Briefing Sessions on Application for Clinic Licence and Letter of Exemption (For Clinics with Dental Practice)

Dental Regulatory and Law Enforcement Office

Dental Services

Department of Health

For CPD / CME registration:

- 1. The <u>Display Name</u> [e.g. CHAN Tai Man (D00001)] is used to verify your identity for CPD / CME registration. If you <u>failed to provide</u> it, we <u>could not process your CPD / CME registration</u>.
- 2. If you are unable to change your display name, please **refer to para. 2 and 3 of the confirmation email** for relevant steps.

The briefing will start at 3:00 p.m.



Background of the Private Healthcare Facilities Ordinance (PHFO)

- Gazetted on 30 November 2018
- Premises-based
- Under the Ordinance, all Private Healthcare Facilities (PHFs) where registered medical practitioners and/or registered dentists practise must obtain a licence or a letter of exemption
- PHFs must meet certain standards/requirements for licensing or exemption and apply accordingly

Background of the Private Healthcare Facilities Ordinance (PHFO)

- The Government has been implementing the Ordinance in phases based on the risk level of various types of PHFs
- Application for clinic licence and request for letter of exemption for small practice clinic will start on 13 October 2025

Meaning of clinic



Premises where registered medical practitioners or registered dentists provide medical services without lodging



Continuous confinement of patients within the clinic should not exceed 12 hours



Cannot provide the scheduled medical procedures specified in the PHFO or the hospital-only medical procedures stipulated in the "Code of Practice for Day Procedure Centres"

Scheduled Medical Procedures (附表醫療程序)

- Procedures specified in Schedule 3 to the Ordinance that are carried out in ambulatory settings
- Include the following eight classes of specialized services
 - Surgical procedure
 - Endoscopic procedure
 - Dental procedure
 - Chemotherapy
 - Haemodialysis
 - Interventional radiology and lithotripsy
 - Anaesthetic procedure (such as general anaesthesia and deep sedation)
 - Radiotherapy
- Refer to Section 2 of the Ordinance on the interpretation of "Scheduled Medical Procedure" and Column 2 of Schedule 3 "Classes of Specialized Services" on the particular medical procedures



Cap. 633 Schedule 3

Scheduled medical procedures

(附表醫療程序)

- Schedule 3 Column 3
 - Exceptions to medical procedures described in column 2



Cap. 633, Schedule 3

Column 1 Class of specialized services

Particular medical procedures

Column 2

(e) Insertion of prosthesis or implant

Column 3

Exceptions to medical procedures described in column 2

- Insertion of prosthesis in ear, nose and throat cavity
- Insertion of dental prosthesis and implant
- Insertion of facial implant
- (iv) Insertion of extraocular prosthesis and implant
- (v) Insertion of intrauterine or vaginal prosthesis
- (vi) Insertion of bulking agent of urethra
- (vii) Insertion of prostatic urethral stent
- (viii) Insertion of urethral sling
- Insertion of testicular prosthesis



Scheduled medical procedures

(附表醫療程序)

• Schedule 3 Column 2



Cap. 633, Schedule 3

Schedule 3

[ss. 2, 15, 103 & 123]

Classes of Specialized Services

Column 1 Class of specialized services

Dental procedure

Column 2

Particular medical procedures

Maxillofacial surgical procedure that extends 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 maxillofacial fracture
- (c) Surgical treatment of diagnosed
- (d) Surgical treatment of complex haemangioma
- (f) Open surgery of temporomandibula
- autogenous bone from outside oral cavity
- Primary cleft lip

Column 3 Exceptions to medical procedures described in column 2

- Temporomandibular arthrocentesis
- Temporomandibular arthroscopy

NOT Scheduled Medical Procedures

- malignancies
- (e) Surgery involving major salivary glands
- (g) Harvesting of
- and palate surgery

External sinus lift / lateral window sinus lift



Office for Regulation of Private Healthcare Facilities

Department of Health

Guidance Notes for Application for Day Procedure Centre Licence



Guidance Notes for Application for Day Procedure Centre Licence

External sinus lift / lateral window sinus lift

- Q11 Is external sinus lift / lateral window sinus lift a scheduled medical procedure?
- All External sinus lift / lateral window sinus lift would **not** fall into the scope of scheduled medical procedures under Column 2 of Schedule 3 to the Ordinance, on condition that
 - the procedure reconstructs / restores a resorbing, or severely resorbed, dentalalveolar process to its original form and such reconstruction / restoration is performed within the dento-alveolar process; and
 - (ii) the procedure, including the surgical access, involves areas which belonged to or originally belonged to the dento-alveolar process and does not involve area beyond the original dento-alveolar process.

Scheduled Medical Procedures (附表醫療程序)

- Sedation
 - 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

Schedule 3

[ss. 2, 15, 103 & 123]

Classes of Specialized Services

Column 1 Class of specialized services

Column 2

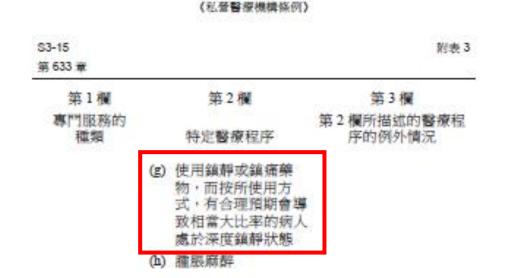
Particular medical procedures

Column 3 Exceptions to medical procedures described in column 2

- Anaesthetic procedure
- General anaesthesia
- Neuroaxial blocks (including spinal, epidural and caudal)
- (c) Major plexus block (including brachial, lumbar and sacral)
- (d) Intravenous regional anaesthesia
- Intercostal nerve block
- Major nerve block-
 - (i) Glossopharyngeal nerve, vagus nerve or their terminal branches (including superior, inferior and recurrent laryngeal nerves):
 - Sciatic and femoral nerves:
 - Posterior tibial nerve, pudendal nerve or paracervical block
- (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
- Tumescent anaesthesia

Scheduled Medical Procedures (附表醫療程序)

