks (spinal, epidural, caudal)

   c) Major plexus block (brachial, lumbar, sacral)

   d) Intravenous regional anaesthesia

   e) Intercostal nerve block

   f) Major nerve block:

      - Glossopharyngeal nerve, vagus nerve or their terminal branches, including superior, inferior and recurrent laryngeal nerves;

      - Sciatic and femoral nerves; or

      - Posterior tibial nerve, pudendal nerve or para-cervical block

   g) Use of sedative or analgesic drugs with reasonable expectation that it will, in the manner used, result in deep sedation[6] for a significant percentage of a group of patients

   h) Tumescent anaesthesia

Patient's Condition

9. A procedure is considered high-risk if it is performed on a patient whose physical status is Class 3-unstable or worse (i.e. Class 3-unstable, Class 4 or Class 5) as classified by the American Society of Anaesthesiologists (ASA) Physical Status Classification System.

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[5] The risks of anaesthesia considered by the Working Group include risk of gross, vital physiological derangement, risk of inadvertent systemic injection (such as neurovascular bundle and intra-dural injection), loss of protective reflexes, prolonged disturbance of mobility or body balance, disturbance/loss of major functions of vital organs.

[6] Definition of "deep sedation" should refer to the "Guidelines on Procedural Sedation" promulgated by the Hong Kong Academy of Medicine.

II. Core Standards for Day Procedure Centres ("the Facility")

1. Management/Governance

1.1. Person-in-charge

1.1.1. There should be a Person-in-charge (PIC), who is a registered medical practitioner, at all times. If the Facility provides dental services, there should be a registered dentist in charge of the dental services of Facility. The Facility should appoint a registered medical practitioner or registered dentist, respectively, to deputise the PIC in the latter's absence from duties.

1.1.2. The PIC is held accountable for the medical management of the Facility. He is responsible for the adoption and implementation of policies and procedures concerning healthcare services in the Facility.

1.1.3. 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.

1.1.4. PIC should ensure that all healthcare professionals working in the Facility have the requisite qualifications, valid registration, training and experience related to the healthcare services they provide.

1.2. Staff training and credentialing

1.2.1. All staff involved in clinical care should be appropriately trained including training in the use of any medical equipment and in assisting in medical procedures. There are at all times a sufficient number of suitably qualified and trained staff in the Facility, taking into account the number and needs of patients and types of services provided.

1.2.2. The PIC should ensure that the staff involved in clinical care are practising within their professional scope of practice and competence and in accordance with the code of practice of relevant professions.

1.2.3. There is a process to recognize and regularly review employees' and visiting healthcare professionals' qualifications, training and competence.

1.2.4. The Facility should provide job orientation programme for new staff. Current operational manuals and clinical guidelines are easily accessible and available to staff for their reference.

1.3. Research

1.3.1. If clinical research is conducted on patients, the PIC should ensure that research ethics have been reviewed and the conduct of research is in accordance with standard that may be prescribed by relevant regulatory authorities. The PIC should also ensure that any clinical drug trial conducted is covered by a valid clinical trial certificate issued under the Pharmacy and Poisons Regulations (Cap 138A).

2. Physical Conditions

2.1. Facility management

2.1.1. The physical design, size, layout and condition of the Facility 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 Facility should be maintained in good operational order.

2.1.3. The Facility should be kept clean and hygienic. Ventilation, lighting and signage should be adequate and appropriate.

2.1.4. The PIC should ensure 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. All equipment used in the establishment should be used as intended for its purposes, in good working order and properly maintained. Records of maintenance and servicing of medical equipment should be kept.

2.2.2. Staff using medical equipment should have completed training in the safe and proper use of the equipment.

2.2.3. The PIC should ensure that the Facility has appropriate and readily accessible medical equipment, instruments, appliances and materials that are necessary for the type and level of patient care it provides. The quantities stored should be appropriate for the safe and effective

provision of its services.

2.2.4. Equipment intended for single use should not be reused.

2.3. Back-up power supply

2.3.1. Where high-risk procedures are conducted or life-support systems are used, back-up power supply is available for the life support systems, for recovering patients, and for safe completion or cessation of high-risk procedures.

3. Service Delivery and Care Process

3.1. Patients' rights

3.1.1. The Facility 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 rank of staff providing services.

3.1.3. Patients have the right to be informed of the treatment planned for them and give informed consent to their treatment.

