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The Incorporation of Medical Practice under the Upcoming Private Healthcare Facilities (PHFs) Regulation – from a Wealth Management Perspective

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Private Healthcare Facilities ("PHFs") Regulation in details:

How Medical Practitioners will be affected?



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1. Introduction

- Hong Kong's healthcare system runs on a dual-track basis comprising both the public and private sectors
- The public sector is predominantly hospital-oriented providing highly-subsidised inpatient and ambulatory services for the community
- Private healthcare is a major provider (more than 70%) of outpatient services and provides more personalised inpatient and same-day ambulatory services

1. Introduction

- Government's proposal to safeguard public health and ensure the sustainable development of dual-track healthcare system
- Government established the Steering Committee on Review of Regulation of Private Healthcare Facilities in October 2012 to conduct a review on the regulation of **private healthcare facilities** (“PHFs”)
 - Based on the recommendations by the Steering Committee, the Food and Health Bureau conducted a public consultation on the Regulation of Private Healthcare Facilities from December 2014 to March 2015, proposing to **replace** the following outdated legislations with a single legislation –**Private Healthcare Facilities Ordinance**
 - Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap.165)
 - Medical Clinics Ordinance (Cap.343)



1. Introduction

- The Private Healthcare Facilities Bill has been introduced on 16 June 2016 and tabled at the Legislative Council on 21 June 2016
- An independent bill committee has been set up and it is now working on the bill
- The Private Healthcare Facilities Bill covers 4 types of PHFs, namely
 - **Hospital**
 - **Clinic** – medical and dental clinics under the management of incorporated bodies
 - **Day Procedure Centre** – ambulatory facilities providing high-risk medical procedures
 - **Health Services Establishment** – premises of an education or scientific (or both) research institution in which medical services with lodging are provided to patients for the purpose of conducting clinical trials

1. Introduction

- A person must not operate a PHF without a licence.
- A person who violates the PHFO commits an offence and is liable— if the facility is not a hospital—on conviction on indictment to a fine at level 6 (i.e. HK\$100,000) and to imprisonment for 3 years
- The licensing requirement does not apply to a person who operates a small practice clinic without a licence if an exemption given under the PHFO for the clinic is in force.

2. Medical Clinics



2. Medical Clinics

- A clinic is any premises
 - (a) that do not form part of the premises of a hospital, a day procedure centre or an outreach facility; and
 - (b) that are used, or intended to be used, for
 - (i) providing medical services to patients, without lodging; or
 - (ii) carrying out minor medical procedures on patients, without lodging

2. Medical Clinics

- The Standards for Medical Clinics were drafted with reference to the existing Code of Practice for Clinics Registered under Cap. 343 and the relevant standards in overseas jurisdictions
- Medical Clinics under the **management of incorporated bodies**
 - The provision of medical service could take a variety of organisational forms
 - Among them, there have long been concerns over ‘medical groups’ or ‘managed care organisations’ operated in the form of incorporated bodies, including statutory bodies and registered societies and incorporated companies in which non-medical investors or managers would take part in the operation of PHFs
 - Registered medical practitioners practising there do not have full control of the PHFs concerned in ensuring effective governance and maintaining high service quality

2. Medical Clinics

- Exemption will be granted to PHFs owned, managed, operated and serviced solely by identical registered medical practitioners because there would not be similarly perceived operational risk
- These practising registered medical practitioners could be held solely accountable for their own practice
- Any matters arising from these PHFs could be followed up by existing established mechanism governing the professional practice of registered medical practitioners

2. Medical Clinics

- A clinic is a small practice clinic if
 - (a) an individual who is a registered medical practitioner or a registered dentist operates the clinic as a sole proprietor;
 - (b) the individual is the only registered medical practitioner or registered dentist who serves the clinic; and
 - (c) the individual has the exclusive right to use the premises forming the clinic.

2. Medical Clinics

For a clinic operated by an individual as a sole proprietor, the condition of “the only registered medical practitioner/dentist” is satisfied if—

(a) where the individual is a registered medical practitioner—the total number of days for which another registered medical practitioner takes up the duties of the individual in the clinic because of the individual’s absence from the clinic does not exceed 60 days in a calendar year; or

(b) where the individual is a registered dentist—the total number of days for which another registered dentist takes up the duties of the individual in the clinic because of the individual’s absence from the clinic does not exceed 60 days in a calendar year.

2. Medical Clinics

A clinic is also a small practice clinic if—

(a) a partnership having not more than 5 partners, each of whom is a registered medical practitioner or a registered dentist, operates the clinic;

(b) the partners are the only registered medical practitioners or registered dentists who serve the clinic; and

(c) one or more of the partners have the exclusive right

to use the premises forming the clinic.

