What’s happened so far?
How will I be affected?
What should I do?
What’s happened so far?
The Journey

Establishment of Steering Committee on Review of Regulation of Private Healthcare Facilities

Oct 2012

Dec 2014 - Mar 2015

Public Consultation

Apr 2016

Consultation Report

Jun 2017

Private Healthcare Facilities (PHFs) Bill
- Introduction into Legislative Council (LegCo)
- Formation of Bills Committee

Nov 2018

- Passed by LegCo
- Gazettal

From 2019 onwards

Phased Implementation of the New Regime
How will I be affected?
Types of PHFs to be Regulated

- Health services establishments: Schedule 9 to the Ordinance
<table>
<thead>
<tr>
<th>Type</th>
<th>Definition</th>
<th>Licences / Letters of Exemption</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private Hospital</td>
<td>• Premises where medical practitioners and/or dentists practise</td>
<td>Licences</td>
</tr>
<tr>
<td></td>
<td>• With lodging</td>
<td>• Application commences in mid-2019</td>
</tr>
<tr>
<td></td>
<td>• Application commences in mid-2019</td>
<td>• Anticipated to take effect in early 2021</td>
</tr>
<tr>
<td>Day Procedure Centre</td>
<td>• Premises where medical practitioners and/or dentists practise</td>
<td>Licences</td>
</tr>
<tr>
<td></td>
<td>• Without lodging</td>
<td>• Application anticipated to commence in 2020</td>
</tr>
<tr>
<td></td>
<td>• Providing “scheduled medical procedures”</td>
<td>• First batch anticipated to take effect in early 2021</td>
</tr>
<tr>
<td>Clinic</td>
<td>• Premises where medical practitioners and/or dentists practise</td>
<td>Licences and Letters of Exemption</td>
</tr>
<tr>
<td></td>
<td>• Without lodging</td>
<td>• Application anticipated to commence in 2021 at the earliest</td>
</tr>
<tr>
<td></td>
<td>• Not providing “scheduled medical procedures”</td>
<td>• Taking effect: will be announced in due course</td>
</tr>
<tr>
<td></td>
<td>• Exemption arrangement available for eligible small practice clinics</td>
<td></td>
</tr>
</tbody>
</table>
Small Practice Clinic - Letter of Exemption

- 1 Sole Proprietor or ≤ 5 Partner(s) / Director(s)
- No medical practitioners are under limited registration

- The sole proprietor / partner(s) / company / director(s) have exclusive right to use the premises

- Only the sole proprietor / partners / directors can practise in the clinic, except for locum:
  - ≤ 60 days for each sole proprietor / partner / director in a calendar year
  - ≤ 180 days per clinic in a calendar year
‘YES’ to all of the above:

Ask the Director of Health for a letter of exemption

Exemption applies to 3 clinics of every registered medical practitioner (not under limited registration) / registered dentist, of his / her choice
<table>
<thead>
<tr>
<th>Requirement</th>
<th>Licence</th>
<th>Letter of Exemption</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requirement on chief medical executive</td>
<td>✔️</td>
<td>✗</td>
</tr>
<tr>
<td>Regular inspection</td>
<td>✔️</td>
<td>✗</td>
</tr>
<tr>
<td>Renewal</td>
<td>✔️</td>
<td>✗</td>
</tr>
<tr>
<td>Distinct and separate premises requirement (section 66)</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Separate entrance requirement (section 67)</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Prohibited use of “operating room” or similar expressions (section 70)</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Prohibited use of certain titles or descriptions (section 92)</td>
<td>✔️</td>
<td>✔️</td>
</tr>
</tbody>
</table>
Key Licensing Requirements for PHFs

- Licensee and Chief Medical Executive
- Medical Advisory Committee
- Price Transparency
- Complaints Management System
- Regulatory Standards
Licensee and Chief Medical Executive

- Wholly responsible for the PHF’s operation
- Appointing the chief medical executive (CME)

- Taking charge of the PHF’s day-to-day administration
- Different requirements on CME for different types of PHFs

Applicable to licensed PHFs (i.e. not for small practice clinics being exempted)
## Requirements on CME

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Private Hospital</th>
<th>DPC</th>
<th>Clinic</th>
<th>Clinic (For clinics operated by the same licensee)</th>
</tr>
</thead>
</table>
| **General**  | • Must possess the necessary qualifications and experience  
• Must be physically and mentally fit to administer a PHF  
• Must be of integrity and good character |   |        |                                              |
| **Qualifications** | Registered medical practitioner | • Medical practice: Registered medical practitioner  
• Dental practice: Registered dentist  
• Both medical and dental practices: Registered medical practitioner (with a registered dentist appointed to assist CME) |  
| **Experience** | ≥ 15 years (Registered in HK) | ≥ 6 years (Registered in HK) | ≥ 4 years (Registered in HK) | ≥ 8 years (Registered in HK) |
| **Others**    | Must not serve as CME of another PHF concurrently | A person must not serve as CME of –  
➢ More than two DPCs;  
➢ More than three clinics; or  
➢ More than one DPC and one clinic, except for the case at the column on the right | A person may serve as CME of more than three clinics of the same licensee concurrently, 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 concurrently |
To be established by the licensee of –
- private hospitals or
- \( \geq 4 \) clinics managed by the same licensee

To advise the licensee on –
- Qualifications and clinical responsibilities of healthcare professionals
- All matters concerning medical diagnosis, treatment and care
- All matters concerning quality of care for, and safety of, patients