3.1.4. The privacy of patients should be considered and respected by all staff of the Facility.

3.1.5. Patients and their carers or representatives have the right to be informed about the procedures for making complaints and the process of managing and responding to their complaints by the Facility.

3.1.6. 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. There should also be appropriate verification process to ensure that the correct patient has the correct procedure performed on the correct site.

3.3. Medical records

3.3.1. There shall be a written policy in place for the creation, management, handling, storage and destruction of all healthcare records.

3.3.2. For every patient, the PIC should ensure that complete, comprehensive and accurate medical records are maintained and retained for specified

minimum period.

3.3.3. 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.

3.3.4. All medical records should be accurate, legible and up-to-date. All entries in the record should be dated and signed where appropriate.

3.3.5. Patient records are confidential and should be kept secure. All stored personal data should be 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 should ensure that the handling and supply of medicines at the Facility are in accordance with the requirements of the 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 the Dental Council of Hong Kong.

3.4.2. The Facility should provide drugs and biological products in a safe and effective manner to meet the needs of the patients and to adequately support the clinical services. The facility should 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 ensure that there are written policy and procedures covering all aspects of medicine management including but not limited to-

- ordering, procurement, receipt, storage, labelling, administration and disposal of medicines; and

- error and adverse incident reporting and management.

3.4.4. 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.

3.4.5. All medicines should be 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.

3.4.6. 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 and radiology support

3.5.1. The PIC should put in place procedures for obtaining routine and emergency laboratory and radiology services to meet the needs of patient.

3.6. Special needs of paediatric patients

3.6.1. If the Facility admits paediatric patients, the PIC should ensure that treatment is provided by persons who have appropriate qualifications, skills and experience in treating children. Resuscitation equipment and medication is made ready in accordance to the age of the patients.

3.7. Continuous quality improvement

3.7.1. The PIC should implement a system for reviewing the quality of services at appropriate intervals. Findings of the review should be followed up to assure that effective corrective actions have been taken.

3.7.2. The PIC should ensure that policies and procedures relating to safe conduct of all patient care activities are developed and implemented.

3.7.3. The PIC should ensure that there is a written incident management system outlining the procedures to follow in the case of an incident or adverse event. The PIC should review all adverse event reports, document the review and quality improvements measures taken and disseminate the lesson learnt regarding the adverse event identified to all staff.

3.7.4. The PIC should report any specified reportable events to the regulatory authority in prescribed form and manner.

3.8. Charges

3.8.1. Patients should be informed of the charges of service whenever practicable. An up-to-date fee schedule covering all chargeable items should be readily available for reference of patients at the admission/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.

3.9. Complaint handling

3.9.1. The PIC should implement a mechanism for handling all complaints made by patients or persons representing the patient. The mechanism consists of procedures for receiving, investigating, responding to the complainant and documentation, with a specified time frame.

3.9.2. The PIC should ensure that patients and/or carers of patients 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 policies and procedures

4.1.1. The PIC should ensure that there is a written infection control policy, procedures and guidance outlining the procedure to prevent or reduce the risk of a patient acquiring an infection while at the Facility. Reference shall be made to guidelines issued by international or local health authorities (e.g. the Centre for Health Protection of the Department of Health).

4.1.2. The Facility should have an active infection control programme which includes measures to prevent, identify and control infections.

4.1.3. Appropriate and adequate stocks of personal protective equipment are available for use by staff.

4.1.4. The PIC should report to the Department of Health any unusual clustering of communicable diseases, in addition to the statutorily reportable infectious diseases stipulated in the Prevention and Control of Disease Ordinance (Cap 599).

4.2. Cleaning, Disinfection and Sterilisation of Medical Equipment

4.2.1. Reusable equipment and supplies used in operative or invasive procedure involving sterile tissue or vascular system should be 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. There should be written policies and procedures on the use of disposable equipment and on method of control to assure cleaning, disinfection and sterilisation of reusable equipment.

4.2.3. 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 waste should be handled properly and safely according to written policies and procedures promulgated by the Environmental Protection Department pursuant to the Waste Disposal Ordinance (Cap 354).

4.3.2. Radioactive waste should be handled properly and safely according to the provisions of the Radiation Ordinance and the Radioactive Substances Licence issued by the Radiation Board in respect of the handling of the waste pursuant to the Radiation Ordinance (Cap 303).

5. Resuscitation and Contingency

5.1. Risk management

5.1.1. The PIC should ensure that there is a written risk management policy and safety inspection procedures for the identification and assessment of risks and hazards in the Facility and its services.

