Code of Practice

for Clinics

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Preface

The *Private Healthcare Facilities Ordinance* (the Ordinance) (Cap. 633) was gazetted on 30 November 2018 introducing a new regulatory regime for hospitals, day procedure centres, clinics and health services establishments. Pursuant to section 102 of the Ordinance, this *Code of Practice for Clinics* (CoP) is issued by the Director of Health (the Director) to provide standards for all clinics licensed under the Ordinance. The CoP sets out the licensing standards in respect of the governance, physical conditions, service delivery and care process, infection control, risk management and contingency, and other matters related to the operation of a clinic. Of note, the scheduled medical procedures prescribed in Schedule 3 to the Ordinance and the hospital-only medical procedures stipulated in the *Code of Practice for Day Procedure Centres* must not be performed in clinics.

Pursuant to section 99 of the Ordinance, the Advisory Committee for Regulatory Standards for Private Healthcare Facilities (Advisory Committee) was established in 2020 to devise, review and update the standards of regulation for private healthcare facilities; and to make recommendations on the codes of practice for private healthcare facilities issued by the Director. This CoP is drawn up with reference to the *Standards for Clinics* developed by the Advisory Committee, with a view to setting out the minimum standards for the safe provision of medical and/or dental services in a clinic setting. When devising the *Standards for Clinics*, the Advisory Committee has taken into account the prevailing local and overseas regulatory standards and professional guidelines. In view of the specific service settings unique to dental service, the Task Force on Infection Control in Dental Clinics was set up in 2021 under the Advisory Committee to deliberate infection control requirements clinically relevant to dental service. The Advisory Committee would regularly review and update the CoP when deemed necessary.

Compliance with the CoP is a condition for issuance and renewal of licences. Under section 47 of the Ordinance, the licensee of a clinic (the licensee) is wholly responsible for the operation of the clinic. The licensee is responsible, in particular, for setting up and enforcing rules, policies and procedures relating to the operation of the facility, the quality of care, and the safety of patients. The licensee shall ensure the clinic is in compliance with the conditions of the licence, the CoP, and any direction that may be given by the Director by notice in writing as to how a clinic is to comply with the CoP pursuant to section 104 of the Ordinance.

Determination of compliance will be based on the standards stipulated in the CoP as well as any applicable technical guidelines, standards and codes of practice. Where such guidelines, standards or codes of practice are specified herein, the version specified applies unless an up-to-date version is approved by the Advisory Committee. The Director may also accept other guidelines, standards or codes of practice if he/she is satisfied that they are capable of ensuring equivalent performance of the clinic. The responsibility of proving those other guidelines, standards or codes of practice to be capable of ensuring equivalent performance rests with the licensee. The licensee is reminded to observe any other applicable legislation in the course of operating the clinic.

Department of Health
May 2025

Interpretation of Terms

The following provides the interpretation of terms under this CoP –

"Adverse Event" –

means an incident that resulted in harm to a patient.

"Chief Medical Executive (CME)" –

means a person appointed by the licensee of a clinic under section 49 of the *Private Healthcare Facilities Ordinance* (Cap. 633).

"Clinic" –

means any premises described in section 6 of the *Private Healthcare Facilities Ordinance* (Cap. 633).

"Complaints Committee" –

means the Committee on Complaints against Private Healthcare Facilities established under section 71 of the *Private Healthcare Facilities Ordinance* (Cap. 633).

"Critical Care Area" –

means any area in a facility where failure of electrical power supply is likely to jeopardise the immediate safety or even cause major injury or death of patients or caregivers. Examples are operating room and recovery area.

"Day Procedure Centre (DPC)" –

means any premises described in section 5 of the *Private Healthcare Facilities Ordinance* (Cap. 633).

"Dental Practice" –

means the professional practice of a dentist.

"Dentist" –

means a dentist registered under the *Dentists Registration Ordinance* (Cap. 156).

"Facility" –

means a clinic.

"Healthcare Professional" –

means a person specified in Schedule 7 to the *Private Healthcare Facilities Ordinance* (Cap. 633).

"Hospital" –

means any premises described in section 4 of the *Private Healthcare Facilities Ordinance* (Cap. 633).

"Licensee" –

means a holder of a licence, including a holder of a provisional licence, to operate a clinic under the *Private Healthcare Facilities Ordinance* (Cap. 633).

