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| **Report for Application for**  **Day Procedure Centre Licence**  **under the Private Healthcare Facilities Ordinance (Cap. 633)**   |  |  | | --- | --- | | **Reference No:** |  | |  |  | | **Name of Day Procedure Centre (DPC):** |  | |  |  |   PHF 25 (10/2023) |

# Introduction

Under the Private Healthcare Facilities Ordinance (Cap. 633) (“the Ordinance”), four types of private healthcare facilities, namely hospitals, day procedure centres (DPC), clinics and health services establishments, are subject to regulation. A person who intends to operate a private healthcare facility is required to obtain a licence under the Ordinance.

To apply for a DPC licence, a completed application form together with a “Report for Application for Day Procedure Centre Licence” (“the Report”) should be submitted to the Department of Health (DH).

*Points to note in completing the Report*

1. Please complete **Part A** – **General** and **Part B – Specialised Service(s)** provided in the day procedure centre.
2. Please check the appropriate box (☑).
3. Submission of documents to substantiate compliance is **NOT** required. However, relevant documents should be available on-site for inspection.

- Part A: List of written policies and procedures (*see* **Annex)**.

- Part B: Documentary evidence such as duty rosters, staff qualifications and training records/ plans, relevant records, policies and procedures, etc.

1. Equipment that directly relates to life saving is considered critical equipment (e.g. defibrillators, ventilators, etc.).
2. If DPC providing surgical procedure, endoscopic procedure, dental procedure or interventional radiology and lithotripsy services also provides sedation involving deep sedation or above, please also complete “**Part B7** **Anaesthetic Procedure**” of this Report.
3. Where amendments to the Report are necessary, please inform DH by a covering letter/ email stating the application **reference number** and the revised parts/ items, and attach the revised pages at least **10 working days** before inspection.

**Department of Health**

# Personal Information Collection Statement

**Purpose of Collection**

1. DH collects personal data during the course of processing your application made under the Ordinance. The personal data provided will also be used by DH for the following purposes:
2. facilitating the implementation of the Ordinance;
3. establishing and maintaining a register under section 107 of the Ordinance for public inspection;
4. preparing statistics for the purpose of implementing the Ordinance without showing any personal data; and
5. facilitating communication among DH, other government bureau/departments and yourself.
6. If you fail to provide the required information or the submitted information fails to clearly indicate that the private healthcare facility fulfils the requirements for the application concerned, DH may be unable to process the application.

**Classes of Transferees**

1. The information you provided are mainly for use within DH but they may also be disclosed to other Government bureaux/departments or relevant parties in the form and for the purposes mentioned in item 1 above, if required.

**Access to Personal Data**

1. You have the right of access and correction with respect to your personal data as provided for in sections 18 and 22 of and Principle 6 of Schedule 1 to the Personal Data (Privacy) Ordinance (Cap. 486). Your right of access includes the right to obtain a copy of your personal data provided under item 1. A fee may be imposed for complying with a data access request.

**Enquiries**

1. Enquiries concerning personal data provided, including the making of a request for access to and/or corrections of the personal data, should be addressed to:

|  |
| --- |
| Senior Executive Officer (PHF) |
| Office for Regulation of Private Healthcare Facilities |
| Department of Health |
| Room 402, 4/F |
| 14 Taikoo Wan Road |
| Taikoo Shing, Hong Kong |
| (Enquiry Telephone Number： 3107 8451) |

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| **Important Notice:** Under section 93 of the Private Healthcare Facilities Ordinance (Cap. 633), any person who furnishes in this application any statement or information that is false or misleading in a material particular may commit an offence. |