- \checkmark GA
- Sedation
 - ✓ 使用鎮靜或鎮痛藥物,而按所使用方式,有合理預期會導致相當大比率的病人處於深度鎮靜狀態

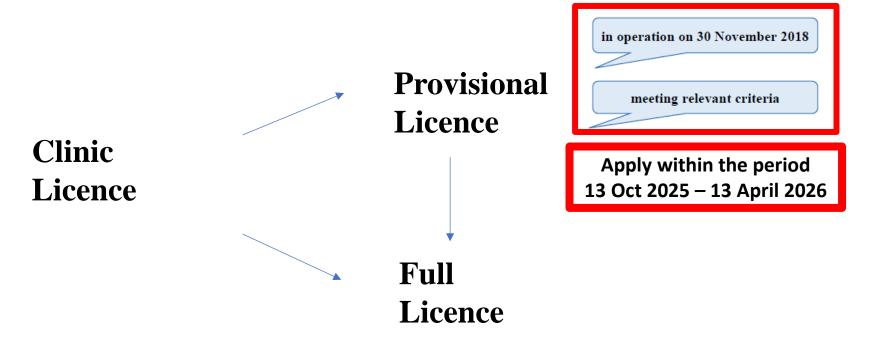


Providing sedation service in clinic — message to dentists

- if MAC is planned:
 - Communicate with the anesthesiologist about the treatment plan of the case, particularly on the level of sedation going to achieve
 - Document clearly in the record
 - Can perform sedation in clinics, but only up to conscious level
 - If deep sedation is intended, must be performed in licenced Day Procedure Centre/Private Hospital
 - In accordance with the Guideline on Procedural Sedation (2025) promulgated by the HKAM (香港醫學專科學院)

Licence vs Letter of Exemption

	Licence	Letter of exemption
Applicable PHF	DPC and Clinic	Small Practice Clinic (SPC)
Renewal	DPC – 3 years Clinic – 5 years	Not required
Fee The state of	Licence fee depends on scale of DPC / Clinic	No application fee
Operation standards	Licensing requirements and the Code of Practice	Exemption condition, requirements promulgated by MCHK/DCHK
Premises	Distinct and separate premises with separate entrance (exception: clinic with provisional licence)	



Letter of exemption



2. The exclusive right of operators to use the premises



Performance of scheduled medical procedures?

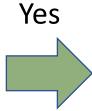


Day procedure centre LICENCE

- Number of doctors/dentists
- The exclusive right of operators to use the premises
- Locum arrangements

No

Eligible for exemption as small practice clinic?



Small practice clinic (SPC)
LETTER OF EXEMPTION

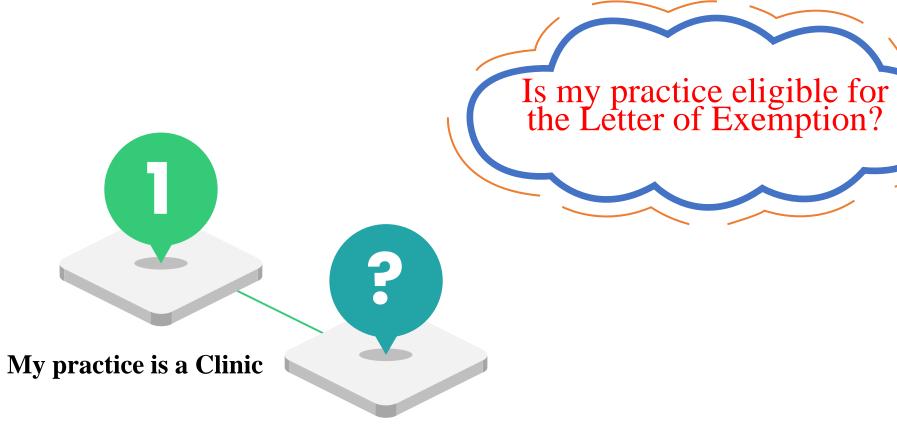


Clinic

LICENCE

 In operation on 30 Nov 2018 and meeting relevant criteria will be issued with a provisional licence





Fulfill the criteria of Small Practice Clinic

Criteria for exemption of SPC

For company, the name of the directors should be the same as the directors in the record of Company Registry

	Clinic operated under a sole proprietorship	Clinic operated under a partnership / company	
Number of		The partnership / company having not more than 5 partners / directors	
medical practitioners or dentists	Operated by a registered medical practitioner or registered dentist /	All partners / directors must be registered medial practitioners or registered dentists	
	No medical practitioners or dentists of	other than the operator(s) serve the clinic	
Right to use the premises	The sole proprietor has the exclusive right to use the premises	At least one partner / director of the partnership/ company has the exclusive right to use the premises	
	Not exceeding 60 days in a calendar year per operator		
Locum arrangement /		The aggregate number of days not exceeding 180 days for all the partners or directors in a calendar year	

Operator(s): The sole proprietor, all partners in the partnership or all director(s) in the company operating the clinic.

Locum: a registered dentist who takes up the duties of a sole proprietor / director/ partner in the clinic because of that person's absence from the clinic

Meaning of SPC

Exclusive Rights to Use the Premises

Operator(s) of an SPC should remain responsible for all services provided or activities carried out on that premises

- Cannot employ other medical practitioners or dentists (except for locum arrangements)
- Must not lease any part of the premises to other person

Requirements on operators for an exemption



- ➤ Not inappropriate to carry on the practice in the clinic without a licence
 - Refer to Guidance Notes for Considering Inappropriateness for a Person to be Issued with a Letter of Exemption for Small Practice Clinic to Carry on Practice in a Clinic Without a Licence.
 - The criteria of the assessment include, but not limited to, contravention of or conviction of offences under the Private Healthcare Facilities Ordinance, professional competence, and business arrangement or financial status
- Each registered medical practitioner / registered dentist may request for exemption for up to 3 SPCs at the same time
 - The operator is required to apply for a licence for the 4th and each of the subsequent clinics





Factors considered in determining inappropriateness for a person making the request to carry on the practice in the clinic without a licence:

Relevant factors	Duration for the decision to be valid	
(A) Contravention of / conviction of offences under PHFO		
Operator(s) contravenes or has contravened PHFO resulting in revocation of a letter of exemption of an SPC	1 year from the date of the revocation	
Operator(s) have been convicted of any offences under the PHFO, for which the person has been sentenced to imprisonment (where suspended or not)	3 years from the date of the conviction	
Operator(s) have been convicted of any offences under the PHFO, for which the person has been fined at level 6 or above	1 year from the date of the conviction	
(B) Professional competence		
Operator(s) have been found guilty of professional misconduct by DCHK, MCHK or similar authorities outside Hong Kong, resulting in removal from the register	Until restoration to the register	
Operator(s) have history of non-compliance with the codes of practice / condition of licence / direction issued under PHFO resulting in suspension or cancellation of licence of a facility	3 years from the date of suspension or cancellation of licence of the facility	

