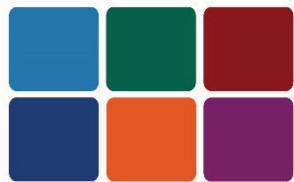




區兆康律師行  
**TONY AU & CO**



TAC Newsletter

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# **The Regulation of Clinics and Day Procedure Centres under the new Private Healthcare Facilities Ordinance**





# 區兆康律師行

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# 1 Parties Concerned

The following are the parties concerned:

- Patients
- Department of Health
- The police
- Medical doctors and dentists who work in private clinics and day procedure centres
- Doctors and dentists who invest in clinics and day procedure centres in addition to working there
- Medical groups that invest in and operate clinics and day procedure centres
- Suppliers and service providers of clinics and day procedure centres
- Professional managers and other professional and technical staff engaged by clinics and day procedure centres
- Accountants, auditors and legal advisers
- Insurers

## 2 Clinics and Day Procedure Centres Licences

Doctors and dentists in private practice in Hong Kong are individually registered with and regulated by the Medical Registration Ordinance (Cap. 161 of the Laws of Hong Kong) and the Dentists Registration Ordinance, (Cap. 156 of the Laws of Hong Kong) respectively. However, private clinics as such have all along not been regulated under any statutory regime. This has brought considerable confusion and uncertainties to the private medical service sector especially as bigger private medical groups are emerging in the healthcare market.

Thanks to the efforts of the Department of Health over the years, the **Private Healthcare Facilities Ordinance** (Cap. 633 of the Laws of Hong Kong) (the “**Ordinance**”) was passed in late 2018. The implementation of the regime is to begin in early 2020.

The Ordinance will regulate 4 types of private healthcare facilities, namely (i) private hospitals, (ii) day procedure centres, (iii) clinics, and (iv) health services establishments. This document discusses about clinics and day procedure centres (“**DPCs**”) only.

As far as private clinics and DPCs are concerned, the Office for Regulation of Private Healthcare Facilities “(**ORPHF**)” will regulate in two major aspects:

- ORPHF’s Licensing Division will be in charge of licensing and regulatory functions under the Ordinance and assist the Hong Kong Police Force in the investigation of suspected illegal medical practices.
- ORPHF’s Quality and Standards Division will be responsible for exemption of small practice clinics under the Ordinance, development of standards and specifications for private healthcare facilities, and provide secretariat and/or research support to advisory committees and committee on complaints.

*Now is the time to start planning and implementing change.*

### 3 Licensing Requirement

#### Clinic Licences

A clinic means any premises that do not form part of the premises of a hospital, a day procedure centre or an outreach facility and 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.

All clinics will be affected by the new regime. A “small practice clinic” may apply for exemption from the licence requirement if it satisfies the following requirements:

- (a) It must be operated by (i) a registered medical practitioner or registered dentist as a sole proprietor; or (ii) a partnership having not more than 5 partners, each of whom is a registered medical practitioner or a registered dentist; or (iii) a company having not more than 5 directors, each of whom is a registered medical practitioner or a registered dentist;
- (b) Except the sole proprietor/partners/directors, no other registered medical practitioners or registered dentists practise in the clinic.
- (c) The sole proprietor/ partner(s)/ director(s)/ company has/ have the exclusive right to use the clinic.

Each registered medical practitioner or registered dentist

may operate at most three small practice clinics with valid exemption at the same time.

Licensed clinics will be subject to a code of practice to be issued by the Department of Health. It is now in the form of draft **Standards for Medical Clinics**.

The draft standards for Medical Clinics contain the following sections:

1. Management/ Governance
2. Physical conditions
3. Service delivery and care process
4. Infection control
5. Risk management and contingency

Applications for clinic licences and requests for letters of exemption are anticipated to commence in **2021** at the earliest.

## Day Procedure Centre Licence

A DPC is any premises that are used, or intended to be used by doctors or dentists for carrying out scheduled medical procedures on patients, without lodging. The period of continuous confinement for patient must be within the facility for not more than 12 hours. Also, the continuous confinement for any patient must be within the same calendar day. A DPC will need a day procedure centre licence from the Department of Health.

A “scheduled medical procedure” means a medical procedure that is described in Schedule 3 to the Ordinance and which is carried out in an ambulatory setting.

DPCs will be subject to the **Code of Practice for Day Procedure Centres**.

The CoP comprises a set of core standards, which applies to all day procedure centres and procedure-specific standards for day procedure centres providing the following procedures:

- Anaesthesia and sedation;
- Chemotherapy;
- Interventional radiology and lithotripsy;
- Surgery, anaesthesia and sedation;
- Endoscopy;
- Dental procedures;
- Haemodialysis; and
- Radiotherapy.

