Standards

for Clinics

Department of Health

December 2023

Preamble

The *Private Healthcare Facilities Ordinance* (the Ordinance) was gazetted on 30 November 2018 introducing a new regulatory regime for hospitals, day procedure centres, clinics and health services establishments. The Ordinance is being implemented in phases based on the risk level of the private healthcare facilities. While applications for hospital licence and day procedure centre licence were commenced on 2 July 2019 and 2 January 2020 respectively, application for clinic licence and request for letter of exemption in terms of small practice clinics will be announced in due course.

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. The *Standards for Clinics* (the Standards) are developed by the Advisory Committee in consultation with relevant stakeholders and are intended to apply to all medical and dental clinics to be licensed under the Ordinance when the relevant provisions are in force. The Standards comprise standards in respect of 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.

In developing the Standards, reference was taken from prevailing local and overseas regulatory standards, professional guidelines and the draft *Standards for Medical Clinics* promulgated by the Department of Health in 2018, with a view to setting out the minimum standards for the safe provision of medical and/or dental services in a clinic setting. In view of the specific service settings unique to dental practices, 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 clinics.

The Standards are subject to review when necessary. The finalised standards will be promulgated as the *Code of Practice for Clinics*, along with other licensing requirements, when the application for clinic licence commences.

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Standards for Clinics

1. Management/Governance

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 medical 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.

1.2. 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. 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 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 (such as operating room and recovery area), specialized ventilation system of operating room 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. Service Delivery and Care Process

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 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 health 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 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 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).

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 are disposed of properly.

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* (2020) 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[1];
(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 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:

[1] In addition to the healthcare staff named by the *Guidelines on Procedural Sedation*, 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 medical practitioner or dentist who retains personal responsibility for the monitoring.

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-to-date 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 the 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 is provided, there are policies and procedures in place to ensure 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. Infection Control

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* 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 practice

4.4.1. For a facility with dental practice, 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 dento-alveolar 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. Risk Management and Contingency

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 regular intervals and 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.