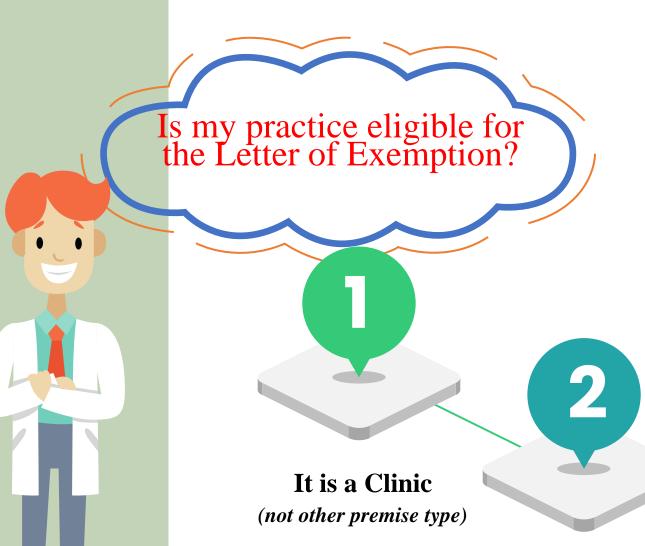
DCHK: The Dental Council of Hong Kong; MCHK: The Medical Council of Hong Kong

Inappropriate to carry on the practice in the clinic without a licence (con't)



Relevant factors	Duration for the decision to be valid	
(C) Business arrangement / financial status		
The individual has become bankrupt or made a voluntary arrangement with the individual's creditors within the meaning of the Bankruptcy Ordinance (Cap. 6) (if the person that operates, or intends to operate, the clinic is an individual as a sole proprietor)	Until the bankruptcy is discharged	
The company has commenced to be wound up or dissolved (if the person that operates, or intends to operate, the clinic is a company)	Not applicable*	
(D) Other reasons		
The person making the request under Section 42 in relation to the clinic has made a false statement in the request, or in any information or document required by the Director under this Ordinance	Each case to be considered on an individual basis	
The Director considers that the clinic has been operated in a way contrary to the public interest		
The Director considers it otherwise inappropriate for the person making the request to carry on the practice in the clinic without a licence		

^{*} Such company is considered inappropriate to be issued with a letter of exemption for small practice clinic.



permitted facility (獲准機構) means—

- (a) a private healthcare facility for which a licence is in force; or
- (b) an exempted clinic;



Fulfill other requirements for Permitted Facilities

Fulfill the criteria Permitted Fac of Small Practice Clinic



Cap. 633 Part 1, Section 2

Other Requirements for the Permitted Facilities

	Small Practice Clinic with Letter of Exemption	DPC / Clinic with full licence
Distinct and separate premises requirement (PHFO, section 66)		
Separate entrance requirement (PHFO, section 67)		
Continuous confinement of patients (PHFO, section 68)		
Prohibited use of "operating room" or similar expressions (PHFO, section 70)		

Premises and its entrance

Sections 66, 67

- ➤ Physically separated from premises <u>not reasonably incidental to</u> the type / practice of facility
- > Distinct and exclusive unit, able to perform functions independently
- > Direct and separate entrance



Cap. 633 s66



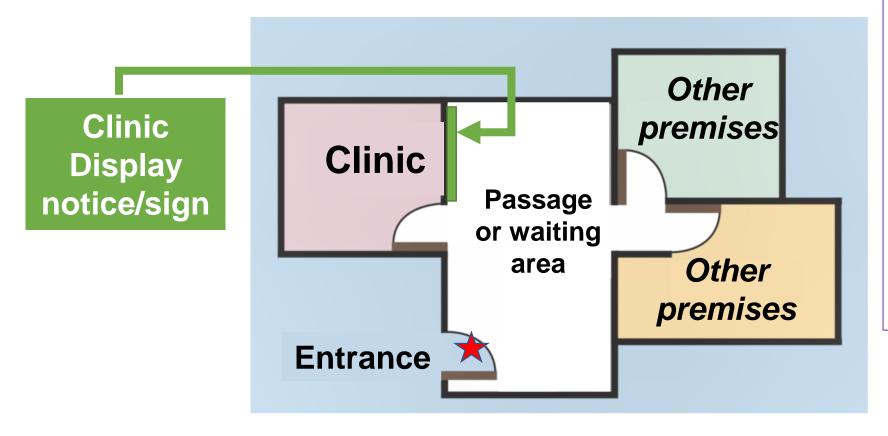
Cap. 633 s67

Shared entrance acceptable in some cases (s138)



ONLY for Clinic covered by a **Provisional Licence**

Shared entrances allowed but...



Clinic having a private entrance that is shared with premises (shared entrance) that serve a purpose that is not reasonably incidental to the clinic (other premises) should satisfy:

- The other premises are also managed or controlled by the licensee
- Clinic notice/sign is only displayed only at, or in the immediate vicinity of, the direct entrance to the clinic;
- The passage area is not designated for a purpose other than passage or waiting
- The passage area is clear from obstruction that blocks access to the clinic
- Access to the other premises does not involve passing through the clinic

After considering the circumstances, the DH may issue a provisional licence. If the requirements in s.138 is not complied with, provisional licence may not be granted.

Continuous confinement of patients

Sections 68

- > This section applies in relation to any of the following private healthcare facilities—
 - (a) a day procedure centre for which a licence is in force;
 - ➤ (b) a clinic for which a licence is in force;
 - (c) an exempted clinic.
- Subject to subsection (3), the operator of the facility must not provide to any person a medical procedure that may require the person's continuous confinement within the facility for more than 12 hours.
- If the facility is a day procedure centre, the period of continuous confinement referred to in subsection (2) must be within the same calendar day.