Applications for day procedure centre licences will be accepted from **2 January 2020**.

## Critical dates

<u>Type</u>	<u>Commencement of licence applications</u>	<u>First batch of licences take effect</u>	<u>All facilities operate with licence (or have exemption)</u>
DPC	2 January 2020	Early 2021 (Full/provisional)	To be determined
Clinics	2021# (at the earliest)	To be determined	To be determined

# This timeline also applies to requests for exemption of Small Practice Clinics

## 4 The Licensee and the Chief Medical Executive

The Ordinance provides that a clinic/ DPC licensee will be wholly responsible for the operation of the facility. This requirement does not apply to small practice clinics with exemption in force. Under the regulatory regime, the licensee of a clinic or DPC can be a legal person (eg a limited company) or a natural person.

The clinic/ DPC licensee must:

- set up the relevant rules, policies and procedures;
- enforce relevant rules, policies and procedures;
- ensure the facility's compliance with the licence conditions, codes of practice, etc.; and
- appoint a Chief Medical Executive (“**CME**”) for the facility.

The CME must be a medical practitioner or dentist (as the case may be). He/ she will be responsible for:

- the day-to-day administration of the clinic/ DPC;
- the adoption and implementation of rules, policies and procedures concerning the healthcare services provided in the clinic/ DPC.

The licensee of a clinic DPC can also be appointed as the CME for the same clinic DPC.

A doctor or a dentist may only serve as a CME of one of the following units at the same time:

- 1 private hospital; or
- 2 day procedure centres; or
- 3 clinics; or
- 1 day procedure centre and 1 clinic; or
- a group of 4 or more clinics operated by the same licensee with:
  - a Medical Advisory Committee established (see Part 5 below); and
  - a registered medical practitioner or a registered dentist appointed for each of the clinics to assist the CME in carrying out the day to day administration of the clinic.

A doctor or dentist who operates, or intends to operate, a small practice clinic may request the Director of Health for exemption for the clinic, regardless of whether he/ she is serving as a CME of other one or more than one private healthcare facility.

## Summary table: Who can be a chief medical executive?

DPC	Clinic	<b>Group of 4 or more clinics operated by the same licensee</b>
<ul style="list-style-type: none"> <li>• Possess the necessary qualifications and experience</li> <li>• Physically and mentally fit to administer the facility</li> <li>• Of integrity and good character</li> <li>• Dental practice only: Registered dentist; Other cases: Registered medical practitioner;</li> <li>• Combined medical and dental practices: Registered medical practitioner (with a registered dentist appointed to assist CME)</li> </ul>		
Registered in Hong Kong for 6 years or more	Registered in Hong Kong for 4 years or more	Registered in Hong Kong for 8 years or more
Must not serve as CME of more than two DPCs, or more than three clinics, or more than one DPC and one clinic, except for the case of 4 or more clinics of the same licensee		<p>A person may serve as CME of 4 or more clinics of the same licensee at the same time provided that:</p> <ul style="list-style-type: none"> <li>• Medical Advisory Committee is established for the clinics;</li> <li>• for each clinic, a registered medical practitioner / registered dentist serving the clinic is appointed to assist CME; and</li> <li>• the person does not serve as CME of another private healthcare facility at the same time</li> </ul>

## 5 Medical Advisory Committee

If 4 or more clinics are operated at the same time by the same licensee, the licensee may appoint a single CME for the clinics if the licensee (a) has established a Medical Advisory Committee (“**MAC**”) for the clinics and has (b) appointed for each of the clinics a doctor or dentist (as the case may be) who is serving the clinic to assist the chief medical executive in carrying out the day to day administration of the clinic.

The MAC must consist of a chairperson and other members decided by the licensee. At least half of the members must be registered medical practitioners or registered dentists, including at least 1 registered medical practitioner who is not employed by, or practising in, the facility.

If the practice is a dental practice only, the chairperson must be a registered dentist. In any other case, the chairperson must be a registered medical practitioner. The MAC may determine its own procedure.

The function of the MAC is to advise the licensee of the facility on:

- (a) the qualifications of healthcare professionals for providing services in the clinics and delineation of their clinical responsibilities;
- (b) all matters concerning medical diagnosis, treatment and care given, or to be given, in the clinics;
- (c) all matters concerning the quality of care for, and the safety of, patients in the clinics.

Both the licensee and the CME of the clinics are responsible for ensuring that the advice given by the MAC is properly implemented. The licensee and the CME are also each primarily responsible for implementing the MAC's advice on matters that fall within their respective areas of responsibility.

