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**Paper for the House Committee**

**Report of the Subcommittee on Private Healthcare Facilities Ordinance  
(Specification of Date for Section 135(1)(a)) Notice  
and Private Healthcare Facilities Ordinance  
(Specification of Date for Section 136(1)(a)) Notice**

**Purpose**

This paper reports on the deliberations of the Subcommittee on Private Healthcare Facilities Ordinance (Specification of Date for Section 135(1)(a)) Notice and Private Healthcare Facilities Ordinance (Specification of Date for Section 136(1)(a)) Notice ("the Subcommittee").

**Background**

2. The Private Healthcare Facilities Bill was passed by the Legislative Council ("LegCo") on 15 November 2018. The Private Healthcare Facilities Ordinance (Cap. 633) ("the Ordinance"), which mainly regulates premises where registered medical practitioners and registered dentists practise, provides for a new regulatory regime for four types of private healthcare facilities, namely hospitals,<sup>1</sup> day procedure centres,<sup>2</sup> clinics<sup>3</sup> and health services establishments.<sup>4</sup>

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<sup>1</sup> Under section 4 of the Ordinance, a "hospital" is any premises that are used, or intended to be used, for providing medical services to patients, with lodging; carrying out medical procedures on patients, with lodging; or receiving a pregnant woman for childbirth or a woman immediately after she gives birth to a child, but does not include the premises specified in Schedule 2 to the Ordinance.

<sup>2</sup> Under section 5 of the Ordinance, a "day procedure centre" is any premises that do not form part of the premises of a hospital; and that are used, or intended to be used, for carrying out scheduled medical procedures that are described in section 2 of and Schedule 3 to the Ordinance on patients, without lodging, whether or not the premises are also used, or intended to be used, for providing medical services to patients, without lodging; or carrying out minor medical procedures on patients, without lodging.

The Ordinance was published in the Gazette on 30 November 2018 and will come into operation on a day to be appointed by the Secretary for Food and Health ("the Secretary") by notice published in the Gazette. The Ordinance prohibits a person from operating a private healthcare facility without a licence except in the case of a small practice clinic<sup>5</sup> for which a valid letter of exemption is issued under section 43 of the Ordinance. Transitional arrangements for those existing facilities that will fall into the new regulatory regime are provided for in the Ordinance.

**Private Healthcare Facilities Ordinance (Specification of Date for Section 135(1)(a)) Notice (L.N. 261 of 2018) and Private Healthcare Facilities Ordinance (Specification of Date for Section 136(1)(a)) Notice (L.N. 262 of 2018)**

3. On 7 December 2018, L.Ns. 261 and 262 of 2018 ("the two Notices") were published in the Gazette. The two Notices are made by the Director of Health ("the Director") under sections 135 and 136 of the Ordinance which provide for the transitional arrangements for application for licence in respect of an existing day procedure centre and an existing clinic respectively. Under sections 135(6)(a) and 136(6)(a) of the Ordinance, the Director may, by notice published in the Gazette, specify the date on which a day procedure centre and a clinic that are operating will count as an existing day procedure centre and an existing clinic for the transitional arrangements ("the specified date"). It is specified in the two Notices that 30 November 2018 is the specified date.

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<sup>3</sup> Under section 6 of the Ordinance, a "clinic" is 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 providing medical services to patients, without lodging; or carrying out minor medical procedures on patients, without lodging.

<sup>4</sup> Under section 7 of the Ordinance, a "health services establishment" is any premises that fall within a category specified in Schedule 9 to the Ordinance; that do not form part of the premises of a hospital, a day procedure centre or a clinic; and that are used, or intended to be used, in relation to assessing, maintaining or improving the health of patients; or diagnosing or treating illnesses or disabilities, or suspected illnesses or disabilities, of patients.

<sup>5</sup> Under section 41 of the Ordinance, a small practice clinic refers to a clinic which (a) is operated by a registered medical practitioner or registered dentist as a sole proprietor; or a partnership having not more than five partners, each of whom is a registered medical practitioner or a registered dentist; or a company having not more than five directors, each of whom is a registered medical practitioner or a registered dentist; (b) except the sole proprietor or partners or directors, no other registered medical practitioners or registered dentists practise in the clinic; and (c) the sole proprietor or one or more of the partners or directors or the company has/have the exclusive right to use the premises forming the clinic.