2. Medical Clinics

A clinic is also a small practice clinic if—

(a) a company having not more than 5 directors, each of whom is a registered medical practitioner or a registered dentist, operates the clinic;

(b) the directors are the only registered medical practitioners or registered dentists who serve the clinic; and

(c) either the company has, or one or more of the directors have, the exclusive right to use the premises forming the clinic.

2. Medical Clinics

For a clinic operated by a partnership or company, the Condition of “only registered medical practitioners/dentists” is satisfied if—

(a) where the partners or directors or any of them are registered medical practitioners, then, for each of the registered medical practitioners (that person)—subject to subsection (6), the total number of days for which another registered medical practitioner takes up the duties of that person in the clinic because of that person’s absence from the clinic does not exceed 60 days in a calendar year; or



2. Medical Clinics

(b) where the partners or directors or any of them are registered dentists, then, for each of the registered dentists (that person)—subject to subsection (6), the total number of days for which another registered dentist takes up the duties of that person in the clinic because of that person’s absence from the clinic does not exceed 60 days in a calendar year.

Subsection (6) - The aggregate number of days for the taking up of duties by other registered medical practitioners or registered dentists for the partners or directors operating the clinic must not exceed 180 days in a calendar year.

2. Medical Clinics

Request for letter of exemption

A person that operates, or intends to operate, a small practice clinic may ask the Director of Health (“Director”) for a letter of exemption for the clinic.

The request—

- (a) must be made in the form and way specified by the Director;
- (b) must be accompanied by the information and documents specified by the Director;
- (c) must state the practice carried on, or to be carried on, in the clinic;
- (d) if the person that operates, or intends to operate, the clinic is an individual as a sole proprietor—must be signed by the individual;



2. Medical Clinics

(e) if the person that operates, or intends to operate, the clinic is a partnership—must be signed by each of the partners of the partnership; and

(f) if the person that operates, or intends to operate, the clinic is a company—must be signed by each of the directors of the company.



2. Medical Clinics

On receiving a request from a person for a clinic with a stated practice, the Director may issue to the person a letter of exemption for the clinic if the Director is satisfied that—

- (a) the clinic is a small practice clinic; and
- (b) none of the individuals signing the request is for the time being in any of the following capacities (in whatever combination) for 3 or more other exempted clinics—
 - (i) the sole proprietor of an exempted clinic;
 - (ii) a partner of a partnership operating an exempted clinic;
 - (iii) a director of a company operating an exempted clinic.



2. Medical Clinics

A letter of exemption issued to a person—

- (a) must specify the clinic and practice stated in the request; and
- (b) permits the person to operate without a licence the clinic in which the practice is carried on (exemption).

The Director must refuse to issue a letter of exemption if the Director considers it inappropriate for the person making the request to carry on the practice in the clinic without a licence.

If the Director refuses to issue a letter of exemption, the Director must, in writing, inform the person making the request of the refusal and the reasons for the refusal.

2. Medical Clinics

Changes in management and other particulars

The operator of an exempted clinic must give the Director not less than 14 days' notice in writing of—

- (a) any intended change of the clinic's operators;
- (b) any intended change of the clinic's address;
- (c) any intended cessation of the clinic's operation; or
- (d) any intended cessation of the clinic's operating as a small practice clinic.

If the change occurs because of the death or deregistration of an operator, the notice may be given within 14 days after the date of the operator's death or deregistration.

2. Medical Clinics

A person who, without reasonable excuse, contravenes the notification requirements commits an offence.

Revocation of exemption

The Director may, by notice in writing to the operator of an exempted clinic, revoke the exemption.

Before revoking the exemption, the Director must give the operator not less than 14 days' notice in writing of the intended revocation and the ground for the intended revocation.



2. Medical Clinics

The exemption may be revoked only on any of the following grounds:

- an operator of the clinic contravenes or has contravened the PHFO;
- an operator of the clinic has been convicted of an offence under the PHFO;
- for a clinic operated—
 - (i) by an individual as a sole proprietor—the individual has become bankrupt or made a voluntary arrangement with the individual's creditors within the meaning of the Bankruptcy Ordinance (Cap. 6);
 - (ii) by a partnership—the partnership has been dissolved;
 - (iii) by a company—the company has commenced to be wound up or dissolved;

2. Medical Clinics

The exemption may be revoked only the following grounds:

- the person making the request for a letter of exemption in relation to the clinic has made a false statement in the request, or in any information or document required by the Director under the PHFO;
- the Director is satisfied that the clinic has ceased to exist or be operated;
- the Director is satisfied that the clinic has ceased to be operated as a small practice clinic.

