

**Summary of Key Features under the  
Proposed New Regulatory Regime  
for Private Healthcare Facilities**

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## Types of Private Healthcare Facilities and Definitions of Terms

- Three main types of private healthcare facilities will be regulated :

***hospital*** is any premises that is used, or intended to be used, for–

- (a) providing any medical diagnosis, treatment (other than treatment by way of first aid) or care by a registered medical practitioner or a registered dentist to a patient, with lodging;
- (b) carrying out any medical procedure for a patient, with lodging; or
- (c) receiving –
  - (i) a pregnant woman for childbirth; or
  - (ii) a woman immediately after giving birth to a child,

but does not include any premises specified in Annex A.

***day procedure centre*** is any premises that is used, or intended to be used, for–

- (a) providing any medical diagnosis, treatment (other than treatment by way of first aid) or care by a registered medical practitioner or a registered dentist to a patient, without lodging; and
- (b) carrying out any medical procedure (including one listed in column 2 of Annex B) for a patient, without lodging;

which does not form part of the premises of a hospital.

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**clinic** is any premises that is used, or intended to be used, for—

- (a) providing any medical diagnosis, treatment (other than treatment by way of first aid) or care by a registered medical practitioner or a registered dentist to a patient, without lodging; or
- (b) carrying out any medical procedure (other than one listed in column 2, but subject to the exceptions listed in column 3, of Annex B) for a patient, without lodging;

which does not form part of the premises of a hospital or a day procedure centre.

Also, **clinic** does not include any premises which is not normally used for medical purposes but is temporarily or occasionally used for providing “outreach medical service” (see below).

- In determining the **premises forming** a clinic, day procedure centre or hospital, it comprises any places—
  - (a) that are physically—
    - (i) connected with internal access among themselves; or
    - (ii) attached or in close proximity to, or adjoining, one another; and
  - (b) that form a distinct whole for the clinic, day procedure centre or hospital to function as a single entity.
  
- The premises forming a private healthcare facility must be physically separated from any premises that provides services not serving a purpose reasonably incidental to the type of private healthcare facility or the practice (i.e. medical or dental) carried on in the facility. It must be a distinct and exclusive unit that is able to perform its functions independently. It must also have a direct

and separate entrance not sharing with, or passing through, any premises that provides services not serving a purpose reasonably incidental to the facility concerned.

- Proposed definitions of some other key terms are set out below :

***patient*** means an individual—

- (a) who is suffering, or believed to be suffering, from any disease, injury or disability of mind or body;
- (b) to whom healthcare service is provided; or
- (c) for whom a medical procedure is carried out.

***premises*** includes any place and, in particular, includes the following—

- (a) any land or building;
- (b) any vehicle or vessel.

***outreach medical service*** means any medical diagnosis, treatment (other than treatment by way of first aid) or care by a registered medical practitioner or a registered dentist to a patient—

- (a) that—
  - (i) does not, except in case of emergency, involve any medical procedure—
    - (A) requiring a form of sedation or anaesthesia (other than local anaesthesia); or
    - (B) being one listed in column 2 of Annex B; and
  - (ii) is given—

- (A) as part of the healthcare services provided in a temporary setting by the Government or the Hospital Authority;
  - (B) as part of the healthcare services provided in a premises listed in Annex C;
  - (C) as part of the healthcare services provided in a temporary setting by a person registered as a medical practitioner with limited or temporary registration under the Medical Registration Ordinance (Cap. 161);
  - (D) as part of the medical escort for patient transfer;
  - (E) in a temporary setting for providing vaccination for disease prevention;
  - (F) in a temporary setting for providing medical service to an individual taking part in, or attending, a sporting event; or
  - (G) in a patient's home or place of accommodation on an individual basis;
- (b) that—
- (i) does not involve any medical procedure; and
  - (ii) is given in a temporary setting for providing physical examination and medical consultation for health promotion; or
- (c) that is given in a temporary setting as part of the healthcare services provided without charge for charitable purposes as approved by the Director of Health.