Cap. 633 s68

Use of names and descriptions

Sections 70

Except with the prior approval in writing of the Director, a room, unit or section of a private healthcare facility must not bear a name or description that includes the expression "operating room", "operation room", "operating theatre", "operation theatre", "手術室", "手術房" or "手術間", or a similar expression



Cap. 633 s70

Small Practice Clinic - Letter of Exemption





'YES' to all of the above:

Ask the Director of Health for a letter of exemption



Exemption applies to <u>3 clinics</u> of every registered medical practitioner (not under limited registration) / registered dentist, of his / her choice

Small Practice Clinic - Letter of Exemption

	Licence	Letter of Exemption
Requirement on chief medical executive		X
Regular inspection	\bigcirc	X
Renewal		X
Distinct and separate premises requirement (section 66)	\bigcirc	
Separate entrance requirement (section 67)		
Continuous confinement of patients (section 68)	\bigcirc	
Prohibited use of "operating room" or similar expressions (section 70)	\checkmark	

- Private Healthcare Facilities Ordinance (Cap. 633)
 - Section 44 Notice of intended change or cessation
 - operator of exempted clinics must give DoH not less than 14 days' notice in writing of:
 - Any intended change of the clinic's operators
 - Any intended change of clinic's address
 - Any intended cessation of the clinic's operation
 - Any intended cessation of the clinic's operating as a small practice clinic



Cap. 633 s.44



Cap. 633 s.46

- Private Healthcare Facilities Ordinance (Cap. 633)
 - Section 46 Grounds for revoking exemption
 - The grounds for revoking an exemption for a small practice clinic under section 45 are as follows—
 - (a) an operator of the clinic contravenes or has contravened this Ordinance;
 - (b) an operator of the clinic has been convicted of an offence under this Ordinance;
 - (c) 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;



Cap. 633 s.46

- Private Healthcare Facilities Ordinance (Cap. 633)
 - Section 46 Grounds for revoking exemption
 - The grounds for revoking an exemption for a small practice clinic under section 45 are as follows—
 - (d) the person making the request under section 42 in relation to the clinic has made a false statement in the request, or in any information or document required by the Director under this Ordinance;
 - (e) the Director is satisfied that the clinic has ceased to exist or be operated;
 - (f) the Director is satisfied that the clinic has ceased to be operated as a small practice clinic;
 - (g) the Director considers that the clinic has been operated in a way contrary to the public interest;
 - (h) The Director considers for another reason that it would be inappropriate for the exemption to continue to be in force.

- Dentists Registration Ordinance (Cap. 156)
 - Section 16 Inspection of premises used for the practice of dentistry
 - Section 12G(5)
 - must report to the Registrar any change of the address (including the address as changed and reported under this subsection) within 2 months after the date on which the change occurs
- Code of Professional Discipline for the Guidance of Dental Practitioners in Hong Kong



Cap. 156 s.12G



Cap. 156 s.16



Code of Professional Discipline [DCHK]

Making a request for Letter of Exemption

Electronic submission



using



- Fast
- Identity verified by "iAM Smart+"
- No need to attend DH's designated office in person for identity verification
- Decrease transcription errors
- Can check the request progress on e-Licensing
- Can retrieve the letter of exemption from e-Licensing anytime after its issuance

Making a request for Letter of Exemption Preparation for electronic submission

Clinic address proof

Electronic copy in pdf or .jpg format with the name of the clinic or the operator(s)

For examples:

- copy of a valid Business Registration Certificate
- bills or invoices issued by utility companies (i.e. water, electricity or towngas suppliers) within the last 3 months

E-mail address(es)

Prepare e-mail addresses to fill in the request form:

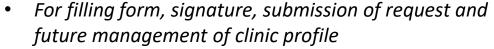
- Correspondence information of the sole proprietor / partnership / company
- Contact information of the clinic, if available

Appoint authorized partner / director

- Partnership /
- For representing the partnership / company to communicate with the DH on matters related to the SPC
- For holding the e-Licensing account

e-Licensing account

e-Licensing



- Use the e-mail address of the sole proprietorship / partnership / company to register an account
- If the SPC is operated by a partnership / company, the authorized partner / director should maintain the account. All operators should have access to information related to the clinic

"iAM Smart+" 智方便[†]

 All operators need to have an "iAM Smart+" account in order to sign the form digitally

If you cannot sign the form using iAM Smart+ or cannot upload the clinic address proof electronically, you may still **fill the request form on e- Licensing system**. The completed form can be **printed out and signed on paper**. Then submit it to our office.









1. Register an e-**Licensing account**



USER GUIDE



Request for Letter of Exemption (For Small Practice Clinics)

3. Fill in request form

Reference No.

C2500444E

Section I	
Particulars of the Small Practice Clinic	•

Section II

Declaration of the Small Practice Clinic → Particulars of the Operator → Particulars of the Operator → Confirm Information

Section III

(Part 1)

(Part 2)

Confirmation





Licence Application

2. Request for a letter of exemption for SPC

Exemption for Small Practice Clinic

Request for a letter of exemption

I would like to request a letter of exemption for Small Practice Clinic



Request for Letter of Exemption for Small Practice Clinic - New Request

Request Status Pending Submission	
Request Type Letter of Exemption for Small Practice Clinic - New Request	
Reference No.	C2500371E

Your request has **NOT** been submitted yet. Please upload the proof of address now.

Checklist of Documents	
PHF 51 Request for Letter of Exemption for Small Practice Clinics completely signed by all operators	Sign and Submit
	via "iAM Smart+"
Proof of address of the clinic with the name of the clinic or the operator (sole proprietor, one of the partners / directors or company)	Upload
e.g. bills or invoices issued by utility companies (i.e. water, electricity or towngas suppliers) or record of procurement / maintenance of drugs / medical equipment within the last three months from the request date, copy of a valid Business Registration Certificate, etc.	
Provide upon submission of the request form	

or enquiries, please contact the Department of Health by phone or email as indicated below.

4. Upload clinic address proof and digitally sign the request form using "iAM Smart+"

Address and contact information of DRLEO (Clinic involving dental practice only)

地址: Address:	香港灣仔愛群道32號愛群商業大廈18樓1801室牙科規管及執法辦公室 Dental Regulatory and Law Enforcement Office Dental Services, Department of Health Room 1801, 18/F, Guardian House, 32 Oi Kwan Road, Wan Chai, Hong Kong
交表時間*: Form submission time*:	星期一至星期五 Monday to Friday: <u>08:45 – 12:30, 14:00 – 17:00</u> 星期六、日及公衆假期休息 Saturday, Sunday and Public Holidays: <u>closed</u>
辦公室電話: Office Tel:	2631 1782
電郵: Email:	drleo@dh.gov.hk

^{*}Subject to change

Provisional licence vs full licence

Provisional licence

Applicable to clinic in operation on 30 Nov 2018 only

Documentary proof of operation of the relevant services at the premises on 30 Nov 2018