5.1.2. The PIC should ensure that there is a written emergency response policy outlining the procedures to be followed in the event of an emergency affecting the provision of services at the Facility.

5.2. Resuscitation of patients

5.2.1. The PIC should ensure that there are written policies and procedures for resuscitation of patients and resuscitation facilities for emergencies.

Resuscitation equipment should be easily accessible and checked at regular interval. The PIC should ensure that there are sufficient staff who are trained for cardiopulmonary resuscitation on duty at all times. The Facility should carry out resuscitation drills regularly.

5.2.2. If the Facility provides services to paediatric patients, there should be resuscitation equipment and drugs appropriate for paediatric patients and staff with appropriate training and skills to perform the resuscitation.

5.3. Emergency transfer

5.3.1. There should be written protocol in place for emergency transfer of patients to acute care hospitals when necessary.

5.3.2. Clinical records of sufficient content to insure continuity of care should accompany the patient, but the preparation of records should not delay the transfer.

5.4. Fire safety and evacuation

5.4.1. The PIC should ensure that there are adequate precautions against the risk of fire.

5.4.2. The PIC should ensure that there is an internal fire and emergency response plan incorporating evacuation procedures. Fire evacuation exercise is conducted at regular intervals. Records of the drills should be documented.

Annex I

Project Steering Committee on

Standards for Ambulatory Facilities

Terms of reference

The terms of reference of the Project Steering Committee on Standards for Ambulatory Facilities are:

- to steer the development and promulgation of standards for ambulatory facilities providing high-risk medical procedures;
- to make recommendations on the procedure-specific standards and, where appropriate, on the essential core standards for ambulatory facilities for the legislative review; and
- to steer the conduct of impact assessment survey for regulatory control of ambulatory facilities

Annex II

Project Steering Committee on
Standards for Ambulatory Facilities

Chairperson -
Prof LIANG Hin-suen, Raymond

Members -
Hong Kong Academy of Medicine and Academy Colleges

Dr LEUNG Ka-kit, Gilberto	Hong Kong Academy of Medicine
Dr CHOW Yu-fat	Hong Kong College of Anaesthesiologists
Dr LAW Chun-key	Hong Kong College of Radiologists
Prof LI Kam-tao, Philip	Hong Kong College of Physicians
Dr WONG Yiu-kai	College of Dental Surgeons of Hong Kong
Dr YIP Wai-chun, Andrew	College of Surgeons of Hong Kong

Co-opted Members -

Dr KWOK Po-yin, Samuel	Association of Private Medical Specialists of Hong Kong
Dr LAM Tzit-yuen, David	Hong Kong Medical Association
Ms LAM Yin-ming	Hong Kong Academy of Nursing
Prof LAW Wai-lun	Li Ka Shing Faculty of Medicine, The University of Hong Kong
Dr LEE Kai-Yiu, Anthony	Hong Kong Private Hospitals Association
Dr LEUNG Sai-man, Sigmund	Hong Kong Dental Association
Dr LO See-kit, Raymond	Federation of Medical Societies of Hong Kong
Prof NG Kwok-wai, Enders	Faculty of Medicine, The Chinese University of Hong Kong
Dr YEUNG Chiu-fat	Hong Kong Doctors Union

Ex-officio Members –

Mr LI Chi-pang, Bill	Food and Health Bureau
Dr CHIU Pui-yin, Amy	Department of Health
Dr LAM Tak-chiu, Wiley	Department of Health
Dr SO Wing-yee	Hospital Authority

Annex III

Project Steering Committee on Standards for Ambulatory Facilities

Task Force on Anaesthesia and Sedation

Convenor -

Dr CHOW Yu-fat	Hong Kong College of Anaesthesiologists

Members -

Dr CHAN Chi-keung	Hong Kong College of Anaesthesiologists
Dr CHAN Kin-cheong, Simon	Hong Kong College of Anaesthesiologists
Dr CHEUNG Chi-wai	Hong Kong College of Anaesthesiologists
Dr CHOW Sui-ping, Alice	Hong Kong College of Anaesthesiologists
Dr KONG Kau-fung, Vincent	Hong Kong College of Anaesthesiologists
Dr LEE Yeuk-ying, Samantha	Hong Kong College of Anaesthesiologists
Dr LIU Kam-tim	Hong Kong College of Paediatricians
Dr LIU Tak-chiu	Hong Kong College of Anaesthesiologists
Dr LOW John M	Hong Kong College of Anaesthesiologists