Both licensee and CME are responsible for ensuring that MAC’s advice is properly implemented
<table>
<thead>
<tr>
<th></th>
<th>Private Hospital</th>
<th>DPC</th>
<th>Clinic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provision of Fee Schedules / Price Information</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Provision of Budget Estimates</td>
<td>✓</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Disclosure of Historical Bill Sizes Statistics</td>
<td>✓</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
A two-tier complaints handling system is proposed

**First Tier**
- PHF to manage complaints at source
- Licensee to put in place a complaints handling procedure

**Second Tier**
- Unresolved complaints to be handled according to a centralized mechanism
  (*Committee on Complaints against Private Healthcare Facilities*)
Regulatory Measures

Tackle with breaches of the law and licensing requirements (e.g. Code of Practice)

Examples

Example 1: Cancellation of licence

Example 2: Suspension of facility service
Regulatory Measures and Sanctions

Offences

- To deter serious and intentional non-compliance
- Licensees could be subject to sanctions for certain contraventions

Examples

**Example 1:** Operating a PHF that is not licensed or exempted (Maximum penalty - a fine of $5 million and imprisonment for five years)

**Example 2:** Failing to comply with a suspension order to suspend a facility service (Maximum penalty - a fine of $1 million and imprisonment for two years)
What should I do now?
If your DPC / clinic requires a licence and was in operation on 30 Nov 2018...

- In application for a full licence, you will be issued a provisional licence if meeting certain conditions
  - The applicant is fit and proper person
  - CME to be appointed is fit and proper person
  - Operation would not be contrary to public interest

- The provisional licence allows the DPC / clinic to continue to operate during the transitional period under the new regulatory regime before being qualified for a full licence
If your DPC / clinic requires a licence and was in operation on 30 Nov 2018...

Examples of documentary proof (not for small practice clinics):

01. Copy of Business Registration Certificate showing medical services were carried out

02. Records of procurement or maintenance of drugs and medical equipment

03. Other licence(s) relating to the provision of medical services concerned

04. Records of employment / appointment of healthcare staff
If your DPC / clinic requires a licence, and was not in operation on 30 Nov 2018 …

• You should aim at fulfilling the requirements under the new regulatory regime at the time of application for licence
Thank you
Private Healthcare Facilities Ordinance
Department of Health
Implementation of Licensing Scheme

✓ Transitional Arrangement and Licence Application

✓ Upcoming Publicity Activities
### Phased Implementation

<table>
<thead>
<tr>
<th>Types of PHFs</th>
<th>Commencement of Licence Application</th>
<th>First batch of Licences Taking Effect</th>
<th>All Facilities Operating with Licence</th>
<th>All Facilities Operating with Full Licence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital</td>
<td>Mid-2019</td>
<td>2021 (Full only)</td>
<td>2021</td>
<td>2021</td>
</tr>
<tr>
<td>Day Procedure Centres (DPC)</td>
<td>2020</td>
<td>2021 (Full/provisional)</td>
<td>To be determined</td>
<td>To be determined</td>
</tr>
<tr>
<td>Clinics</td>
<td>2021 (at the earliest) #</td>
<td>To be determined</td>
<td>To be determined</td>
<td>To be determined</td>
</tr>
</tbody>
</table>

All critical dates to be specified by subsidiary legislation

# Timeline equally applies to request for exemption of Small Practice Clinics
Transitional Arrangement - Provisional Licence

Eligible PHFs

✓ Day procedure centres (section 135) and clinics (section 136)
✓ in operation on a specified date (30 November 2018)
✓ application for licence made within specified period (to be announced)
[subject to conditions specified in s135/136)

Application

✓ Made in accordance with s13 by operators
✓ PHFs eligible for provisional licence - documentary proof of operation of the relevant services at the relevant premises on the specified date. E.g. business registration, records of procurement/maintenance, licences, and other relevant proof
DPCs or Clinics not in operation until after 30 Nov 2018

✓ Apply for **full** license after commencement of licensing scheme (2020 for DPCs; 2021 tentatively for clinics)

✓ May continue operation without license until section 10 takes effect (i.e. prohibition of operation without license/exemption)

✓ Licensees must fully comply with licensing standards
Code of Practice

✓ Issued by the Director of Health in accordance with s102
✓ Compliance with Code of Practice is a licensing condition
✓ Sets out standards to be complied by relevant type of licensed PHFs
✓ CoP for DPCs and clinics – based on standards developed by or in consultation with the Project Steering Committee on Standards for Ambulatory Facilities
Code of Practice (cont’d)

Standards for DPCs
- Core Standards
- Procedure-specific Standards
  - Surgery
  - Endoscopy
  - Dental Procedures
  - Haemodialysis
- To be promulgated:
  - Chemotherapy
  - Anaesthesia & Sedation
  - Interventional Radiology and Lithotripsy

Standards for Clinics
- [Draft] Standards for Medical Clinics
Announcement of Licensing Arrangements

- **Briefings for operators**
  - Hospital and nursing homes → first half 2019
  - Licensing and transitional arrangements for DPCs/clinics → second half of 2019

- Latest news and documents publicized on the website of the Office for Regulation of Private Healthcare Facilities, DH
  - Promulgation of Standards
  - Announcements on related subsidiary legislation for specifying the critical dates ([https://www.legco.gov.hk/yr18-19/english/hc/sub_leg/sc55/general/sc55.htm](https://www.legco.gov.hk/yr18-19/english/hc/sub_leg/sc55/general/sc55.htm))

- Letters to doctors/dentists and other relevant stakeholders
THANK YOU