Will be followed by processing of full licence application

Valid until

- 1) a full licence is issued;
- 2) the application of full licence is refused or withdrawn; or
- 3) a date specified by Secretary for Health

Full licence

Applicable to **ALL** clinic

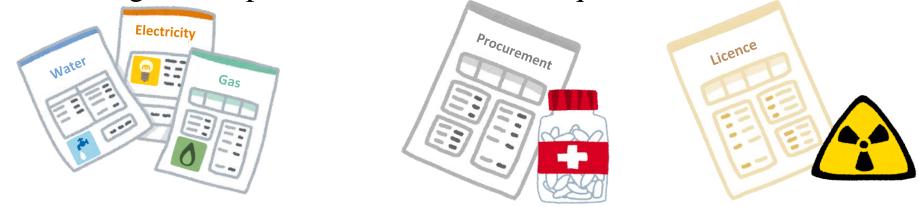
Proof of compliance of all licensing requirements and the Code of Practice

Renewal: Clinic – every 5 years



Proof for eligibility for provisional licence

• Clinics eligible for provisional licence are required to submit:



proof of address AND proof of providing clinic services

that the clinic has been in operation at the premises since 30 November 2018.

• Alternatively, the applicant / authorized representative of the applicant shall make a **statutory declaration in person by appointment** at the ORPHF or DRLEO (applicable to dental clinic only)

Full licence (Clinic)

- for clinics which commenced operation after November 30, 2018 (including those which started businesses or moved to new premises)
- Proof of compliance of all licensing requirements and Code of Practice
- Renewal every 5 years

Process of application





Refer to "Guidance Notes for Application for Clinic Licence" available later on ORPHF website for details.

Submit all the Required Documents

Clinic was in operation on 30 Nov 2018: Submit evidence / make declaration

Receipt of general demand note

Submit Payment for Application

Site Inspection(s)*

Submit follow-up documents

Receipt of Full / Provisional Clinic Licence#

First batch of clinic licences take effect tentatively around 12 months after commencement of application.

^{*} Operators should ensure that the clinic fulfils the standards set out in the "Code of Practice for Clinics" and get ready the required documents prior to site inspection.





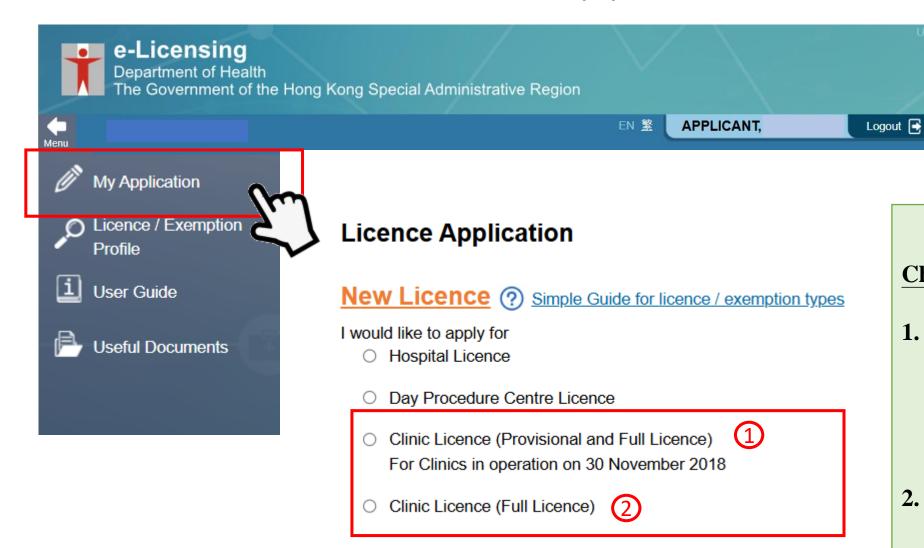
→ SIGN IN	
User ID	8
LOGIN	
Forgot Password?	
Continue with iAM Smart	
More Info	



- ✓ Register a User ID for your clinic or clinic group
- ✓ Activate your e-Licensing account via emails from orphf.system
- ✓ Apply Licence / Letter of Exemption
- ✓ Track application processes
- ✓ View Licence / Exemption Profiles

Create a clinic licence application (PHF 32)





Choose ONE

1. Provisional and Full Licence

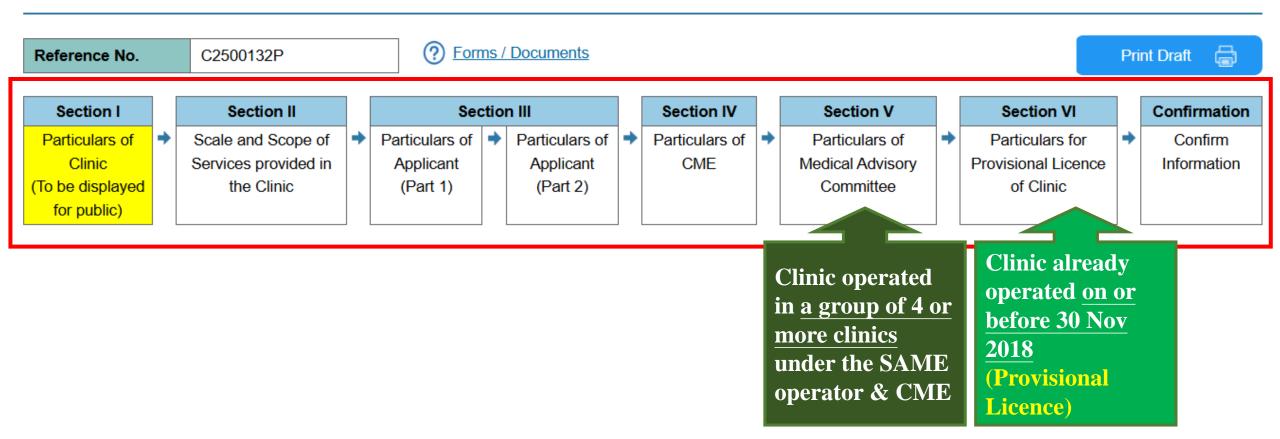
Clinics already operating on 30 Nov 2018

2. Full LicenceAny clinics

Fill in the application form (PHF 32) at e-Licensing







Check and confirm information in the application form

Clinic LICENCE

Section	L		Section II				Section III				Section IV		Section V		Section VI		Confirmation
Particulars	of '	+	Scale and Scope	→	Particulars of	•	Particulars of	→	Particulars of	→	Particulars of	+	Particulars of	→	Particulars for	→	Confirm
Clinic			of Services		<u>Applicant</u>		<u>Applicant</u>		<u>Applicant</u>		<u>CME</u>		<u>Medical</u>		<u>Provisional</u>		Information
<u>(To be</u>			provided in the		(<u>Part 1)</u>		<u>(Part 2)</u>		(Part 3)				<u>Advisory</u>		Licence of		
<u>displayed</u>	for		<u>Clinic</u>										<u>Committee</u>		Clinic		
<u>public)</u>																	

Important Notices

The information you have input are now displayed below for confirmation. The information cannot be amended online once it is confirmed. Any subsequent amendment must be submitted through written request.