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| ***Content***  **Part A – General** | |
| A1 | Management and Governance |
| A2 | Physical Conditions |
| A3 | Service Delivery and Care Process |
| A4 | Infection Control |
| A5 | Resuscitation and Contingency |
| A6 | Healthcare Engineering Systems |
| **Annex** | **Written policies and procedures to be available for on-site inspection** |

|  |  |  |
| --- | --- | --- |
| **Part B – Specialized Service(s)** | | **Please check the applicable box(es)** |
| B1 | Surgical Procedure |  |
| B2 | Endoscopic Procedure |  |
| B3 | Dental Procedure |  |
| B4 | Chemotherapy |  |
| B5 | Haemodialysis |  |
| B6 | Interventional Radiology and Lithotripsy |  |
| B7 | Anaesthetic Procedure |  |
| B8 | Radiotherapy |  |

# Management and Governance

# Chief Medical Executive (CME)

|  |  |  |
| --- | --- | --- |
| Name in English | (Surname) | (Given names) |
| Name in Chinese | (Surname) | (Given names) |
| Qualifications |  | |

# Arrangement in the absence of CME[[1]](#footnote-1)

# Particulars of deputising medical practitioner/dentist

(a) Day procedure centre **does not operate** during CME’s absence from duties

(b) Day procedure centre **operates** during CME’s absence from duties

Particulars of deputising medical practitioner/dentist in the absence of CME:

|  |  |  |
| --- | --- | --- |
| Name in English | (Surname) | (Given names) |
| Name in Chinese | (Surname) | (Given names) |
| Registration Number under Medical Registration Ordinance (Cap. 161) or Dentists Registration Ordinance (Cap. 156) | |  |
| Qualifications |  | |
| Telephone number | (Daytime) | (Emergency) |
| E-mail address |  | |

# Emergency contact in the absence of CME

|  |  |  |
| --- | --- | --- |
| Name in English | (Surname) | (Given names) |
| Name in Chinese | (Surname) | (Given names) |
| Telephone number | (Daytime) | (Emergency) |
| E-mail address |  | |

# Particulars of the registered dentist to assist CME in carrying out the day to day administration of the dental practice (For combined medical and dental practices ONLY)

|  |  |  |
| --- | --- | --- |
| Name in English | (Surname) | (Given names) |
| Name in Chinese | (Surname) | (Given names) |
| Registration Number under Dentists Registration Ordinance (Cap. 156) | |  |
| Qualifications |  | |
| Telephone number |  | |
| E-mail address |  | |

# Staff training and credentialing

|  | | | **Evidence to substantiate compliance** |
| --- | --- | --- | --- |
| 1. Regular check on the registration status/ practising certificate of professional personnel | Yes | No | Copy of certificates/ record |
| Frequency: | Every       month(s) | |
| 1. Job orientation programme for RN/ EN | Yes | No  NA | Record/ policy of orientation programme |
| Duration: | |
| 1. Job orientation programme for other healthcare professional staff and healthcare workers | Yes | No | Record/ policy of orientation programme |
| Duration: | |
| 1. All staff are appropriately trained, including but not limited to training in the safe and proper use of medical equipment and assisting in medical procedures | Yes | No | Record/ policy of training |

# Physical Conditions

# Accommodation

|  |  |  |  |
| --- | --- | --- | --- |
|  | | | **Evidence to substantiate compliance** |
| 1. There are adequate ventilation, lighting and signage for the safe operation of the day procedure centre | Yes | No | Site environment |
| 1. There are patient-to-staff call systems or devices where a patient may be left alone temporarily | Yes | No | Call bell/ call help mechanism |
| 1. There is a regular cleansing schedule for the day procedure centre and records are maintained | Yes | No | Cleansing schedule/ record |
| 1. The premises of the day procedure centre are maintained in good operational order and records of maintenance and repair are kept | Yes | No | Maintenance schedule/ record |

# Equipment

|  | | | **Evidence to substantiate compliance** |
| --- | --- | --- | --- |
| 1. The day procedure centre has the necessary and appropriate equipment which are used as intended for their purposes, in good working order and properly maintained | Yes | No | Maintenance schedule/ record |
| 1. Records of maintenance and servicing of medical equipment are kept | Yes | No | Maintenance schedule/ record |
| 1. Medical equipment, instruments, appliances, and materials of appropriate quantities are readily accessible | Yes | No | Critical/ major equipment list |
| 1. Back-up power supply is available for the life support systems, for recovering patients, and for safe completion or cessation of high-risk procedures | Yes | No  NA | Catalogue/ specification of system/ equipment with built-in battery/ connection with emergency power supply |