"Medical Advisory Committee" –

means the committee established under section 57 of the *Private Healthcare Facilities Ordinance* (Cap. 633) for the clinic.

"Medical Practitioner" –

means a medical practitioner registered under the *Medical Registration Ordinance* (Cap. 161).

"Medical Record" –

means the formal documentation maintained by the clinic on patients' history, physical findings, investigations, treatment and clinical progress. It may be handwritten, printed, or electronically generated, and may include audio and visual recording.

"Operating Room" –

means a room described in Annex II of *Code of Practice for Day Procedure Centres* which is permitted by the Director of Health in writing pursuant to section 70 of the *Private Healthcare Facilities Ordinance* (Cap. 633).

"Patient" –

means an individual who is, or may be, suffering from a disease, injury or disability of mind or body, to whom healthcare service is provided, or on whom a medical procedure is carried out.

"Pharmacist" –

means a pharmacist registered under the *Pharmacy and Poisons Ordinance* (Cap. 138).

"Service" –

includes those provided directly by employees of the clinic, or indirectly through services that have been contracted out or run through a separate business contract at location of the registered address.

"Specialized Ventilation System" –

means the ventilation system of an operating room in a facility.

Standards for Clinics

1. Management/Governance

1.1. Chief medical executive

1.1.1. There must be a chief medical executive (CME), who is a medical practitioner, at all times. If there is dental practice in the facility, there must be a dentist in charge of such services. For a facility with dental practice only, the CME must be a dentist. The facility must appoint a medical practitioner or dentist, respectively, to deputise the CME in the latter's absence from duties.

1.1.2. The CME must be held accountable for the clinical management of the facility. He/she must be responsible for the adoption and implementation of policies and procedures concerning healthcare services in the facility.

1.1.3. The CME must ensure that the policies and procedures are consistent with the *Code of Professional Conduct* promulgated by the Medical Council of Hong Kong and/or the *Code of Professional Discipline for the Guidance of Dental Practitioners in Hong Kong* promulgated by the Dental Council of Hong Kong wherever applicable.

1.1.4. The CME must ensure that all healthcare professionals working in the facility have the requisite qualifications, valid registration and practising certificates, and relevant training related to the healthcare services they provide. The CME must 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.

1.1.5. If 4 or more clinics are operated at the same time by the same licensee, the licensee may appoint a single CME for that group of clinics if the licensee:

(a) has established a Medical Advisory Committee for that group of clinics; and

(b) has appointed for each of the clinics under that group a medical practitioner, or a dentist, who is serving the clinic to assist the CME in carrying out the day to day administration of the clinic.

1.1.6. If there is a change of the CME, the licensee must, before the expiry of 14 days after the change has occurred, notify the Director of Health in writing of the

change, and the qualifications, training and experience of the CME appointed, or to be appointed, in replacement. If there is a change in the membership of the Medical Advisory Committee, the licensee must, before the expiry of 14 days after the change has occurred, provide in writing to the Director of Health an updated list of the Medical Advisory Committee members.

1.2. Staff training and supervision

1.2.1. All staff involved in clinical care must be appropriately trained, including training in the safe and proper use of any medical equipment present in the facility.

1.2.2. Clinical assistants must work under the supervision of a healthcare professional. Clinical assistants must have received appropriate training relevant to their duties.

1.2.3. The facility must provide job orientation programme for new staff. Current operational manuals and clinical guidelines must be easily accessible and available to staff for their reference.

2. Physical Conditions

2.1. Facility management

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

2.1.3. The facility must be kept clean and hygienic. Ventilation, lighting and signage must be adequate and appropriate.

2.1.4. The CME must ensure that the construction and use of the facility are in compliance with relevant ordinances and regulations of the Laws of Hong Kong.

2.2. Equipment and store

2.2.1. The facility must have the necessary and appropriate equipment which is used as intended for its purposes, in good working order and properly maintained. Records of maintenance and servicing of medical equipment must be kept.

2.2.2. Equipment intended for single use must not be reused.

2.2.3. Where healthcare engineering systems, namely electrical installation in critical care areas, specialized ventilation system and medical gas supplies, are installed in the facility, the design, installation, operation and maintenance of the systems must comply with the relevant requirements in the *Code of Practice for Day Procedure Centres*.

2.2.4. The manufacture, storage, supply and use of medical gases in the facility must comply with the relevant requirements in the *Code of Practice for Day Procedure Centres*.