Section I - Particulars of Clinic (To be displayed for public) a. Name of the Clinic in Chinese: 示範健康診所 b. Name of the Clinic in English: Demo Healthy Clinic c. Address of the Clinic in Chinese: 九龍旺角加列山道100號新陽光商業大樓10A至C室 Address of the Clinic in English: Flat A-C, 10, New Sunshine Commercial Building, 100 Mount Kellett Road, Mongkok, Kowloon e. Telephone Number of the Clinic: 22002200 (Telephone Number 1) 22009988 (Telephone Number 2) f. Fax Number of the Clinic: (Not provided) E-mail Address of the Clinic: info@newclinic.com Website of the Clinic: (Not provided) i. Type(s) of practice of the Clinic: Medical Practice Dental Practice Section II - Scale and Scope of Services provided in the Clinic a. Scale of Services provided in the Clinic: Room type Number Operating room

I understand that the information cannot be amended online once it is confirmed.





Submit completed form (PHF 32) and supporting documents to DH





Application for Clinic Licence (Provisional and Full Licence) - New Application

Reference No.	C2500132P	Porms / Documents
Application Type	Clinic Licence (Provisional and Full Licence) - New Application	
Estimated Application Fee	HK\$ 10,900	
Application Status	Pending Submission	

Your application has NOT been completed yet. Please prepare the documents below and submit to the Office for Regulation of Private Healthcare Facilities through (i) electronic or (ii) paper channel.

#	Checklist of Documents	Submission	channel
		Electronic ①	Paper 🛈
1	Application Form for Clinic Licence PHF 32	Sign and Submit via "iAM Smart+"	Print and Sign
2	Declaration by the Chief Medical Executive of the clinic PHF 34	Sign and Submit via "iAM Smart+"	Print and Sign
3	Documentation substantiating authorization in respect of the authorized representative to represent the applicant in the application for licence	Upload	
4	Layout plan of the clinic premises (drawn to the scale and format as specified in the Guidance note PHF(E) 32A)	Upload	
5	Report for Application for Clinic Licence PHF 35	Upload	
6	Proof of address on or before 30 November 2018 e.g. Photocopy of the Business Registration Certificate, bills issued by the utility companies (water, electricate) towngas)	Upload	
7	Proof of providing clinic services issued no more than 1 year prior to 30 November 2018 e.g. Record of procurement or maintenance of drugs and medical equipment, licence issued under the Radiation Ordinance (Cap. 303) for radioactive substances and irradiating apparatus	Upload	
8	Checklist of documents of healthcare engineering systems and summary of healthcare engineering standard(s / code(s) PHF 212#	Upload	
9	Schematic diagram(s) of the electrical installations#	Upload	

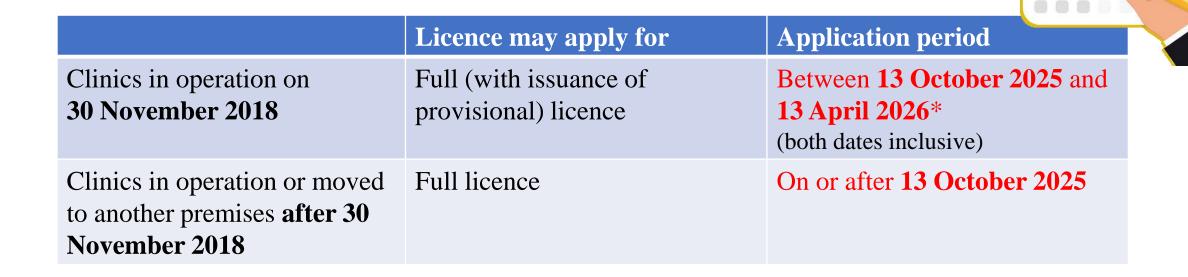


Electronic submission

- 1. Sign the forms using iAM Smart +
- 2. Upload supporting documents to e-Licensing







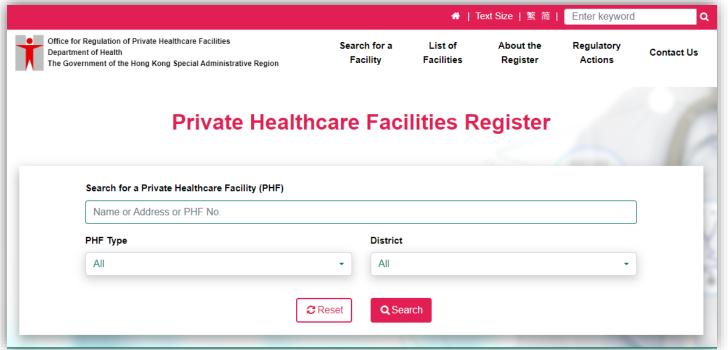
^{*}Applicants who wish to issued a provisional licence must pay the application fee on/before the due date stated on the general demand note and no later than 13 April 2026, whichever is the earlier. Late applications will **not** be accepted.

PHF Register

Relevant information (e.g. clinic name, address, contact information, type of practice, operator names) of exempted clinics will be uploaded to the Register.

The Register will be uploaded to the **ORPHF website** and will be available in **DH's designated office** for

public inspection.