4. The two Notices were tabled before LegCo at its meeting of 12 December 2018 and are subject to negative vetting by LegCo. They will come into operation on the day(s) on which sections 135 and 136 of the Ordinance come into operation.

### **The Subcommittee**

5. At the House Committee meeting on 14 December 2018, Members agreed to form a Subcommittee to study the two Notices. Under the chairmanship of Dr Pierre CHAN, the Subcommittee has held two meetings with the Administration. The membership list of the Subcommittee is in the **Appendix**.

6. To allow more time for the Subcommittee to study the two Notices, a motion was moved by the Chairman of the Subcommittee at the Council meeting of 9 January 2019 to extend the scrutiny period of the two Notices to the Council meeting of 30 January 2019.

### **Deliberations of the Subcommittee**

#### Issuance of licences

7. Members note that the provisions on application for different licences under the Ordinance will be commenced in phases, with those on riskier types of private healthcare facility to be commenced earlier. The plan of the Administration is that application for hospital licence may be made starting mid-2019, whereas application for day procedure centre licence may be made starting 2020. For clinics, applications for clinic licence and letter of exemption, as the case may be, are anticipated to commence in 2021 the earliest. By virtue of sections 135 and 136 of the Ordinance and the two Notices, on receiving an application for a day procedure centre licence or a clinic licence which is made within the specified periods<sup>6</sup> from a person who operates a day procedure centre or a clinic on 30 November 2018 on the premises for which the application is made, the Director must issue a provisional licence permitting the applicant to operate the facility concerned on the premises if certain conditions are satisfied<sup>7</sup>.

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<sup>6</sup> Under sections 135(6)(b) and 136(6)(b) of the Ordinance, the Director may, by notice published in the Gazette, specify a period within which an application for a day procedure centre licence and a clinic licence under section 13 of the Ordinance may be made in reliance on sections 135 and 136 respectively.

<sup>7</sup> Sections 135(2) and 136(2) of the Ordinance refer.

8. The Administration has informed the Subcommittee that given the nature of the provisional licence, it would be appropriate to set the specified date as the date on which the Ordinance was gazetted. Members in general support the specified date proposed in the two Notices. However, they have urged the Administration to make public as early as possible the licence application procedures, including the types of documents that an applicant has to provide to prove that the day procedure centre or the clinic concerned was already in operation on the premises on 30 November 2018. The Administration has assured members that it will announce in a timely manner details of application procedures and the supporting documents required. Some examples of documentary proof of a day procedure centre or a clinic operating on the specified date are a copy of Business Registration Certificate showing that medical services concerned were carried out on the premises by the applicant, records of procurement or maintenance of drugs and medical equipment, other licence(s) relating to the provision of medical services concerned, and records of employment or appointment of healthcare staff.

9. Noting that the plan of the Administration is that the first batch of day procedure centre licences will take effect in early 2021, Dr Pierre CHAN has sought clarification as to whether these cover only the provisional day procedure centre licences. The Administration has advised that the specified period for applicants to make a day procedure centre licence application in reliance on section 135 will begin in early 2020 and last for about four months. It is expected that the Office for Regulation of Private Healthcare Facilities ("the PHF Office") of the Department of Health ("DH") will have six to eight months' time before issuing the first batch of provisional day procedure centre licences in early 2021.

10. Section 137 of the Ordinance provides that a provisional licence is valid for the period beginning on the date specified by the Director in the provisional licence and ending on the day on which a licence under section 17 of the Ordinance ("full licence") is issued to the licensee of the provisional licence (or the application for licence is refused or withdrawn) or the day of expiry of the transitional arrangements to be appointed by the Secretary by notice published in the Gazette (which must be at least one year after the day on which the notice is published), whichever is earlier. Dr Pierre CHAN and Dr KWOK Ka-ki have expressed concern about the time required by the PHF Office to process an application and issue a full licence.