The licensee of the clinics must provide in writing to the Director a list of the members of the Medical Advisory Committee. In addition, on request, the licensee must also report to the Department of Health on any activity or advice of the MAC.

## 6 Transition for DPCs/Clinics already in Operation on 30 November 2018

If the conditions below are met, the operator of a DPC or a clinic in operation on 30 November 2018 will receive a provisional licence upon application for a full licence:

- The operator is a fit and proper person to exercise control over or operate the clinic or DPC;
- The person to be appointed as the CME for the clinic or DPC is a fit and proper person to administer the centre/clinic; and
- The operation of the clinic or DPC by the operator would not be contrary to the public interest.

The provisional licence allows the clinic or DPC to continue to operate during the transitional period under the new regulatory regime before it is qualified for a full licence.

## 7 Transition for DPCs/Clinics that Start Operation after 30 November 2018

Operators who start operating clinics and DPCs after 30 November 2018 must comply with requirements under the new regulatory regime. No provisional licence will be available.

## 8 Appeals

There is right of appeal in relation to various matters, eg refusal to grant a licence to a clinic/ DPC, refusal to renew a licence, a decision to suspend or cancel a licence, etc.

The appeals are to be made to the Administrative Appeals Board following the procedures under the Administrative Appeals Board Ordinance (Cap. 442 of the Laws of Hong Kong).

An appeal may only be made within 14 days after the aggrieved person receives notice of the decision.

## 9 Powers of Enforcement of the Director of Health

Where the Department of Health 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 Ordinance, the Department of Health may, for the purpose of conducting an investigation on the contravention, require, by written notice, the person to provide or produce the information or documents that are necessary for the investigation.

### Entering licensed facilities without warrant

Authorised officers of the Department of Health may, without a warrant issued by a magistrate, enter a licensed private healthcare facility at any reasonable time for ascertaining:

- (a) whether they take such steps as appear to be necessary for preserving such thing or preventing interference with it; and (i) 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, a condition of the licence, a code of practice or a direction has been complied with; and

- (b) the safety, legality, quality and appropriateness of the services provided in the facility or the medical procedures carried out in the facility.

## Entering any place with warrant

Authorized officers of the Department of Health may, with a warrant issued by a magistrate, also enter by the use of reasonable force if necessary any premises to investigate whether a contravention is being, or has been, committed.

Where immediate entry into the premises is necessary for protecting public health it is not reasonably practicable to obtain a warrant in the circumstances of the case, authorised officers of the Department of Health may also enter any premises to investigate.

## Powers of authorised officers

Extensive investigative powers after entry are given to the Department of Health. Authorised officers may:

- (a) inspect and search the premises;
- (b) examine, remove and detain any apparatus, appliance, equipment, instrument, substance, record or document used or found on the premises;

- (c) examine, take samples of, remove, detain and demand any part or produce of a human body found on the premises;
- (d) observe any procedure or test provided at the premises;
- (e) take any photograph and video recording inside the premises;
- (f) observe, with a patient's consent, the services provided to the patient in the facility;
- (g) do anything necessary for ascertaining whether the Ordinance, a condition of the licence, a code of practice or a direction has been complied with;
- (h) 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
- (i) require any person present on the premises to provide any assistance or information necessary to enable the Department of Health officers to perform their functions under the Ordinance.

## 10 Consequences of Contravention of the Ordinance

The following table provides a quick glance at some of the offences under the Ordinance relating to clinics and DPCs when it is in full effect:

Note: Level of fines for offences:

- Level 1 - \$2,000
- Level 2 - \$5,000
- Level 3 - \$10,000
- Level 4 - \$25,000
- Level 5 - \$50,000
- Level 6 - \$100,000

Section	Offence	Punishment
10	Operating facility without licence	On conviction on indictment - a fine at level 6 and imprisonment for 3 years.
11	Failure to display licence in facility	On summary conviction - a fine at level 4.
12	Non-healthcare professional performing medical treatment or procedure	On summary conviction - a fine of \$200,000 and imprisonment for 3 years; or On conviction on indictment - imprisonment for 7 years.
32	Failure to comply with a suspension order: operating unauthorized type of private healthcare facility	On conviction on indictment - a fine at level 6 and imprisonment for 3 years.