# Facilities and equipment for operating room

No operating room is equipped (Please proceed to A3)

|  | | | **Evidence to substantiate compliance** |
| --- | --- | --- | --- |
| 1. The operating room is suitably designed, equipped and maintained for the purpose it is to be used; and maintained at acceptable level of sterility | Yes | No | Site environment |
| 1. The ceiling, walls and floors are made from materials that can be easily cleaned and disinfected as needed | Yes | No | Site environment |
| 1. The ventilation system of the operating room is regularly inspected and maintained, with documentation of repair and maintenance | Yes | No | Maintenance schedule/ record |
| Frequency of inspection: | Every       month(s) | |
| 1. There is adequate area for scrub and gowning | Yes | No | Site environment |

# Service Delivery and Care Process

# Policies and procedures

|  |  |  |  |
| --- | --- | --- | --- |
|  | | | **Evidence to substantiate compliance** |
| 1. Frequency of reviewing policies and procedures | Every       year(s) | | Document/ record |
| 1. Frequency of circulating policies and procedures to staff | Every       month(s) | | Schedule/ record of circulation |
| 1. Policies set for clinical trials | Yes | No  NA | Document/ record |
| 1. Any clinical drug trial conducted is covered by a valid clinical trial certificate issued under the relevantordinance/ regulations | Yes | No  NA | Certificate |

# Patient rights and identification

|  |  |  |  |
| --- | --- | --- | --- |
|  | | | **Evidence to substantiate compliance** |
| 1. There are policies and procedures to protect patients’ right | Yes | No | Document (such as patient charter) |
| 1. There are policies and procedures for patient identification | Yes | No | Form/ document |
| 1. There are facilities and measures to protect for privacy of patients, e.g. screens, partitions, patient changing rooms | Yes | No | Site environment |
| 1. There is access for patients to obtain their own health records | Yes | No | Document/ notice |

# Medical records

|  | | | **Evidence to substantiate compliance** |
| --- | --- | --- | --- |
| 1. There are policies and procedures for creation, management, handling, storage and destruction of medical records | Yes | No | Document/ record |
| 1. All personal data are kept secure and protected from unauthorized access, alteration or loss | Yes | No | Records with personal data are locked in restricted access room |
| 1. Back-up storage of medical records are kept for medical records stored in the electronic format | Yes | No  NA | Back-up storage |

# Pharmacy and drug management

|  | | | **Evidence to substantiate compliance** |
| --- | --- | --- | --- |
| 1. There are policies and procedures for medicine management (including but not limited to ordering, procurement, receipt, storage, dispensing, labelling, administration, handling and disposal, and error and adverse incident reporting and management) | Yes | No | Document/ form |
| 1. Appropriate storage with restricted access are provided for medicines and controlled drugs to ensure security | Yes | No | Medicine are locked or kept in restricted access area  Dangerous drugs are kept in locked receptacle |
| 1. Suitable storage facilities are provided for medicines in accordance with manufacturer’s recommendation | Yes | No | Fridge for cold chain medicine  Temperature monitoring record for fridge (twice daily with high, low and real time temperature for vaccines and biologicals) (at least 3 days’ monitoring record for new DPC)  Medicine are properly stored |
| 1. An up-to-date drug formulary is kept | Yes | No | Document |
| 1. All medicines supplied are registered pharmaceutical products in Hong Kong | Yes | No | Drug supply |
| 1. Drug procurement documents are kept | Yes | No | Document/ record |
| 1. All medicines are clearly labelled and stored appropriately | Yes | No | Labelling of medicine  Medicine for disposal/ recall are stored separately from those ready for use |
| 1. Expiry dates of medicines are checked on regular basis | Yes | No | Checking schedule/ record  Segregated storage for expired medicines |
| 1. Medicines are dispensed under the supervision of a medical practitioner, dentist, or pharmacist | Yes | No  NA | Dispensing practice |
| 1. System is in place to monitor accuracy of dispensing and administration of medicines | Yes | No | Document/ record |
| 1. Staff responsible for dispensing and administering medicines have received appropriate training | Yes | No | Training record |
| 1. Storage of medicines is segregated from food and other laboratory samples to avoid cross-contamination | Yes | No | Site environment |