Project Steering Committee on
Standards for Ambulatory Facilities

Task Force on Surgery

Convenor -

Dr YIP Wai-chun, Andrew	College of Surgeons of Hong Kong

Members -

Dr CHAN Hin-lee, Henry	Hong Kong College of Physicians
Dr CHAN Wai-keung, Ricky	College of Surgeons of Hong Kong
Dr HO Chiu-ming	College of Surgeons of Hong Kong
Dr HO Hok-ming	Hong Kong College of Orthopaedic Surgeons
Dr KAM Ting-kwong	College of Ophthalmologists of Hong Kong
Dr LEONG Heng-tat	College of Surgeons of Hong Kong
Dr LEUNG Wai-yip, Michael	College of Surgeons of Hong Kong
Dr MAN Chi-wai	College of Surgeons of Hong Kong
Dr SIU Wing-tai	College of Surgeons of Hong Kong
Dr SOO Ming-soon, Gordon	Hong Kong College of Otorhinolaryngologists
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PROCEDURE-SPECIFIC STANDARDS FOR

DAY PROCEDURE CENTRES

SURGERY

AND

ANAESTHESIA & SEDATION

May 2017

Department of Health

Hong Kong Academy of Medicine

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Preface

This document is developed by the Project Steering Committee on Standards for Ambulatory Facilities (PSC), set up by the Department of Health and the Hong Kong Academy of Medicine (HKAM), and the Task Force on Surgery and Task Force on Anaesthesia & Sedation formed under the PSC.

In preparation for the new regulatory regime, the PSC was formed in April 2015 to develop regulatory standards for ambulatory facilities, co-opting members from the medical faculties of local universities, private hospitals and practitioners' associations. Seven Task Forces were formed under the PSC by nomination from the HKAM and its constituent Colleges, comprising members practising in hospital and/or ambulatory settings and from both the public and private sectors. The PSC is tasked to develop a set of basic standards for all day procedure centres ("Core Standards") and additional standards for specific classes of medical procedures ("Procedure-specific Standards").

This document sets out the basic standards for the operation and management of day procedure centres where surgery, and/or anaesthesia and sedation, are performed. The Procedure-specific Standards should be read with the Core Standards promulgated by the HKAM. The Guidance Notes on Use of Operating Room for Surgical Procedures in Day Procedure Centres ("Guidance Notes") aims to provide a general guidance on the use of an operating room in a day procedure centre for surgery. The Guidance Notes is enclosed with this document at **Annex IV** as reference.

The Core Standards and Procedure-specific Standards serve to provide guidance to the operators of the day procedure centres in anticipation of a new licensing system and to provide a framework for the medical and dental professionals within which they plan and organize their private practices. They are subject to review as and when necessary and will be adopted as part of the regulatory standards when the statutory licensing system is implemented.

Procedure-specific Standards for Day Procedure Centres (Surgery and Anaesthesia & Sedation)

1. Management/Governance

1.1. Staff requirement and training

1.1.1. An appropriate number of suitably qualified and experienced staff are in attendance during each surgical procedure.

1.1.2. Staff have received adequate training before assisting in new surgical procedures.

1.1.3. Person-in-charge develops and implements a policy to determine the scope of surgical procedures that may be performed in the facility with reference to the guidelines promulgated by the Hong Kong Academy of Medicine and/or its Colleges and taking into account of the following factors:

(a) risk of surgical infections*;*
(b) necessity to quickly and safely convert to an open surgical procedure due to complications or technical difficulties; and
(c) physical design, staffing and equipment resources of the facility.

1.1.4. For a facility equipped with operating room, a registered nurse who has relevant experience or training is assigned to oversee the day-to-day operation of the operating room.[1] A registered specialist may assume the role of overseeing the day-to-day operation of the operating room if he/she has the relevant experience or training.

[1] As a transitional arrangement, an experienced enrolled nurse overseeing the day-to-day operation of the operating room of an existing DPC may continue to assume such role under the supervision of a registered medical practitioner or a registered dentist. The DPC seeking to obtain a full license under a statutory licensing system shall fully meet clause 1.1.4.

2. Physical Conditions

2.1. Facility management

2.1.1. Doors and corridors enable transfer of patients on wheelchair or stretchers.

2.1.2. The following functional areas in a facility are separate:
(a) reception and waiting area;
(b) perioperative or procedural area;
(c) area for equipment reprocessing; and
(d) dirty utility room.