2. Medical Clinics

- Except with the prior approval in writing of the Director, or except as provided or permitted by any other law, a clinic must not bear a title or description that includes the expression “hospital”, “day procedure centre”, “醫院” or “日間醫療中心”, or a similar expression.
- If a person makes a statement or representation in an application under the PHFO, or in a request for exemption, or to the Complaints Committee, the person commits an offence if— (a) the statement or representation is false or misleading in a material particular; and (b) the person knows or is reckless as to whether the statement or representation is false or misleading in a material particular.

2. Medical Clinics

Defence

In any proceedings for an offence under the PHFO, the person charged is entitled to be acquitted if

(a) sufficient evidence is adduced to raise an issue that—

(i) the commission of the offence was due to a cause beyond the person's control; and

(ii) the person took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by— (A) the person; or (B) any person under the person's control; and

(b) the contrary is not proved by the prosecution beyond reasonable doubt.

2. Medical Clinics

Powers of Investigation

If the Director has reasonable cause to suspect that a person has, or may have, possession or control of information or documents in relation to a matter that constitutes, or may constitute, a contravention of the PHFO, a PHF licence, a code of practice or a direction, the Director may, by notice in writing, require the person to provide or produce the information or documents that are necessary for the investigation.

2. Medical Clinics

A person commits an offence if the person, without reasonable excuse, refuses or fails to provide or produce any information or document required by the Director.

If a person provides or produces any information or document to the Director, the person commits an offence if—

- (a) the information or document is false or misleading in a material particular; and
- (b) the person knows or is reckless as to whether the information or document is false or misleading in a material particular.



1. Introduction

The Director or an authorized officer may, without a warrant issued by a magistrate, enter a PHF for which a licence is in force at any reasonable time and exercise certain powers for ascertaining—

(a) whether the following is complied with:

- (i) the PHFO;
- (ii) a condition of the licence;
- (iii) a code of practice;
- (iv) a direction; and

(b) the safety, legality, quality and appropriateness of—

- (i) the services provided in the facility; or (ii) the medical procedures carried out in the facility.

1. Introduction

The Director or an authorized officer may, with a warrant issued by a Magistrate (by application), enter, by the use of reasonable force if necessary, any premises and exercise certain powers in relation to the premises and do any other thing necessary for investigating whether a Contravention of the PHFO, the PHF, the code of practice or direction is being, or has been, committed.

Power of entry in emergencies

- Necessary for protecting of public health; or
- Not reasonably practicable to obtain a warrant in the circumstances of the case

2. Medical Clinics

Powers after entry:

- to inspect and search the premises;
- to examine, remove and detain any apparatus, appliance, equipment, instrument, substance, record or document used or found on the premises;
- to examine, take samples of, remove, detain and demand any part or produce of a human body found on the premises;
- to observe any procedure or test provided at the premises;
- to take any photograph and video recording inside the premises;

2. Medical Clinics

Powers after entry:

- to observe, with a patient's consent, the services provided to the patient in the facility;
- to do anything necessary for ascertaining whether the PHFO, a condition of the licence, a code of practice or a direction has been complied with;
- to seize and detain anything which is, or which appears to be or to contain, or which is likely to be or to contain, evidence of the commission of a contravention, or to take such steps as appear to be necessary for preserving such thing or preventing interference with it; and
- to require any person present on the premises to provide any assistance or information necessary to enable the Director or an authorized officer to perform their functions under this Ordinance.
- Legal Professional Privilege?

2. Medical Clinics

Provisional clinic licence

On receiving an application from an existing clinic for a PHF licence, the Director must issue a provisional clinic licence permitting the applicant to operate the existing clinic on the premises if the Director is satisfied that—

- (a) the applicant is a fit and proper person to operate or exercise control over the clinic;
- (b) a person is to be appointed as the chief medical executive for the clinic is a fit and proper person to administer the clinic; and
- (c) the operation of the clinic by the applicant would not be contrary to the public interest.