# Laboratory and radiology support

|  |  |  |  |
| --- | --- | --- | --- |
|  | | | **Evidence to substantiate compliance** |
| 1. Procedures for obtaining routine laboratory services are in place | Yes | No  NA | Form/ document/ record |
| 1. Procedures for obtaining emergency laboratory services are in place | Yes | No  NA | Form/ document/ record |
| 1. Procedures for obtaining routine radiology services are in place | Yes | No  NA | Form/ document/ record |
| 1. Procedures for obtaining emergency radiology services are in place | Yes | No  NA | Form/ document/ record |

# Continuous quality improvement

|  | | | **Evidence to substantiate compliance** |
| --- | --- | --- | --- |
| 1. System for reviewing the quality of services at appropriate intervals | Yes | No | Policy/ record |
| Frequency: | Every       month(s) | |  |
| 1. Written incident management system outlining the procedures to follow in the case of an incident or adverse event | Yes | No | Policy/ record |
| 1. The CME reviews all adverse event reports, documents the review and quality improvement measures taken, and disseminates the lesson learnt regarding the adverse event identified to all staff | Yes | No | Document/ record |

# Charges

|  |  |  |  |
| --- | --- | --- | --- |
|  | | | **Evidence to substantiate compliance** |
| 1. An up-to-date fee schedule covering all chargeable items and services is available in the day procedure centre for reference by patients | Yes | No | Fee schedule |

# Complaint handling

|  |  |  |  |
| --- | --- | --- | --- |
|  | | | **Evidence to substantiate compliance** |
| 1. There is information provided for patients and their carers or representatives about the procedure for making complaints, and the process for managing and responding to any complaints | Yes | No | Notice |
| 1. Dedicated officer to handle complaints | Yes | No | Document |
| 1. There is a specified time frame for initial response to the complainant | Yes,        day(s) | No | Document/ record |

# Infection Control

# Infection control facilities and equipment

|  | | | **Evidence to substantiate compliance** |
| --- | --- | --- | --- |
| 1. Hand hygiene facilities are readily available in all patient care areas | Yes | No | Site environment |
| 1. Appropriate and adequate stocks of personal protective equipment are available for use by staff | Yes | No | Stock list |
| 1. There are policies and procedures for use of disposable equipment and method of control to assure cleaning, disinfection and sterilisation of reusable equipment | Yes | No | Document |
| 1. Reusable equipment and supplies used in invasive procedure are properly reprocessed by appropriate disinfection and sterilisation methods | Yes | No  NA | Disinfection and sterilisation record |
| 1. Where sterilisation by bench-top steam steriliser (autoclave) is performed, there is a system to monitor and record all sterilisation process | Yes | No  NA | Sterilisation record |
| Type of bench-top steriliser | Gravity Displacement  (Type N steriliser)  Dynamic-air-removal (Type B/S steriliser)  Other: | |  |
| 1. Method for monitoring: | Routine monitoring | | Record/ report |
| For routine monitoring: |  | |  |
| i. Mechanical indicator for every load | Yes | No | Mechanical indicator record (record of cycle time/ exposure time, temperature and pressure, etc.) |
| ii. External chemical indicator | Frequency: | | External chemical indicator record and mechanism |
| iii. Internal chemical indicator | Frequency: | | Internal chemical indicator record and mechanism |
| iv. Biological indicator | Frequency: | | Biological indicator record |
| v. Steam penetration test | Type of test:  Frequency:  NA | | Steam penetration test record |
| vi. Other test(s) | Type of test:  Frequency:  NA | | Other test record(s) |
| 1. Other method for monitoring | Parametric release | | Record / report |
| 1. Sterile equipment and supplies are stored in a clean and dry area | Yes | No | Monitoring equipment and record |
| * 1. Temperature range for storage | -       oC | |  |
| * 1. Frequency of temperature monitoring | times daily | |  |
| * 1. Humidity range for storage | -       % | |  |
| * 1. Frequency of humidity monitoring | times daily | |  |
| 1. There is regular checking of expiry of sterile supplies | Yes | No  NA | Checking record |
| Frequency of checking: | Every       day(s) | |
| 1. All sterilising equipment are regularly inspected and maintained with proper documentation | Yes | No  NA | Maintenance record |
| Frequency of checking: | Every       month(s) | |
| 1. Sharps box is available in a convenient place for disposal of used sharps | Yes | No  NA | Site environment |