2.1.3. There is access control to pre-operative area, areas for conducting procedure and postoperative care area.

2.1.4. In a facility where procedures under deep sedation, general anaesthesia or major regional anaesthesia are performed, doors within the relevant perioperative or procedure area permit transfer of patient on trolleys or stretchers with attachment.

2.1.5. The clinical areas have immediate access to hand-washing facilities.

2.2. Operative / procedure area

2.2.1. Surgical procedures are performed in a location that is spacious enough to accommodate all personnel, fittings and equipment required for the procedure without contamination and to allow the procedure and resuscitation to be carried out effectively.

2.2.2. The lighting is adequate for the procedure undertaken.

2.2.3. For a facility equipped with operating room, each operating room is suitably designed, equipped and maintained for the purpose it is to be used. The operating room is maintained at acceptable level of

sterility. The ceiling, walls and floors are made from materials that can be easily cleaned and disinfected as needed to meet infection control requirements.

2.2.4. The operating room is equipped with specialised ventilation system of internationally acceptable standards of air quality, including but not limited to adequate number of fresh air exchange per hour, to prevent the spread of airborne infectious disease and to minimise surgical site infection.

2.2.5. The ventilation system of the operating room is regularly inspected and maintained to ensure effective functioning for patient and staff safety. Documentation of repair and maintenance of the systems is kept.

2.2.6. Where gaseous anaesthetic agents are used, appropriate gas administration devices and exhaust systems are in place, and relevant requirements on occupational safety should be observed.

2.2.7. Adequate area for scrub and gowning is provided for operating room.

2.3. Equipment reprocessing area and sterile stores

2.3.1. A one-way dirty to clean traffic flow is designated in the equipment reprocessing area to prevent contamination.

2.4. Equipment and store

2.4.1. The facility has the necessary facilities for supporting its scope of surgical services, including but not limited to:

(a) tilting table, trolley or chair that accommodates the procedures performed and provides for adequate range of movement for anaesthetic procedures;
(b) suitable devices for administering anaesthesia;
(c) surgical instruments;

(d) monitoring and resuscitation equipment; and
(e) any other special equipment required for a particular surgery to be performed.

2.4.2. There are adequate facilities and space for the collection and storage of specimens.

2.4.3. The facility is equipped with devices for monitoring vital signs of patients, such as blood pressure, oxygen saturation.

2.4.4. In a facility where procedures under sedation are performed, there are sufficient equipment for monitoring of patient in accordance with the *Guidelines on Procedural Sedation*, published by the Hong Kong Academy of Medicine.

2.4.5. In a facility where procedures under general anaesthesia or major regional anaesthesia are performed, there are sufficient equipment for monitoring of patient in accordance with the *Guidelines on Monitoring in Anaesthesia*, published by the Hong Kong College of Anaesthesiologists.

3. Service Delivery and Care Process

3.1. General

3.1.1. The PIC develops and implements written policies and procedures relating to the safe conduct of surgical procedures and anaesthesia in the facility, including but not limited to the following:
(a) staffing arrangements for surgical procedures and anaesthesia;
(b) informed consent;
(c) pre-procedural assessment;
(d) pre-procedural instructions (e.g. fasting, medication) and care;
(e) documentation of procedures;
(f) patient discharge and care after discharge; and
(g) arrangement for post-operative complications (e.g.

arrangement for inpatient care).

3.1.2. In developing policies and procedures in relation to high-risk anaesthetic procedures, reference is taken from relevant guidelines promulgated by the Hong Kong Academy of Medicine and the Hong Kong College of Anaesthesiologists.

3.2. Pre-procedure

3.2.1. Patients receiving surgical procedures are provided with information on the procedure and anaesthesia, including but not limited to the indication of the procedure, treatment alternative(s), the likely outcomes and risk of complications, before giving consent. Informed consent is documented in the medical record and/or in signed consent form.

3.2.2. Pre-procedural assessment is conducted by a medical practitioner. For patient undergoing procedure under sedation, general anaesthesia or major regional anaesthesia, there is a pre-anaesthetic assessment of the patient by the medical practitioner who performs the sedation or anaesthesia, in accordance with the *Guidelines on the Pre-anaesthetic Consultation* published by the Hong Kong College of Anaesthesiologists. When this is not possible, there is an adequate documented mechanism for conveying findings of the consultation to the anaesthesiologist performing the anaesthesia. The final assessment by the anaesthesiologist for performing the anaesthesia is documented.