2. Medical Clinics

- Under the proposed regulatory regime, the PHFs will each be subject to their own set of regulatory standards
 - **Code of Practice** (for private hospitals)
 - **Standards for Medical Clinics**
 - **Core Standards for Day Procedure Centres**
 - **Procedure-Specific Standards for Day Procedure Centres**

2. Medical Clinics – Standards



2. Medical Clinics - Standards

1. Management / Governance

- **1.1 Registration**
 - Clearly display of the current certificate of registration in a conspicuous place in the clinic
- **1.2 Person-in-charge (PIC) – a registered medical practitioner**
 - The clinic should appoint a registered medical practitioner to deputise the PIC in the latter's absence from duties
 - Accountable for the medical management of the clinic
 - Responsible for the adoption and implementation policies and procedures concerning healthcare services in the clinic
 - Ensure that the policies and procedures are consistent with the Code of Professional Conduct issued by the Medical Council of Hong Kong
 - Ensure that all healthcare professionals working in the clinic have the requisite qualifications, valid registration and practising certificates, and relevant training related to the healthcare services they provide

2. Medical Clinics - Standards

1. Management / Governance

- **1.3 Staff training and supervision**
 - Clinical assistants work under the supervision of the registered medical practitioner, dentist or nurse
 - Clinical assistants shall have received appropriate training relevant to their duties
 - The clinic provides job orientation programme for new staff
 - Current operational manuals and clinical guidelines are easily accessible and available to staff for their reference

2. Medical Clinics - Standards

2. Physical Conditions

- **2.1 Clinic management**

- The physical design, size, layout and condition of the clinic are appropriate for the safe and effective delivery of services and the needs of its patients
- All buildings, furniture, furnishings, fittings and equipment of the clinic are maintained in good operational order
- The clinic is kept clean and hygienic
- Ventilation, lighting and signage are adequate and appropriate
- PIC ensures that the construction and use of the clinic premises are in compliance with relevant ordinances and regulations of the laws

2. Medical Clinics - Standards

2. Physical Conditions

- **2.2 Equipment and store**
 - The clinic has the necessary and appropriate equipment which are used as intended for their purposes, in good working order and properly maintained
 - Records of maintenance and servicing of medical equipment should be kept
 - Staff involved in clinical care are appropriately trained including training in the safe and proper use of medical equipment present in the clinic
 - Equipment intended for single use are not reused

2. Medical Clinics - Standards

3. Service Delivery and Care Process

- **3.1 Patients' rights**
 - The clinic should establish written policies and procedures to protect the rights of its patients
 - Patients have the right to
 - know the name and post of staff providing services
 - be informed of the investigation, procedure and treatment planned for them, and give informed consent to any investigation, procedure and treatment
 - access their own health records
 - There are measures and facilities to provide for privacy of patients where appropriate
- **3.2 Patients identification**
 - There are written policies and procedures for patient identification and appropriate verification processes to ensure that the correct patient receives the correct information, investigation, procedure or treatment

2. Medical Clinics - Standards

3. Service Delivery and Care Process

- **3.3 Medical records**

- There is a written policy in place for the creation, management, handling, storage and destruction of healthcare records
- Medical records should 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

2. Medical Clinics - Standards

3. Service Delivery and Care Process

- **3.3 Medical records**

- All medical records are accurate, legible and up-to-date
- All entries in the record should be dated and signed where appropriate
- Medical records are maintained and retained for specified minimum period
- Patient records are confidential and kept secure. All stored personal data are protect from unauthorised access, alteration or loss
- The staff handling personal data should be aware of the provisions of the Personal Data (Privacy) Ordinance (Cap 486) and have due regard to their responsibilities under that Ordinance

2. Medical Clinics - Standards

3. Service Delivery and Care Process

- **3.6 Charges**

- Patients should be informed of the charges of services whenever practicable
- An up-to-date fee schedule covering all chargeable items, written in both Chinese and English, should 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 could be presented in the form of a price range or could be marked to indicate that price information will be available upon request

2. Medical Clinics - Standards

3. Service Delivery and Care Process

- **3.7 Complaint handling**

- PIC should implement a mechanism for handling all complaints made by patients or persons representing the patients
- The mechanism consists of procedures for receiving, investigating, responding to the complainant and documentation, with a specified time frame
- Patients and their carers or representatives are provided with information about the procedure for making complaints and the process for managing and responding to any complaints

3. Day Procedure Centres



3. Day Procedure Centres

- With the advancement in medical technology and rapid changes in medical practices, high-risk medical procedures / practices once confined to hospitals are increasingly performed in ambulatory setting
- High-risk medical procedures may be performed in ambulatory setting if:
 - a) the patient is discharged in the same calendar day of admission;
 - b) expected total duration of procedure & recovery requiring continuous confinement within the facility does not exceed 12 hours; and
 - c) patient's condition is not Class 4 or worse (i.e. Class 4 or 5) by American Society of Anaesthesiologist (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