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## Exemption for Small Practice Clinics

- A *small practice clinic* may be exempted from obtaining a licence. It refers to a clinic that :
  - (a) is operated by an individual under a sole proprietorship and he is the only registered medical practitioner or registered dentist who serves the clinic and has exclusive right to use the premises forming the clinic;
  - (b) is operated by a partnership of not more than [3]\* partners, each of whom is a registered medical practitioner or a registered dentist, and those partners are the only registered medical practitioners or registered dentists who serve the clinic, and one or more of them have the exclusive right to use the premises forming the clinic; or
  - (c) the clinic is operated by a company with not more than [3]\* directors, each of whom is a registered medical practitioner or a registered dentist, and those directors are the only registered medical practitioners or registered dentists who serve the clinic, and either the company has, or one or more of the directors have, the exclusive right to use the premises forming the clinic.
  
- If a person concurrently operates more than [2]\* small practice clinics, the exemption applies to [2]\* of those clinics of the person's choice.
  
- Another registered medical practitioner/dentist (as the case may be) may take up the duty of a registered medical practitioner/dentist in the small practice clinic because of his absence from the clinic as

long as the period concerned does not exceed [60]\* in a calendar year.

- Procedure-wise, we propose that a person must give the Director of Health a ***notification*** if the person intends to be exempted in operating a small practice clinic. The Director of Health may grant the exemption which will be in force as long as the status of the clinic (to which the notification relates) as a small practice clinic remains unchanged.

\*Note: The Department of Health is conducting a survey to assess the number of private healthcare facilities affected by the proposed new regulatory regime and collect information on their operation. Our proposals (including the numbers) set out above are indicative only and subject to change.

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## Management of Private Healthcare Facilities

- The legislation will set out explicitly the authorities and duties of the *licensee* and the *chief medical executive* in operating a private healthcare facility :

### *Licensee*

- (1) The licensee of a private healthcare facility assumes the full authority and responsibility for the operation of the facility.
- (2) The licensee is responsible, in particular, for—
  - (a) ensuring the facility's compliance with licence conditions, code of practice, etc.
  - (b) setting up and enforcing rules, policies and procedures relating to the quality of care for, and the safety of, patients in the facility and for the operation of the facility.
  - (c) appointing a chief medical executive to take charge of the day to day administration of the facility.

### *Chief medical executive*

- (1) The chief medical executive of a private healthcare facility is, at all times when the facility is in operation, responsible for the day to day administration of the facility and the adoption and implementation of rules, policies and procedures concerning the healthcare services provided in the facility.
- (2) In particular, the chief medical executive must—
  - (a) ensure that every healthcare professional working in the facility has a valid practising certificate, or a registration that is still in force, for the professional capacity concerned; and every healthcare personnel working in

the facility has the requisite qualification, training and experience related to the healthcare services that he provides.

- (b) keep and maintain registers in the form and manner specified by the Director of Health, such as—
  - (i) a staff register;
  - (ii) an attendance register;
  - (iii) an admission register.
- (c) supply any information or document required by the Director.

- The chief medical executive of a private healthcare facility must be a registered medical practitioner or a registered dentist who possesses the experience and qualification that are necessary for administering a private healthcare facility. He must be of integrity and good character, and is physically and mentally fit, to operate a private healthcare facility.
- We also propose that the chief medical executive of a private healthcare facility, i.e. hospital, day procedure centre or clinic (as the case may be) must have a certain length of experience. Moreover, in line with the objective that the chief medical executive should take charge of the day to day administration of the private healthcare facility concerned, we propose setting a limit of the number of facilities that a person may serve as a chief medical executive concurrently. Details are to be further ironed out.