3.2.3. Pre-procedural assessment includes, but is not limited to:

(a) history and physical examination;
(b) all current medications;
(c) allergies;
(d) relevant investigations and consultation(s) with other specialty if any; and
(e) fitness for the procedure and the sedation or anaesthesia to be performed.

3.2.4. Patients are given adequate instructions for pre-procedural preparation (e.g. fasting), and post-operative care and discharge (e.g. a responsible adult to escort and care for patient after sedation).

3.2.5. PIC ensures that there are written policies and procedures on the following processes before surgical procedures:

(a) checking of consent forms;
(b) verification processes, including time-out, to ensure correct patient, surgical site and procedure; and
(c) accomplishment of pre-operative preparation (e.g. fasting, pre-medication).

3.3. Intra-procedure

3.3.1. All general anaesthesia and major regional anaesthesia are administered only by an anaesthesiologist or by a trained medical practitioner under the supervision of an anaesthesiologist.

3.3.2. Staffing arrangements and monitoring of patients undergoing procedural sedation are in accordance with the *Guidelines on Procedural Sedation*, published by the Hong Kong Academy of Medicine.

3.3.3. In addition to 3.3.1, care process, staffing arrangement and monitoring of patients undergoing general anaesthesia or major regional anaesthesia and the documentation of the anaesthetic care are in accordance with the *Guidelines on Monitoring in Anaesthesia*, published by the Hong Kong College of Anaesthesiologists.

3.3.4. There are written policies and procedures on the counting of items used during the procedures, such as swabs, needles, blades and other operative instruments and supplies, and what to do if items cannot be accounted for.

3.4. Post-procedure

3.4.1. A medical practitioner or registered nurse trained in post-anaesthetic care is in-charge of the operation of the recovery area. Staff working in the recovery area must be trained for their roles.

3.4.2. All patients after surgical procedures are observed for an adequate length of time commensurate with the anaesthesia given and the surgical procedure performed, and their fitness for discharge are determined by the doctor-in-charge of the patient, subject to 3.4.3.

3.4.3. Recovery of patients who have received sedation or major regional or general anaesthesia takes place in an area that is adequately equipped and staffed for post-anaesthetic care, in accordance with *Guidelines on Postanaesthetic Recovery Care* published by the Hong Kong College of Anaesthesiologists.

3.4.4. The anaesthesiologist or the medical practitioner administering the sedation or anaesthesia, unless he/she has delegated another medical practitioner to take up the role, is responsible for supervising the post-anaesthetic recovery of the patient until he or she can be safely discharged. Medical or nursing staff trained in the post-anaesthetic care must be present at all times when a patient is in recovery and is/are able to promptly reach the supervising medical staff when need arises.

3.4.5. Monitoring of patients recovering from procedural sedation is in accordance with the Guidelines on Procedural Sedation, published by the Hong Kong Academy of Medicine.

3.4.6. Monitoring of patients recovering from general or major regional anaesthesia is in accordance with the *Guidelines on Postanaesthetic Recovery Care*, published by the Hong Kong College of Anaesthesiologists.

3.4.7. There are written policies and procedures for discharge of patients after procedures under sedation or anaesthesia, including but not

limited to:

(a) discharge criteria;
(b) discharge instructions and advice (e.g. medication, care of post-operative site, complications, refraining from certain activities); and
(c) arrangements for enquiries or assistance outside operating hours.

3.4.8. For a patient who has received general anaesthesia, major regional anaesthesia or deep sedation, there is a responsible adult to escort him/her home.

3.4.9. There is written protocol on transfer of patients to hospital for those who are not fit to be discharged home after the procedure or anaesthesia.

3.5. Medical records

3.5.1. The following records are kept:

(a) detailed procedure or operation records of all procedures performed;
(b) investigation reports;
(c) consent forms;
(d) anaesthetic records;
(e) records of post-operative care and pre-discharge evaluation;
(f) pathology report, if specimen of body tissue or fluid was taken; and
(g) outcome of the procedure.

3.5.2. Procedure or operation records include, but are not limited to:

(a) name(s) of the medical practitioner(s) performing the procedure and the assistant(s), if any;
(b) date, time, operation diagnosis, start time and end time of the procedure, anaesthesia and sedation method, name, details of the procedure, surgical findings, and any tissue removed and/or sent for pathology;

(c) record of the name, dose, time and route of administration of all medications and fluids given for the operation; and
(d) blood and other fluid losses of the patient at the conclusion of the surgery.