2.2.5. Where dental compressed air and vacuum systems are installed in the facility, the CME may refer to the relevant requirements in the *Code of Practice for Day Procedure Centres* for general guidance on the design, installation, operation and maintenance of such systems.

3. Service Delivery and Care Process

3.1. Patients' rights

3.1.1. The facility must 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 the 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 must 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 medical records.

3.2. Patient identification

3.2.1. The facility must have written policies and procedures for patient identification. There must be 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 must be a written policy in place for the creation, management, handling, storage and destruction of all medical records.

3.3.2. Medical records must 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 must be accurate, legible and up-to-date. All entries in the record must be dated, signed where appropriate, and the person could be identified. Medical records must be maintained and retained for specified minimum period.

3.3.4. Medical records are confidential and must be kept secure. All stored personal data must be protected from unauthorized access, alteration or loss. The staff handling personal data must 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. Management of drugs and other injectable and infusible products

3.4.1. The CME must ensure that the handling and supply of medicines, and other injectable and infusible products at the facility are in accordance with the requirements of the legislation in Hong Kong and prevailing guidelines promulgated by relevant regulatory authorities, including but not limited to the codes of professional conduct or discipline promulgated by the Medical Council of Hong Kong and the Dental Council of Hong Kong.

3.4.2. The facility must provide medicines, other injectable and infusible products, 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 must ensure proper vaccine storage and handling, with reference to the *Module on Immunisation* in the *Hong Kong Reference Framework for Preventive Care for Children in Primary Care Settings* (2019) promulgated by the Health Bureau.

3.4.3. Injectable and infusible products may be used only where they qualify under one or more of the following categories or under clause 3.4.4.:

(a) pharmaceutical products registered under the *Pharmacy and Poisons Regulations* (Cap. 138A), or pharmaceutical products exempted from registration under Cap. 138A, including, where the relevant exemption applies,

products imported under a valid import licence issued under the *Import and Export Ordinance* (Cap. 60) for the treatment of a particular patient by a medical practitioner or a dentist;

(b) medical devices listed under the Medical Device Administrative Control System (MDACS)[1] ; or

(c) human organ or human tissue products to which the *Human Organ Transplant Ordinance* (Cap. 465) applies and which comply with its applicable requirements, or human organ or human tissue products covered by a valid exemption granted under that Ordinance and used in accordance with the conditions of that exemption.[2]

Where more than one regulatory classification referred to in this clause applies, the product must satisfy the corresponding requirements of every applicable subparagraph. Compliance with one subparagraph does not dispense with compliance with another.

3.4.4. Injectable and infusible autografts[3] that are not advanced therapy products[4] may be used where the material is obtained from and administered to the same individual for homologous use[5].

3.4.5. The CME must keep an up-to-date drug formulary at the facility. Where injectable and infusible products that are not pharmaceutical products are supplied at the facility, the CME must also keep an up-to-date list of those products. Procurement documents for pharmaceutical and other injectable and infusible products must be kept at the facility for future reference and inspection. Where applicable, valid import licences for unregistered pharmaceutical products issued under the *Import and Export Ordinance* (Cap. 60) for the treatment of a particular patient by a medical practitioner or a dentist must also be kept at the facility for inspection.

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[1] As a transitional arrangement, the requirement that all injectable and infusible medical devices must be listed under the MDACS will take effect from 1 March 2027.

[2] Transplant of any cell, tissue or organ is a scheduled medical procedure and must not be performed in clinics unless the procedure falls within an exception specified in Column 3 of Schedule 3 to the *Private Healthcare Facilities Ordinance* (Cap. 633).

[3] Autograft means a tissue graft (including cells and organs in this context) taken from one part of the body and transferred to another part of the same individual. For the purpose of clause 3.4.4., the term also includes platelet-rich plasma obtained from and administered to the same individual.

[4] An autograft may be classified as an advanced therapy product, which constitutes a specific class of pharmaceutical products, if its cells or tissues have undergone substantial manipulation or are intended for non-homologous use. Reference should be made to the Pharmacy and Poisons Board of Hong Kong's *Guidance on Classification of Advanced Therapy Products* for guidance on advanced therapy product classification.

[5] Homologous use means using cells or tissues to perform the same essential function in the recipient as in the donor. For the purpose of clause 3.4.4., the donor and the recipient are the same person.

3.4.6. All medicines and other injectable and infusible products must be clearly labelled and stored appropriately. A system must be in place to check their expiry dates. Expired products must not be used for dispensing or administration and must be properly disposed of.