11. The Administration has advised that it is expected that at the early stage of the commencement of application for day procedure centre licence and clinic licence during the specified periods, the PHF Office will receive a large number of applications. It is therefore difficult to estimate at this stage the time required to process an application. On the time required to issue a full licence to the licensee of a provisional licence, it would depend on when the facility concerned

could meet the licensing requirements. Prior to the issuance of a full licence, staff of the PHF Office would inspect the premises (including the fittings and equipment in the premises) of the private healthcare facility to which the application relates upon receipt of notification of compliance with the relevant licensing requirements from the applicant. Where necessary, the applicant concerned would be required to make amendment to the application, or alteration or improvement to the premises. Follow-up inspection(s) by staff of the PHF Office would be conducted upon receipt of the applicant's notification on the readiness for re-inspection after alteration or improvement. A full licence will be issued when full compliance with the licensing requirements is confirmed.

12. Taking into account that the Administration would seek to increase by around 100 staff in phases, from the existing establishment of about 40 staff in the PHF Office involved in licensing work, in order to support the new regulatory regime, Dr Pierre CHAN and Dr KWOK Ka-ki are of the strong view that there should be no difficulty for the Administration to work out a pledge in respect of the time required to process a licence application by making reference to the findings of DH's Survey on Private Ambulatory Facilities that the projected number of day procedure centres and medical and/or dental clinics in the territory is around 500 and 5 000<sup>8</sup> respectively. In so doing, persons intending to operate a day procedure centre or a clinic would have a better estimation of when the facility could commence operation, as well as the rental and staff expenditure to be incurred before the commencement of operation of the facility.

13. In view of the concerns raised by members, the Administration has agreed to consider setting target processing times for different stages of licence application, such as the target time to conduct verification inspection upon receipt of notification of compliance with the relevant licensing requirements from the applicant, in the light of the actual experience in the processing of applications for day procedure centre licence and clinic licence. The Administration has further advised that to ensure smooth processing of licence applications upon the full implementation of the new regulatory regime (i.e. when all private healthcare facilities are required to operate with licences or letters of exemption), applicants for a day procedure centre licence should submit the application with all required documents to the PHF Office at least two months before commencement of the centre's operation. It is hoped that a licence will be issued within 15 working days upon verification of meeting the licensing requirements. As regards application for a clinic licence or letter of exemption, it should best be made at least one month before the clinic commences operation. Subject to full compliance with all licensing or exemption requirements, as the case may be, it is hoped that a licence or letter of exemption will be issued within 10 working days.

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<sup>8</sup> According to the estimation of the Administration, small practice clinics being eligible for exemption account for around 70% of the some 5 000 clinics in Hong Kong.

14. Dr KWOK Ka-ki has suggested that in processing the licence applications, those applications not being made by a person who operated a day procedure centre or a clinic on 30 November 2018 (who could continue to operate the facility with a provisional licence) should be processed first, such that the facilities concerned could commence operation at an earlier time.

15. The Administration has advised that all licence applications will be processed in accordance with the order of their application dates. It has drawn members' attention that provisions of the Ordinance in relation to the prohibition against operating a type of a private healthcare facility without a licence and other related offences would be put in force when the Administration considers that both members of the public and the stakeholders are ready for full-scale regulation of the type of private healthcare facilities (including when they have obtained provisional licences or letters of exemption).

#### Separate entrance

16. Section 138 of the Ordinance provides that if on the date the provisional clinic licence is issued, the clinic concerned has a private entrance that is shared with premises ("shared entrance") that serve a purpose that is not reasonably incidental to the clinic ("other premises") and it is necessary to pass from the shared entrance through part of the other premises in order to access the clinic, the clinic is not required to, during the validity period of its provisional licence, comply with the requirements of having a direct and separate entrance as set out in section 67 of the Ordinance, subject to certain conditions.

17. Mr SHIU Ka-fai has enquired as to whether the above provision would still apply if the lease of the premises of a clinic which was in operation on the specified date is renewed before the commencement of application for clinic licence. The Administration has affirmed that the provision would apply as long as there is no change in the operator of the clinic.