3.5.3. Without limiting 3.5.4 and 3.5.5, anaesthetic records include but are not limited to:
(a) name(s) of the medical practitioner(s) administering the anaesthesia; and
(b) the name, dose, route of administration of all anaesthetic drugs given.

3.5.4. For procedures under general anaesthesia or major regional anaesthesia, records of anaesthetic care are in accordance with the *Guidelines on Minimum Requirements for an Anaesthetic Record,* published by the Hong Kong College of Anaesthesiologists.

3.5.5. For procedures under sedation, records of anaesthetic care are in accordance with the *Guidelines on Procedural Sedation,* published by the Hong Kong Academy of Medicine.

3.6. Continuous quality improvement

3.6.1. The PIC develops and implements policies and procedures to review the appropriateness of patient care and monitoring of clinical performance and outcomes (e.g. surgical site infection, emergency transfer, unanticipated hospital admission).

4. Infection Control

4.1. Infection control policies and procedures

4.1.1. There are written infection control policies, procedures and guidelines for prevention of surgical infection, including but not limited to:

(a) standard precautions;
(b) use of aseptic techniques;
(c) environmental cleansing and disinfection;
(d) cleaning, disinfection and sterilization and storage of surgical and/or anaesthetic equipment; and
(e) monitoring of effectiveness of infection control measures.

Reference is taken from guidelines issued by relevant health and professional authorities (e.g. *Recommendations on Prevention of Surgical Site Infection*, published by the Centre for Health Protection of the Department of Health*; Guidelines on Infection Control in Anaesthesia*, published by the Hong Kong College of Anaesthesiologists).

5. Resuscitation and Contingency

5.1. Risk management

5.1.1. There are staff-to-staff communication systems for emergency in the operating / procedure room and recovery area.

5.1.2. There are patient-to-staff call systems or devices (e.g. call bells) where a patient may be left alone temporarily (e.g. patient changing room in the facility).

5.2. Resuscitation of patients

5.2.1. There are adequate and appropriate resuscitation equipment including but not limited to:
(a) device that can ventilate the lungs;
(b) oxygen supply;
(c) suction;
(d) basic intravenous setup; and
(e) defibrillator.

5.2.2. In a facility where procedural sedation is conducted, resuscitation equipment and emergency medications as required in the *Guidelines*

on Procedural Sedation, published by the Hong Kong Academy of Medicine, are in place. Regular checks on their viability are conducted and documented.

5.2.3. In a facility where general anaesthesia or major regional anaesthesia is performed, resuscitation equipment as required in the *Recommended Minimum Facilities for Safe Anaesthetic Practice in Operating Suites*, published by the Hong Kong College of Anaesthesiologists, are in place. Selection of medications to deal with emergency arising from anaesthesia shall be in consultation with an anaesthesiologist. Regular checks on their viability are conducted and documented.

5.2.4. Emergency medications are stored in a designated and easily accessible area in the facility.

5.3. Emergency transfer

5.3.1. If the patient requires emergency transfer to a hospital, the anaesthesiologist and/or the surgeon is responsible for the care of the patient until the patient has been transferred to another appropriate medical staff.

5.3.2. There are policies and procedures in place for emergency transfer of patient to hospital for management of urgent adverse outcome.

5.3.3. Drills for emergency transfer are conducted at regular intervals and documented.

Reference

Hong Kong

1. Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes. Department of Health
2. Recommendations on Prevention of Surgical Site Infection. Scientific Committee on Infection Control , and Infection Control Branch, Centre for Health Protection, Department of Health
3. Guidelines on Procedural Sedation. Hong Kong Academy of Medicine
4. Guidelines on Minimum Requirements for an Anaesthetic Record. Hong Kong College of Anaesthesiologists
5. Guidelines on Monitoring in Anaesthesia. Hong Kong College of Anaesthesiologists
6. Guidelines on Postanaesthetic Recovery Care. Hong Kong College of Anaesthesiologists
7. Recommendations for the Perioperative Care of Patients Selected for Day Care Surgery. Hong Kong College of Anaesthesiologists
8. Recommended Minimum Facilities for Safe Anaesthetic Practice in Operating Suites. Hong Kong College of Anaesthesiologists

Australia

9. The Clinical Services Capability Framework for Public and Licensed Private Health Facilities – Perioperative. Queensland Department of Health
10. Australasian Health Facility Guidelines Part B - Health Facility Briefing and Planning - Day Surgery Procedure Unit. Australasian Health Infrastructure Alliance