## **Annex A**

### **Premises excluded from definition of *hospital***

1. A residential care home under the Residential Care Homes (Elderly Persons) Ordinance (Cap. 459)
2. A treatment centre under the Drug Dependent Persons Treatment and Rehabilitation Centres (Licensing) Ordinance (Cap. 566)
3. A residential care home for persons with disabilities under the Residential Care Homes (Persons with Disabilities) Ordinance (Cap. 613)
4. A boarding school within the meaning of the Education Regulations (Cap. 279 sub. leg. A)

## Annex B

### Classes of Specialized Services<sup>(Notes)</sup>

<u>Column 1</u> <b>Class of specialized service</b>	<u>Column 2</u> <b>Medical procedures that may be carried out in day procedure centres but not in clinics</b>	<u>Column 3</u> <b>Exceptions to medical procedures listed in column 2 that may be carried out in clinics</b>
1. Surgical Procedure	(a) Creation of surgical wound to allow access to major body cavity or viscus (including access to central large joints)	(i) Creation of surgical wound to allow access to peripheral joints distal to knee and elbow (i.e. ankle and below, and wrist and below) (ii) Needle injection into joint cavity (iii) Intraocular injection with fine needle by ophthalmologists (iv) Injection of botox
	(b) Removal of tissue or fluid, or both, of a total volume of 500ml or above	Suprapubic tap
	(c) Removal of tissue or fluid, or both, of any	

	volume from deep seated organ in children aged under 12 years old	
	(d) Removal of any volume of fluid or tissue, or both, from thoracic cavity	Diagnostic pleural tapping
	(e) Insertion of prosthesis	<ul style="list-style-type: none"> <li>(i) Prosthesis in ear, nose and throat cavity</li> <li>(ii) Dental prosthesis and implant</li> <li>(iii) Facial implant</li> <li>(iv) Extra-ocular prosthesis and implant</li> <li>(v) Intrauterine or vaginal prosthesis</li> <li>(vi) Bulking agent of urethra</li> <li>(vii) Prostatic urethral stent</li> <li>(viii) Urethral sling</li> <li>(ix) Testicular prosthesis</li> </ul>
	(f) Core biopsy	<ul style="list-style-type: none"> <li>(i) Core biopsy of superficial tissue (such as skin, prostate, breast and uterus) but not including thyroid or salivary glands</li> <li>(ii) Core biopsy of</li> </ul>

		superficial muscle (iii) Core biopsy of peripheral muscle
(g)	Biopsy of organ or tissue requiring image guidance	(i) Biopsy of breast tissue (ii) Biopsy of superficial lymph node
(h)	Fine needle biopsy of deep-seated organ	
(i)	Lumbar puncture	
(j)	Transplant of any cell, tissue and organ (including autograft, allograft, xenograft, processed tissue or blood products <sup>1</sup> ), skin flap (including face lift)	(i) Skin graft less than 1% of total body surface area (ii) Conjunctival autograft (iii) Transplant procedures which primarily involve dental-alveolar region
(k)	Termination of pregnancy	
(l)	Dilation and curettage	
(m)	Circumcision with use of skin sutures in paediatric patients	

<sup>1</sup> Includes platelet-rich plasma (PRP).

2. Endoscopic procedure	(a) Endoscopic procedure requiring image guidance (such as endoscopic retrograde cholangiopancreatography (ERCP))	
	(b) Endoscopic procedures involving invasion of a sterile cavity (such as arthroscopy, laparoscopy and hysteroscopy) or gastrointestinal tract	Cystoscopy <sup>2</sup>
	(c) Therapeutic endoscopic procedure (such as endoscopic resection)	Minor therapeutic procedure (such as removal of foreign body)
3. Dental procedure	Maxillofacial surgical procedures that extend beyond dento-alveolar process, including but not limited to (a) Maxillary osteotomies and mandibular osteotomies including angle reduction (b) Open reduction and fixation of complex	(i) Temporomandibular arthrocentesis (ii) Temporomandibular arthroscopy

<sup>2</sup> Cystoscopy does not include therapeutic cystoscopic procedures such as cystoscopic insertion or removal of ureteric catheter or stent, endoscopic urethral dilatation or urethrotomy, cystoscopic removal of stone or foreign body or polyp, cystoscopic injections/diathermy/cautery or haemostasis, cystoscopic lithotripsy.