#### Communication with stakeholders

18. Members note that briefing on the Ordinance is among the various topics to be covered in the Symposium on Healthcare Facilities Management 2019, a capacity building activity jointly organized by DH and the Hong Kong Academy of Medicine on two consecutive Saturdays in January 2019 to raise awareness among healthcare professionals and operators of private healthcare facilities of the prevailing legislation relevant to the operation of a private healthcare facility. To help the relevant sectors to prepare for the new regulatory regime, they have requested the Administration to maintain close communication with different sectors and relevant professional bodies by means of organizing sector targeted

briefings, issuing newsletters, producing online videos, setting up a general enquiry hotline, and uploading a set of frequently asked questions and answers onto the PHF Office's website for the reference of facility operators.

19. According to the Administration, more briefings will be arranged in the months to come and on invitation. For instance, it will meet with the Hong Kong Private Hospitals Association in the second half of January 2019 to prepare private hospitals for application for hospital licence which will commence in mid-2019. Arrangements have also been made to brief members of the Hong Kong Dental Association and certain healthcare facilities under the management of incorporated bodies on the new regulatory regime. The above apart, a dedicated enquiry line and webpage have been set up by the PHF Office. Letters would also be sent to registered medical practitioners, registered dentists and other relevant stakeholders to keep them posted of the development. The Administration assured members that efforts would continuously be made to raise different sectors' awareness of the licensing scheme through different channels.

#### Full implementation of the new regulatory regime

20. Members have urged the Administration to ensure that operators of day procedure centres and clinics, as well as the medical and dental professions are fully prepared before the new regulatory regime comes into force in full scale. Dr KWOK Ka-ki has expressed particular concern about the readiness of the premises of the existing day procedure centres to meet the accommodation and equipment standards under the new regulatory regime.

21. The Administration has informed the Subcommittee that a Project Steering Committee on Standards for Ambulatory Facilities was set up by DH and the Hong Kong Academy of Medicine in mid-2015 to, among others, draw up standards for day procedure centres which will comprise a set of core standards and sets of procedure-specific standards for the provision of relevant class(es) of specialized services including anaesthesia and sedation; surgery; endoscopy; dental procedures; chemotherapy; haemodialysis; and interventional radiology and lithotripsy. A set of Core Standards for Day Procedure Centres and four sets of Procedure-specific Standards for Day Procedure Centres have been developed and published so far. These sets of standards will be adopted to become codes of practice for day procedure centres to be issued by the Director under section 102 of the Ordinance when the new regulatory regime comes into force. In the meantime, DH is conducting the Phase III Survey on Private Ambulatory Facilities to collect information from day procedure centres currently in operation to assess how far their operating rooms and designated rooms for medical procedures could meet the regulatory standards.

22. At the request of members, the Administration has undertaken to brief the Panel on Health Services on a yearly basis on the progress made towards the full implementation of the new regulatory regime.

### **Recommendation**

23. The Subcommittee raises no objection and will not move any amendments to the two Notices.

### **Follow-up actions by the Administration**

24. The Administration has undertaken to:

- (a) consider setting target processing times for different stages of licence application in the light of the actual experience in the processing of applications for day procedure centre licence and clinic licence (paragraph 13 refers); and
- (b) brief the Panel on Health Services on a yearly basis on the progress made towards the full implementation of the new regulatory regime (paragraph 22 refers).

### **Advice sought**

25. Members are invited to note the deliberations of the Subcommittee.



**Subcommittee on Private Healthcare Facilities Ordinance  
(Specification of Date for Section 135(1)(a)) Notice  
and Private Healthcare Facilities Ordinance  
(Specification of Date for Section 136(1)(a)) Notice**

**Membership list**

**Chairman** Dr Hon Pierre CHAN

**Members** Hon CHAN Han-pan, BBS, JP  
Dr Hon KWOK Ka-ki  
Hon SHIU Ka-fai

(Total : 4 members)

**Clerk** Ms Maisie LAM

**Legal Adviser** Ms Clara TAM

**Date** 21 December 2018