33	Failure to comply with suspension order: other grounds	On summary conviction - a fine at level 6 and imprisonment for 3 months.
34	Failure to comply with suspension order: providing certain facility service	On summary conviction - a fine at level 6 and imprisonment for 3 months.
35	Failure to request cancellation of licence before cessation of operation or comply with requirement for the cancellation	On summary conviction - a fine at level 4 and imprisonment for 3 months.  Without reasonable excuse, contravening a requirement imposed for the cancellation- on summary conviction - a fine at level 4 and imprisonment for 3 months.
44	Failure to give notice of intended change or cessation	On summary conviction a fine at level 4 for failure to give notice regarding:  (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.  On summary conviction - a fine at level 4 and to imprisonment for 3 months for failure to give notice of any intended cessation of the clinic's operating as a small practice clinic.
49	Failure to appoint chief medical executive and notify of change	On summary conviction - a fine at level 4 and, in the case of a continuing offence, a further fine of \$2,000 for each day during which the offence continues.

57	Failure to establish and keep in operation a MAC	On summary conviction - a fine at level 6 and, in the case for a continuing offence, a further fine of \$10,000 for each day during which the offence continues.
92	Unauthorised use of titles and names	On summary conviction - a fine at level 6 and imprisonment for 2 years.
93	Making false or misleading statements or representations	On summary conviction - a fine at level 6 and imprisonment for 2 years.
112	Refusal/ failure to provide or produce information or document	On summary conviction - a fine at level 4 and, in the case of a continuing offence, a further fine of \$2,000 for each day during which the offence continues.
112	Providing false information	On summary conviction - a fine at level 6 and imprisonment for 2 years
117	Obstructing Director or authorized officer in performing functions	On summary conviction - a fine at level 6 and imprisonment for 2 years and, in the case of a continuing offence, a further fine of \$10,000 for each day during which the offence continues
118	Refusal or failure to provide information on costing and financing of healthcare services, etc	On summary conviction - a fine at level 4 and, in the case of a continuing offence, a further fine of \$2,000 for each day during which the offence continues

## 11 Complaints

There will be a two-tier complaints handling system.

### **The Clinic's/ DPC's Own Complaints Management**

The licensee must put in place a complaints handling procedure for receiving, managing and responding to complaints that are received against the clinic/ DPC. The complaints handling procedure must be made known in an appropriate way to the patients of the clinic/ DPC and (if the case requires) persons acting on behalf of the patients.

The licensee must, on receiving a complaint, ensure that an investigation of the complaint is conducted and findings made. If the case requires, an improvement measure, whether general or specific to the complaint, must be implemented. The complainant must be informed of the findings of the investigation and any improvement measure and, if the case requires, of any follow-up action taken or to be taken.

The CME of the clinic/ DPC must, on request, provide to the Director of Health a summary of the following matters

that the Director considers necessary for performing the Director's functions under the Ordinance:

- (a) the complaints against the clinic/ DPC received by it;
- (b) the findings of the investigations of the complaints;
- (c) the actions (including improvement measures) taken in response to the complaints.

## **Committee on Complaints against Private Healthcare Facilities**

Complaints can be made to the Committee on Complaints against Private Healthcare Facilities (the “**Complaints Committee**”). The following persons may make a complaint to the Complaints Committee against a licensed clinic/ DPC:

- (a) a patient of the clinic/ DPC;
- (b) a next of kin of the patient;
- (c) a substitute decision maker of the patient;
- (d) a person authorized by the patient in writing;
- (e) the personal representative of the patient.

A licensed clinic/ DPC must fully cooperate with the Complaints Committee in providing any information or documents requested and giving any assistance necessary for concluding the case, but may still effect a settlement with the complainant.

## 12 How TAC may Assist

With knowledge, experience and diligence we serve in relation to the following:

- Corporate and compliance legal advice for clinic and day procedure centre applicants and licensees
- Contracts with Chief Medical Executive, doctors/ dentists, professional, technical and general staff
- Advising clinics and day procedure centres on handling complaints
- Advising/ representing clients in relation to complaints received via their own complaints handling procedures and complaints made to the Complaints Committee
- Advising clinics and day procedure centres on relevant civil and criminal liabilities;
- Handling relevant due diligence for investors/ investees
- Reviewing/ advising on existing/ new shareholders' agreements, investment agreements and related collaboration agreement
- Reviewing/ advising on existing/ new agreements with suppliers and service providers of clinics and day procedure centres
- Serving as a member of a Medical Advisory Committee or providing independent legal advice to a committee

For enquiries, please contact us.

# Tony Au & Co

Office: Room 1808, 18/F, Tower One, Lippo Centre,  
89 Queensway, Hong Kong

Tel: (852) 2530 0391

Fax: (852) 2530 0367

Email: mail@tony-au.com



Website: [www.tony-au.com](http://www.tony-au.com)