3.4.7. Medicines must be dispensed under the supervision of a medical practitioner, dentist or pharmacist. Staff responsible for dispensing and administering medicines must have received appropriate training. A system must be in place to monitor the accuracy of dispensing and administration of medicines.

3.5. Pathology and radiology support

3.5.1. The CME must put in place procedures for obtaining laboratory and radiology services to meet the needs of patients.

3.5.2. Where pathology or radiology service (including magnetic resonance imaging service) is provided in the facility, the requirements on equipment, service delivery and care process stipulated in the relevant chapters of the *Code of Practice for Private Hospitals*, where applicable, must be complied with.

3.6. Procedural sedation

3.6.1. Where procedural sedation is performed, it must be performed in accordance with the *Guidelines on Procedural Sedation* (2025) promulgated by the Hong Kong Academy of Medicine, including but not limited to the following aspects:

(a) Equipment for monitoring of patients under sedation;
(b) Pre-sedation assessment;
(c) Staff arrangement and monitoring of patients undergoing procedural sedation[6];
(d) Monitoring of patients recovering from procedural sedation;
(e) Patient discharge and care after discharge;
(f) Medical records; and
(g) Resuscitation equipment and emergency medications.

[6] In addition to the healthcare staff named by the *Guidelines on Procedural Sedation* (2025), clinical assistants with relevant training or qualification in monitoring vital signs of patients undergoing sedation and procedural complications may also assume the role of such monitoring for patients undergoing procedural sedation, under the following conditions:

(a) hold a valid Basic Life Support certificate; and
(b) work under the direct supervision of a medical practitioner or dentist who retains personal responsibility for the monitoring.

3.7. Patient safety incident reporting and learning system

3.7.1. The CME must ensure that there is a written incident management and reporting system outlining the procedures to follow in the case of an incident or adverse event. The CME must review all incident reports, document the review, remedial and quality improvement measures taken, and disseminate the lesson learnt regarding the adverse event identified to all relevant staff. The CME must also ensure all actions, including those instructed by the regulatory authority, are undertaken with documentation.

3.7.2. Reportable events: sentinel events and serious untoward events

The CME must ensure that any sentinel event or serious untoward event is reported to the Director of Health within 24 hours upon identification, and a full report is submitted to the Director of Health within 4 weeks. The reporting and management of incidents must comply with the *Guidance Notes for Reportable Sentinel Events and Serious Untoward Events of Clinics Licensed under Private Healthcare Facilities Ordinance (Cap. 633)* promulgated by the Department of Health. Sentinel events and serious untoward events include:

<u>Sentinel events</u>

(a) Surgery/interventional procedure involving a wrong patient or body part;
(b) Retained instruments or other material after surgery/interventional procedure;
(c) Medication error resulting in major permanent loss of function or death;
(d) Intravascular gas embolism resulting in death or neurological damage; and
(e) Other adverse events resulting in permanent loss of function or death (excluding complications).

<u>Serious untoward events</u>

(a) Medication error which could have led to death or permanent harm or carries a significant public health risk; and
(b) Patient misidentification which could have led to death or permanent harm.

3.7.3. Other reportable events

The CME must ensure that the following events are reported to the Director of Health upon identification:

(a) Unplanned transfer of a patient to a hospital directly from a clinic during or after a planned procedure, which emergency management was required at the hospital; and
(b) Other events of public health significance (for example, radiation health incidents, or serious incidents, such as cessation of water or electricity supply,

resulting in harm to patients who are receiving care in the facility).

3.8. Price information

3.8.1. Patients must be informed of the charges of service whenever practicable. An up-to-date fee schedule covering all chargeable items must 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 must be presented in the form of a price range or be marked to indicate that price information will be available upon request.

3.9. Complaint handling

3.9.1. The CME must implement a mechanism for handling all complaints made by patients or persons representing the patients. The mechanism must include procedures for receiving, managing, responding to the complainant, and documentation, with a specified time frame.

3.9.2. The CME must 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.

3.9.3. A notice on the channels for receiving complaints must be posted up for patients' information at the admission or reception office, cashier, and where appropriate. The notice must also include contact information of the Complaints Committee.

3.9.4. If the Complaints Committee is considering a complaint, upon request from the Complaints Committee, the CME must provide any information or documents requested, in a timely manner, for concluding the case. The information provided to the Complaints Committee must be complete and accurate.