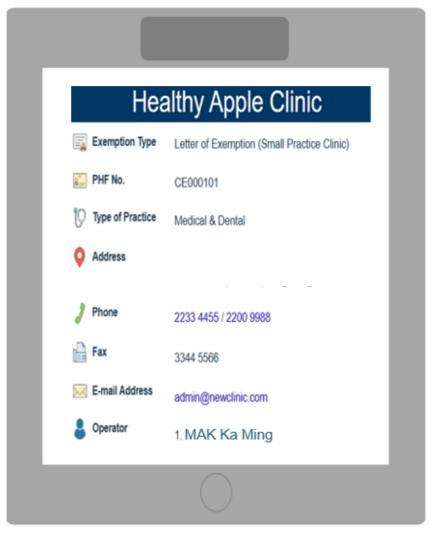
PHF Register (con't)

On the letter of exemption, you will receive a QR code, which links to the page of your exempted clinic on PHF Register.

You are recommended to **display the QR code** at your clinic to facilitate public to access information in the Register.



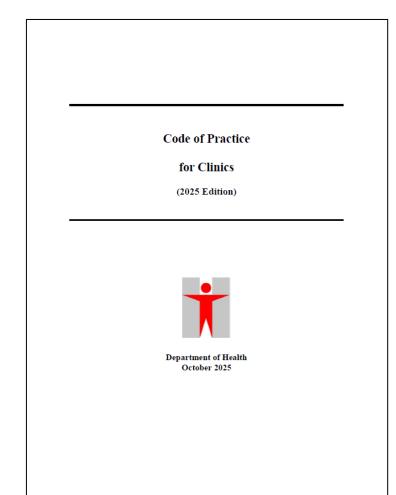




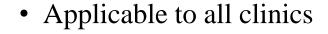
PHF Register

QR code

Code of Practice for Clinics



• 2025 edition





CoP for Clinics

• Compliance is a condition for issuance and renewal of licences

Code of Practice for Clinics

- Management/Governance
- Physical Conditions
- Service Delivery and Care Process
- Infection Control
- Risk Management and Contingency

Management and Governance

- The licensee is wholly responsible for the operation of the clinic to ensure that it complies with the requirements of the PHFO, licence and CoP
- The licensee must appoint a Chief Medical Executive (CME) for the clinic
 - Responsible for taking charge of the day to day administration of the clinic
 - adoption and implementation of the rules, policies and procedures concerning healthcare services provided in the clinic

Chief Medical Executive (CME) (醫務行政總監)

For a clinic with medical practice	the CME must be a registered medical practitioner
If the clinic also provides dental practice	the licensee must also appoint a registered dentist to assist the CME (registered medical practitioner) in carrying out the day to day administration of the dental practice
For a clinic with only dental practice	the CME must be a registered dentist

Management and Governance

• Chief Medical Executive

	Clinic	Group of ≥ 4 clinics operated by the same licensee
General	 Must possess the necessary qualifications and experience. Must be physically and mentally fit to administer and the most of integrity and good character. 	
Qualifications		dentist tal practices: Registered medical ed dentist appointed to assist
Experience (registered in Hong Kong)	≥4 years	≥8 years

Management and Governance

• Chief Medical Executive

	Clinic	Group of ≥ 4 clinics operated by the same licensee
Others	 Must not serve as CME of: More than 2 DPCs; More than 1 DPC & 1 clinic; or More than 3 clinics, except for the case at the column on the right 	 A person may serve as CME of ≥ 4 clinics of the same licensee at the same time, provided that — A Medical Advisory Committee is established for the clinics; For each clinic, a registered medical practitioner / registered dentist serving the clinic is appointed to assist CME; and The person does not serve as CME of another PHF at the same time

Medical Advisory Committee (MAC)

(醫務顧問委員會)

Type of practice	Chairperson	Number of members
Medical	Medical Practitioner	To be decided by the
Medical + Dental	Medical Practitioner	licensee
Dental	Dentist	 At least half of the members must be registered medical practitioners or registered dentists Including one registered medical practitioner who is not employed by, or practising in the concerned PHE
		practising in the concerned PHF

Medical Advisory Committee (MAC)



Both licensee and CME are responsible for ensuring that MAC's advice is properly implemented

Physical Conditions

- Facility management
 - Design, size, layout and condition of the facility
 - Equipment are in good operational order
 - Clean and hygienic. Ventilation, lighting and signage are adequate and appropriate
- Equipment and store
 - Properly maintained (records)
 - Equipment intended for single use is not reused

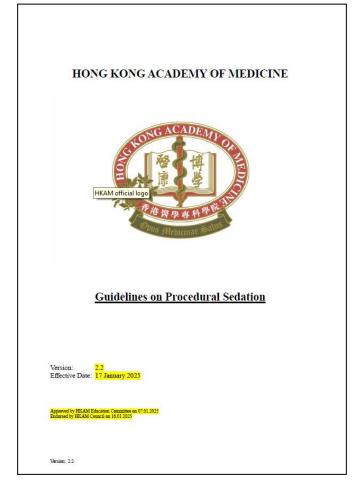
- Patient's rights
- Patient identification
- Medical records
 - Include at least the following:
 - Unique identifier, patient's name, gender, DOB, residential address, contact number, drug allergy, consultation notes and investigations, treatment, sick leave and referral records
 - Accurate, legible and up-to-date
 - Dated, signed and the person could be identified
 - Maintain and retain for specified minimum period
 - Confidential, kept secure, protect from unauthorized access, alternation or loss

- Drug management
 - Codes of Professional Discipline for the Guidance of Dental Practitioners in Hong Kong promulgated by the DCHK
 - Keep up-to-date drug formulary
 - All medicines supplied are registered pharmaceutical products in HK
 - Drug procurement documents are kept for reference and inspection
 - All medicines are clearly labelled and stored
 - A system is in place to check the drug expiry dates
 - Expired medicines should be properly disposed of

- Procedural sedation
 - In accordance with the Guideline on Procedural Sedation (2025) promulgated by the HKAM



Guideline on Procedural Sedation (2025)



• 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

- Deep Sedation
 - Scheduled Medical Procedure
 - Must be performed in Day Procedure Centre/ Private Hospital

Schedule 3 [ss. 2, 15, 103 & 123] Classes of Specialized Services Column 1 Column 2 Column 3 Exceptions to medical Class of procedures described in Particular medical specialized services procedures column 2 Anaesthetic General anaesthesia Neuroaxial blocks (including spinal, epidural and caudal) Major plexus block including brachial. lumbar and sacral) Intravenous regional anaesthesia Intercostal nerve block Major nerve block-(i) Glossopharyngeal nerve, vagus nerve or their terminal branches (including superior. inferior and recurrent laryngeal nerves): Sciatic and femoral Posterior tibial nerve, pudendal nerve or para-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

Prohibition on operating facility without licence



- **Penalty provision** pertaining to the operation of a hospital and a DPC without a licence has commenced on 1 January 2021 and 30 June 2022 respectively.
- Any person operating a hospital without a licence commits an offence and is liable on conviction to a fine of HK\$5,000,000 and to imprisonment for five years.
- Any person operating a DPC without a licence commits an offence and is liable on conviction to a fine of HK\$100,000 and to imprisonment for three years.
- The commencement of penalty provision pertaining to the operation of a clinic without a licence will be announced later.