# Waste management

|  |  |  |  |
| --- | --- | --- | --- |
|  | | | **Evidence to substantiate compliance** |
| 1. Clinical waste are handled properly and safely pursuant to the *Waste Disposal Ordinance* (Cap. 354) | Yes | No  NA | Document/ record/ site environment |
| 1. Chemical waste are handled properly and safely pursuant to the *Waste Disposal Ordinance* (Cap. 354) | Yes | No  NA | Document/ record/ site environment |
| 1. Radioactive substances and waste are handled properly and safely pursuant to the *Radiation Ordinance* (Cap. 303) | Yes | No  NA | Document/ record/ site environment |

# Resuscitation and Contingency

# Resuscitation and contingency

|  | | | **Evidence to substantiate compliance** |
| --- | --- | --- | --- |
| 1. Written risk management policy and safety inspection procedures for identification and assessment of risks and hazards in place | Yes | No | Inspection schedule/ record |
| 1. Written emergency response policy outlining the procedures to be followed in the event of an emergency affecting the provision of services | Yes | No | Drill policy/ record |
| 1. Written policies and procedures for resuscitation of patients | Yes | No | Policy/ record |
| 1. Resuscitation equipment are easily accessible and checked at regular interval | Yes | No | Checking record |
| Frequency of checking: | Every       day(s) | |
| 1. Cardiopulmonary resuscitation (CPR) drills are regularly performed with records documented | Yes | No | Document/ record |
| Frequency of drills: | Every       month(s) | |
| 1. Written protocol in place for emergency transfer of patients to acute care hospitals when necessary | Yes | No | Policy/ record |
| 1. Fire evacuation exercise is conducted at regular intervals and documented | Yes | No | Document/ record |

# Healthcare Engineering Systems

As a transitional arrangement, the requirements of the healthcare engineering systems as specified in Section 1.6 of the Code of Practice for Day Procedure Centres will take effect from **1 January 2028**.

1. No Operating room is equipped *(Proceed to* ***item ii****)*

| **Operating room** | | | **Evidence to substantiate compliance** |
| --- | --- | --- | --- |
| 1. The requirements of electrical installations are complied. | Yes | No | Document/ record/ site environment |
| 1. The requirements of specialized ventilation systems are complied. | Yes | No | Document/ record/ site environment |

1. No critical care area other than operating room *(Proceed to* ***item iii****)*

| **Critical care area other than operating room** | | | **Evidence to substantiate compliance** |
| --- | --- | --- | --- |
| 1. The requirements of electrical installations are complied. | Yes | No | Document/ record/ site environment |

1. No medical gas pipeline system

| **Medical gas pipeline system** | | | **Evidence to substantiate compliance** |
| --- | --- | --- | --- |
| 1. The requirements of medical gas pipeline systems are complied. | Yes | No | Document/ record/ site environment |

1. The CME is still held accountable for the medical management of the facility during his/ her absent. [↑](#footnote-ref-1)