3.9.5. Upon request from the Complaints Committee, the CME must ensure that investigation is conducted and the complainant is replied to. The CME must also ensure that reply and result of investigation are provided to the Complaints Committee within the stipulated time frame.

3.9.6. The CME must ensure that advice, if any, from the Complaints Committee on improvement measures are implemented.

3.10. Telemedicine

3.10.1. Telemedicine is the practice of medicine over a distance, in which interventions, diagnoses, therapeutic decisions and subsequent treatment recommendations are based on patient data, documents and other information transmitted through telecommunication systems.

3.10.2. Where telemedicine service is provided, policies and procedures must be in place to ensure the overall standard of care delivered by telemedicine is not compromised as compared with in-person service.

3.10.3. All staff providing telemedicine service must have the necessary qualification and competence. Staff and patients must be able to identify each other in each encounter.

3.10.4. The facility must have policies and procedures to safeguard privacy and security of data and records for telemedicine service.

3.11. Closure

3.11.1. If the licensee intends to cease operating the facility before the licence expires, the licensee must make a request in writing to the Director of Health to cancel the licence. The licensee must make the request not less than 6 weeks before the intended date of cessation of operation.

3.11.2. The facility must make proper arrangement where necessary for the patient affected to ensure the continuity of care given to them after its closure.

3.11.3. The facility must follow the procedures as issued by the Department of Health for management of its closure.

4. Infection Control

4.1. Infection control measures

4.1.1. The CME must ensure that all staff of the facility observe up-to-date infection control and preventive measures, including but not limited to standard precautions of infections. Reference must be made to relevant guidelines promulgated by international or local health authorities (e.g. the *Guide to Infection Control in Clinic Setting* promulgated by the Centre for Health Protection of the Department of Health).

4.1.2. Appropriate and adequate stocks of personal protective equipment must be available for use by staff.

4.1.3. The CME must 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 invasive procedures involving sterile tissue or vascular system, or used in dental procedures, must be properly reprocessed by appropriate disinfection and sterilisation methods. Sterile equipment and supplies must be stored in a clean and dry area. There must be a system for regular checking of expiry of sterile supplies.

4.2.2. All sterilising equipment must be regularly inspected and maintained with proper documentation. Relevant staff must be appropriately trained in the use of the sterilising equipment.

4.3. Waste disposal

4.3.1. Clinical and chemical wastes must 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 must be 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 pursuant to the *Radiation Ordinance* (Cap. 303).

4.4. Infection control in dental service

4.4.1. For a facility with dental service, the following infection control measures must be followed:

(a) Items not designed to be reused or cannot be sterilised (e.g. saliva ejectors, scalpel blades, needles, local anaesthetic cartridges, sutures, matrix bands, prophylaxis cups) must be disposed of after use;

(b) All dental handpieces that are detachable (including ultrasonic scalers) must be sterilised after use;

(c) Measures must be taken to reduce aerosol and splatters generated during

dental treatment;

(d) Dental laboratory items (e.g. impressions, appliances) must be appropriately disinfected before sending to the dental laboratories. Measures must also be taken to ensure that such items are disinfected before putting them in the patients' mouths;

(e) Measures must be taken to protect X-ray equipment from contamination during taking and processing of radiographs. Contaminated X-ray equipment must be appropriately disinfected;

(f) Measures must be taken to minimise microbial level in Dental Unit Waterlines. Sterile irrigation solution must be used for all surgical procedures, such as dento-alveolar surgeries and implant placement; and

(g) Measures must be taken to protect suction tubing and suction tip connector from contamination. Contaminated suction tubing and suction tip connector must be appropriately disinfected. All the components of a suction system must be cleaned and disinfected at least once a day.

5. Risk Management and Contingency

5.1. The CME must ensure that there are written policies and procedures for resuscitation of patients, taking into account the range of services provided in the facility. Resuscitation equipment and emergency medications must be easily accessible, checked at regular intervals and made ready in accordance with the age of patients. The CME must ensure that there are sufficient staff who are trained for cardiopulmonary resuscitation on duty while providing clinical service.

5.2. Written protocol must be in place for emergency transfer of patients to acute care hospitals when necessary.

5.3. The CME must ensure that there are adequate precautions against the risk of fire.

5.4. The CME must ensure that there is an internal fire and emergency response plan incorporating evacuation procedures. Fire evacuation exercise must be conducted at regular intervals and documented.