Code of Practice

for Clinics

(2025 Edition)



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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.

1. <u>Management/Governance</u>

1.1. Chief medical executive

- 1.1.1. There is a chief medical executive (CME), who is a medical practitioner, at all times. If there is dental practice in the facility, there is a dentist in charge of such services. For a facility with dental practice only, the CME is a dentist. The facility appoints a medical practitioner or dentist, respectively, to deputise the CME in the latter's absence from duties.
- 1.1.2. The CME is held accountable for the clinical management of the facility. He/she is responsible for the adoption and implementation of policies and procedures concerning healthcare services in the facility.
- 1.1.3. The CME ensures 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 ensures 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 ensures 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 are appropriately trained, including training in the safe and proper use of any medical equipment present in the facility.
- 1.2.2. Clinical assistants work under the supervision of a healthcare professional. Clinical assistants have received appropriate training relevant to their duties.
- 1.2.3. The facility provides job orientation programme for new staff. Current operational manuals and clinical guidelines are easily accessible and available to staff for their reference.

2. <u>Physical Conditions</u>

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 are maintained in good operational order.
- 2.1.3. The facility 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 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 has 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 are kept.
- 2.2.2. Equipment intended for single use is not 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 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 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. <u>Service Delivery and Care Process</u>

3.1. Patients' rights

- 3.1.1. The facility establishes 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 is 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. There are written policies and procedures for patient identification. There are 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 all medical records.
- 3.3.2. Medical records 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 are dated, signed where appropriate, and the person could be identified. Medical records are maintained and retained for specified minimum period.
- 3.3.4. Medical records are confidential and are kept secure. All stored personal data are protected from unauthorized access, alteration or loss. The staff handling personal data are 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 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 provides medicines 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 ensures 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. The CME keeps an up-to-date drug formulary. All medicines supplied are registered pharmaceutical products in Hong Kong. Drug procurement documents are 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 are not used for dispensing or administration and should be properly disposed of.

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

3.5. Pathology and radiology support

- 3.5.1. The CME puts 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, are complied with.

3.6. Procedural sedation

- 3.6.1. Where procedural sedation is performed, it is 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 sedation¹;
 - (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.

3.7. Patient safety incident reporting and learning system

3.7.1. The CME ensures 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 reviews all incident reports, documents the review, remedial and quality improvement measures taken, and disseminates the lesson learnt regarding the adverse event identified to all relevant staff. The CME also ensures

¹ 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 the medical practitioner or dentist who retains personal responsibility for the monitoring.

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 ensures 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:

Sentinel events

- (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).

Serious untoward events

- (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 ensures 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 are informed of the charges of service whenever practicable. An up-todate fee schedule covering all chargeable items is readily available for reference of patients at the reception office, cashier and where appropriate. If it is not possible to provide a fixed fee for a particular chargeable item, the fee could be presented in the form of a price range or could be marked to indicate that price information will be available upon request.

3.9. Complaint handling

- 3.9.1. The CME implements a mechanism for handling all complaints made by patients or persons representing the patients. The mechanism consists of procedures for receiving, managing, responding to the complainant, and documentation, with a specified time frame.
- 3.9.2. The CME ensures 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. If the Complaints Committee is considering a complaint, upon request from the Complaints Committee, the CME provides 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.
- 3.9.4. Upon request from the Complaints Committee, the CME ensures that investigation is conducted and the complainant is replied to. The CME also ensures that reply and result of investigation are provided to the Complaints Committee within the stipulated timeframe.
- 3.9.5. The CME ensures 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, there are policies and procedures 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 have the necessary qualification and competence. Staff and patients are able to identify each other in each encounter.

3.10.4. There are 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. <u>Infection Control</u>

4.1. Infection control measures

- 4.1.1. The CME ensures 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 is 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 are available for use by staff.
- 4.1.3. The CME reports 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 are properly reprocessed by appropriate disinfection and sterilisation methods. Sterile equipment and supplies are stored in a clean and dry area. There is a system for regular checking of expiry of sterile supplies.

4.2.2. All sterilising equipment is 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).
- 4.3.2. Radioactive waste is 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 are 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) are disposed of after use;
 - (b) All dental handpieces that are detachable (including ultrasonic scalers) are sterilised after use;
 - (c) Measures are taken to reduce aerosol and splatters generated during dental treatment;
 - (d) Dental laboratory items (e.g. impressions, appliances) are appropriately disinfected before sending to the dental laboratories. Measures are also taken to ensure that such items are disinfected before putting them in the patients' mouths;
 - (e) Measures are taken to protect X-ray equipment from contamination during taking and processing of radiographs. Contaminated X-ray equipment is appropriately disinfected;
 - (f) Measures are taken to minimise microbial level in Dental Unit Waterlines. Sterile irrigation solution is used for all surgical procedures, such as dentoalveolar surgeries and implant placement; and
 - (g) Measures are taken to protect suction tubing and suction tip connector from contamination. Contaminated suction tubing and suction tip connector are appropriately disinfected. All the components of a suction system are cleaned and disinfected at least once a day.

5. <u>Risk Management and Contingency</u>

- 5.1. The CME ensures 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 are easily accessible, checked at regularintervals and made ready in accordance with the age of patients. The CME ensures that there are sufficient staff who are trained for cardiopulmonary resuscitation on duty while providing clinical service.
- 5.2. Written protocol is in place for emergency transfer of patients to acute care hospitals when necessary.
- 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.