	<p>maxillofacial fracture</p> <p>(c) Surgical treatment of diagnosed malignancies</p> <p>(d) Surgical treatment of complex haemangioma</p> <p>(e) Surgery involving major salivary glands</p> <p>(f) Open surgery of temporomandibular joint</p> <p>(g) Harvesting of autogenous bone from outside the oral cavity</p> <p>(h) Primary cleft lip and palate surgery</p>	
4. Chemo-therapy	Administration of chemotherapy (cytotoxic) through parenteral routes regardless of therapeutic indication	
5. Haemo-dialysis	Haemodialysis	
6. Inter-ventional radiology and lithotripsy	Extracorporeal shock wave lithotripsy (ESWL) requiring image guidance	

7. Anaesthetic procedure <sup>3</sup>	(a) General anaesthesia	
	(b) Neuroaxial blocks (spinal, epidural, caudal)	
	(c) Major plexus blocks (brachial, lumbar, sacral)	
	(d) Intravenous regional anaesthesia	
	(e) Intercostal nerve block	
	(f) Major nerve blocks: <ul style="list-style-type: none"> <li>• Glossopharyngeal nerve, vagus nerve or their terminal branches, including superior, inferior and recurrent laryngeal nerves;</li> <li>• Sciatic and femoral nerves; or</li> <li>• Posterior tibial nerve, pudendal nerve or para-cervical block</li> </ul>	

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<sup>3</sup> The risks of anaesthesia considered include risk of gross, vital physiological derangement, risk of inadvertent systemic injection (such as neurovascular bundle and intra-dural injection), loss of protective reflexes, prolonged disturbance of mobility or body balance and disturbance/loss of major functions of vital organs.

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	(g) Use of sedative or analgesic drugs with reasonable expectation that it will, in the manner used, result in deep sedation for a significant percentage of a group of patients <sup>4</sup>	
	(h) Tumescence anaesthesia	

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<sup>4</sup> For definition of “deep sedation”, please refer to the “Guidelines on Procedural Sedation” promulgated by HKAM.

**Notes:**

1. Procedures defined in Column 2 may be performed in a day procedure centre only if -
  - (a) the patient is discharged in the same calendar day of admission;
  - (b) the expected total duration of procedure and recovery requiring continuous confinement within the facility does not exceed 12 hours; and
  - (c) the patient's condition is not Class 4 or worse (i.e. Class 4 or 5) by the American Society of Anesthesiologists (ASA) Physical Status Classification System<sup>5</sup>.
  
2. The following procedures should only be performed in a hospital -
  - (a) Administration of chemotherapy (cytotoxic) into body cavity or deep-seated organ;
  - (b) Image-guided core biopsy of deep-seated organ;
  - (c) Transarterial catheterisation or deep venous catheterisation;
  - (d) Continuous venous-venous haemofiltration or haemodiafiltration;
  - (e) Organ transplant [except corneal transplant] or complicated transplant procedures;
  - (f) Bronchoscopy or pleuroscopy;
  - (g) Therapeutic gastrointestinal endoscopy on children aged under 12 years old; and

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

- (h) Injection of sclerosing or embolisation agents into vascular or lymphatic compartment of deep-seated head and neck region.
3. Medical practitioners and dentists should take into account, in addition to the procedures listed in the table above, the age, body size and other physical conditions of the patient when determining whether a procedure should be performed in a day procedure centre or in a hospital.

## **Annex C**

### **Premises in which Outreach Medical Services are Provided**

1. A place of refuge as defined in section 2 of the Protection of Children and Juveniles Ordinance (Cap. 213)
2. A child care centre under the Child Care Services Ordinance (Cap. 243)
3. A special school under the Education Ordinance (Cap. 279)
4. A residential care home under the Residential Care Homes (Elderly Persons) Ordinance (Cap. 459)
5. A treatment centre under the Drug Dependent Persons Treatment and Rehabilitation Centres (Licensing) Ordinance (Cap. 566)
6. A residential care home for persons with disabilities under the Residential Care Homes (Persons with Disabilities) Ordinance (Cap. 613)
7. A unit for residential care services for children and youth subvented by the Social Welfare Department