- Patient safety incident reporting and learning system
 - The CME ensures any sentinel event or serious untoward event is report to the Director of Health within 24 hours upon identification and a full report is submitted to the Director of Health within 4 weeks
 - The CME ensures that the following events are reported to the Director of Health upon identification:
 - Unplanned transfer of a patient to a hospital directly from a clinic during or after a planned procedure, which emergency management was required at the hospital; and
 - Other events of public health significance (e.g. radiation health incidents, or serious incidents, such as cessation of water or electricity supply, resulting in harm to patients who are receiving care in the facility)

- Price information
 - Up-to-date price schedule
 - Covers all chargeable items
 - Readily available for patient's reference at the reception office, cashier and where appropriate
 - Fixed fee/ range/price information will be available upon request

- Complaint handling
 - Complain handling mechanism (receiving, managing, responding and documentation, with a specified time frame)
 - Complaints Committee
- Closure
 - Make a request in writing to the Director of Health to cancel the licence
 - Not less than 6 weeks before the intended date of cessation of operation
 - Ensure continuity of care given to the patients after closure

- All staff observe up-to-date infection control and preventive measures
- Relevant guidelines promulgated by international or local health authorities



Guide to Infection Control in Clinic Setting



Guide to Infection Control
In Clinic Setting

Prepared by

Infection Control Branch, Centre for Health Protection, Department of Health



- Reusable equipment and supplies used in invasive procedures involving sterile tissue or vascular system are properly reprocessed by appropriate disinfection and sterilization methods
- Store in a clean and dry area
- Regular checking of expiry of sterile supplies
- All sterilizing equipment is regularly inspected and maintained with proper documentation

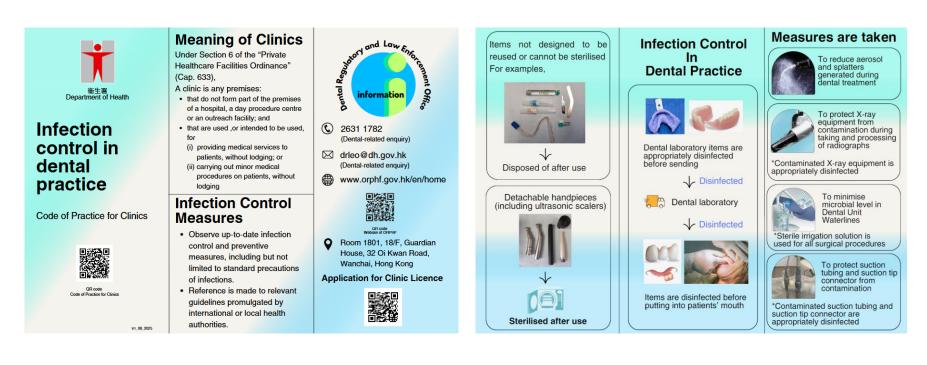
• Clinical waste and chemical waste are handled properly (Waste Disposal Ordinance (Cap.354))



Cap.354



• Infection control in dental service - Leaflet





QR code
Promotional materials – Leaflets

• Infection control in dental service - Videos



https://www.youtube.com/watch?v=-YCqcP-qm8k



QR code
Promotional materials – Videos/Animations

Risk management and contingency

- Policy and procedures for resuscitation
- Equipment and emergency medications are easily accessible, checked at regular intervals and made ready in accordance with the age of patients
- Sufficient staff who are trained for CPR on duty while providing clinical service
- Protocol for emergency transfer



Healthcare engineering systems

- Healthcare engineering systems (HES) in clinics:
 - electrical installation in critical care areas (such as operating room and recovery area);
 - specialized ventilation system of operating room; and
 - medical gas pipeline system for medical gas supplies
- Where HES are installed in the facility, the design, installation, operation and maintenance of the HES comply with the relevant requirements in the *Code of Practice for Day Procedure Centres*#.
- The applicant is required to submit relevant technical submission for assessment.



^{*}A Practical Guide for Healthcare Engineering Systems in Day Procedure Centres is available on ORPHF website: https://www.orphf.gov.hk/s/hesdpc1



Dental compressed air and vacuum systems

- Where dental compressed air and vacuum systems (DAVS) are installed in the facility, the CME may refer to the relevant requirements in the *Code of Practice* for *Day Procedure Centres* for general guidance on the design, installation, operation and maintenance of such systems[#].
- The feasibility of implementing relevant requirements for DAVS as a regulatory requirement would be reviewed as appropriate. Licensees are encouraged to observe such requirements in preparation for its implementation.



^{*} A Practical Guide for Dental Compressed Air and Vacuum Systems in Day Procedure Centres is available on ORPHF website: https://www.orphf.gov.hk/s/davdpc1

For more information...

• Website of the Office for Regulation of Private Healthcare Facilities: www.orphf.gov.hk



• Tel.: 2631 1782

• Email: drleo@dh.gov.hk





Upcoming briefing sessions!!!



★ Home > What's New ▼ > Event > Online Briefing Sessions on Application for Clinic Licence and Letter of Exemption for Small Practice Clinic (For Clinics with Medical Practice)

Online Briefing Sessions on Application for Clinic Licence and Letter of Exemption for Small Practice Clinic (For Clinics with Medical Practice)

Briefing sessions (for clinics with medical practice)

Date	Time	Venue	Enrolment deadline
17 September 2025 (Wednesday)	3:00 – 4:00pm	Webinar session	15 September 2025 (Monday)
24 September 2025 (Wednesday)	3:00 – 4:00pm	Webinar session	22 September 2025 (Monday)
30 September 2025 (Tuesday)	3:00 – 4:00pm	Webinar session	26 September 2025 (Friday)
8 October 2025 (Wednesday)	3:00 – 4:00pm	Webinar session	3 October 2025 (Friday)
15 October 2025 (Wednesday)	3:00 – 4:00pm	Webinar session	13 October 2025 (Monday)



More details to be announced next week...