3. Day Procedure Centres

- The **Core Standards** and **Procedure-specific Standards** serve to provide guidance to the operators of the **day procedure centres** in anticipation of a new licensing system and to provide a framework for the medical and dental professionals within which they plan and organise their private practices
- **Day Procedure Centres** – premises where *high-risk* procedures are performed
 - High-risk means having the
 - **A. Risk of procedures**
 - **B. Risk of anaesthesia involved**
 - **C. Patient's condition**

3. Day Procedure Centres – Core Standards

1. Management / Governance

- 1.1 Person-in-charge (PIC) – a registered medical practitioner
 - Accountable for the medical management of the Day Procedure Centres
 - Responsible for the adoption and implementation of policies and procedures concerning healthcare services
 - Ensure that all healthcare professionals have the requisite qualifications, valid registration, training and experience related to the healthcare services they provide
- 1.2. Staff training and credentialing
 - Training in the use of any medical equipment and in assisting in medical procedures
 - Recognize and regularly review employees' and visiting healthcare professionals' qualifications, training and competence
 - Provide job orientation programme for new staff. Current operational manuals and clinical guidelines are easily accessible and available to staff for their reference

3. Day Procedure Centres – Core Standards

2. Service Delivery and Care Process

• 2.1 Patients' rights

- Day Procedure Centres should establish written policies and procedures to protect the rights of its patients
- Patients have the right to know the name and rank of staff providing services
- Patients have the right to be informed of the treatment planned for them and give informed consent to their treatment
- The privacy of patients should be considered and respected by all staff
- 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
- Patients have the right to access their own health records



3. Day Procedure Centres – Core Standards

2. Service Delivery and Care Process

- **2.2 Patient identification**

- There are written policies and procedures for patient identification. There should also be appropriate verification process to ensure that the correct patient has the correct procedure performed on the correct site.

3. Day Procedure Centres – Core Standards

2. Service Delivery and Care Process

• 2.3. Medical records

- There shall be a written policy in place for the creation, management, handling, storage and destruction of all healthcare records
- For every patient, the PIC should ensure that complete, comprehensive and accurate medical records are maintained and retained for specified minimum period
- Medical records should 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
- All medical records should be accurate, legible and up-to-date. All entries in the record should be dated and signed where appropriate

3. Day Procedure Centres – Core Standards

2. Service Delivery and Care Process

- **2.3. Medical records**

- Patient records are confidential and should be kept secure. All stored personal data should be protected from unauthorized access, alteration or loss. The staff handling personal data should be aware of the provisions of the Personal Data (Privacy) Ordinance (Cap 486) and have due regard to their responsibilities under that Ordinance

3. Day Procedure Centres – Core Standards

2. Service Delivery and Care Process

- **2.4. Charges**

- Patients should be informed of the charges of service whenever practicable. An up-to-date fee schedule covering all chargeable items should be readily available for reference of patients at the admission/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. Day Procedure Centres – Core Standards

2. Service Delivery and Care Process

- **2.5. Complaint handling**
 - PIC should implement a mechanism for handling all complaints made by patients or persons representing the patient. The mechanism consists of procedures for receiving, investigating, responding to the complainant and documentation, with a specified time frame
 - PIC should 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. Day Procedure Centres – Core Standards

3. Resuscitation and Contingency

- **3.1. Risk management**
 - PIC should ensure that there is a written risk management policy and safety inspection procedures for the identification and assessment of risks and hazards in the Day Procedure Centre and its services
 - PIC should ensure that there is a written emergency response policy outlining the procedures to be followed in the event of an emergency affecting the provision of services

3. Day Procedure Centres – Core Standards

3. Resuscitation and Contingency

- **3.2. Resuscitation of patients**

- PIC should ensure that there are written policies and procedures for resuscitation of patients and resuscitation facilities for emergencies. Resuscitation equipment should be easily accessible and checked at regular interval. The PIC should ensure that there are sufficient staff who are trained for cardiopulmonary resuscitation on duty at all times. The Facility should carry out resuscitation drills regularly
- If the Facility provides services to paediatric patients, there should be resuscitation equipment and drugs appropriate for paediatric patients and staff with appropriate training and skills to perform the resuscitation

3. Day Procedure Centres – Core Standards

3. Resuscitation and Contingency

- **3.3. Emergency transfer**
 - There should be written protocol in place for emergency transfer of patients to acute care hospitals when necessary
 - Clinical records of sufficient content to insure continuity of care should accompany the patient, but the preparation of records should not delay the transfer
- **3.4. Fire safety and evacuation**
 - PIC should ensure that there are adequate precautions against the risk of fire
 - PIC should ensure that there is an internal fire and emergency response plan incorporating evacuation procedures. Fire evacuation exercise is conducted at regular intervals. Records of the drills should be documented.

Q & A



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