Canada – Ontario

11. Out of Hospital Premises Inspection Program-Program Standards. College of Physicians and Surgeons of Ontario

Singapore

12. Directives for Private Ambulatory Surgical Centres providing Ambulatory Surgery. Ministry of Health
13. Guidelines on safe sedation practice for non-anaesthesiologists. Ministry of Health

UK

14. Day Surgery Operational Guide. Department of Health
15. Health building note 10-02: Day surgery facilities. Department of Health

USA – Pennsylvania

16. The Pennsylvania Code Chapter 551. The Commonwealth of Pennsylvania, the Government of Pennsylvania

Annex I

Project Steering Committee on Standards for Ambulatory Facilities

Terms of reference

The terms of reference of the Project Steering Committee on Standards for Ambulatory Facilities are:

- to steer the development and promulgation of standards for ambulatory facilities providing high-risk medical procedures;
- to make recommendations on the procedure-specific standards and, where appropriate, on the essential core standards for ambulatory facilities for the legislative review; and
- to steer the conduct of impact assessment survey for regulatory control of ambulatory facilities

Annex II

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Annex III

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Dr TSE Cheuk-wa, Chad	College of Surgeons of Hong Kong
Dr YU Kai-man	Hong Kong College of Obstetricians and Gynaecologist

Annex IV

Guidance Notes on Use of Operating Room for Surgical Procedures in Day Procedure Centres

This documents aims to provide a general guidance on the use of an operating room, as defined below and based on prevailing international standards in respect of specialised ventilation for infection control, for day surgery in ambulatory setting.[1]

Medical practitioners and dentists must exercise professional judgment in deciding whether a procedure should be performed in or outside an operating room in ambulatory setting taking into account, among others, the nature of the procedure, patient's condition, the risks and consequences of infection, and the possibility of converting to open surgery.

Operating room is a room that meets the requirements of a restricted area and is designated and equipped with specialised ventilation, among others, for performing surgical or other invasive procedures that require aseptic surgical field. These procedures usually carry a high risk of infection (either by exposure of a usually sterile body cavity to the external environment or by implantation of a foreign object into a normally sterile site) or the consequences of infection can be devastating. In this context, procedures performed through orifices normally colonised with bacteria are not included. Any form of anaesthesia may be administered in an operating room. When gaseous anaesthetic agents are used, appropriate gas administration devices and exhaust systems are in place and requirements on occupational safety should be observed.

Restricted area is a designated space that can only be accessed through a semi-restricted area. The restricted access is primarily intended to support a high level of asepsis control. Traffic in the restricted area is limited to authorized personnel and patients. Personnel in restricted areas are required to wear surgical attire and cover head and facial hair. Masks are required where open sterile supplies or scrubbed persons may be located.

Examples of high-risk surgical and dental procedures that should be performed in an operating room:
- Implantation of intraocular lens
- Arthroscopy
- Suction and evacuation
- Dilatation and curettage
- Maxillofacial surgery

[1] The prevailing international standards for ventilation of day-case operating room include, among others, a minimum of 15 air changes (ACH) per hour (HTM, UK), or 20 ACH per hour with at least 4 ACH should be fresh air (FGI, US).

Examples of high-risk surgical and dental procedures that may be performed outside an operating room:

- Endoscopic procedures through natural orifices (e.g. GI endoscopy, cystoscopy, hysteroscopy) not involving insertion of implant/prosthesis into a sterile site
- Therapeutic pleural/abdominal tap
- Percutaneous biopsy of liver, kidney
- Colposcopy with loop electrosurgical excision procedure

The examples are provided for reference and not exhaustive.

Reference

Burlingame B. Operating Room Requirements for 2014 and Beyond. *FGI Guidelines Update Series* #3. The Facility Guidelines Institute, USA. 2014 Sep.

Estates and Facilities Division. Health Technical Memorandum 03-01: Specialised ventilation for healthcare premises. Part A - Design and installation. Department of Health, UK. 2007 Nov.

Skues M, ed. *BADS Directory of Procedures*. 4th ed. The British Association of Day Surgery. 2012.

Humphreys H, et al. Guidelines on the Facilities Required for Minor Surgical Procedures and Minimal Access Interventions. *Journal of Hospital Infection*. 2012; 80: 103-109.

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 Healthcare Planning and Development Office of the Food and Health Bureau (http://www.hpdo.gov.hk).

Office for Regulation of Private Healthcare Facilities
Department of Health
January 2018

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 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.

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.

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.