

LEGISLATIVE COUNCIL BRIEF

Private Healthcare Facilities Ordinance (Cap. 633)

COMMENCEMENT AND RELATED NOTICES UNDER, AND AMENDMENT OF SCHEDULE 3 TO THE PRIVATE HEALTHCARE FACILITIES ORDINANCE

INTRODUCTION

The Private Healthcare Facilities Ordinance (Cap. 633) (The Ordinance) will be implemented in phases starting from July 2019. Notices have been made by the Secretary for Food and Health (the Secretary) and the Director of Health (the Director) to –

- (a) provide for the commencement dates of certain provisions under the Ordinance pertaining to the licensing of private hospitals and day procedure centres, as well as exemption for scheduled nursing homes under the new regulatory regime for private healthcare facilities (PHFs);
- (b) specify the relevant application periods for licence/exemption of the aforementioned premises; and
- (c) amend Schedule 3 to the Ordinance, so that premises providing certain radiotherapy services in an ambulatory setting will have to obtain a day procedure centre licence and comply with relevant regulatory standards.

JUSTIFICATIONS

2. The Private Healthcare Facilities Bill was passed by the Legislative Council on 15 November 2018, and the Ordinance was gazetted on 30 November 2018. The Ordinance will further protect patient safety and

consumer rights through the introduction of a new regulatory regime for PHFs. The Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) and the Medical Clinics Ordinance (Cap. 343) currently in force will be replaced by the Ordinance.

Implementation of the Ordinance

3. We will commence the regulatory regime in phases based on the types of PHFs and their risk levels. Applications for licences for private hospitals under the Ordinance will commence in July 2019 and those for day procedure centres will commence in January 2020. For clinics, applications for licences and requests for letters of exemption are anticipated to commence in 2021 at the earliest.

Arrangements for Private Hospitals

4. Applications for licences for private hospitals under the new regime will commence on 2 July 2019 (T1). Operators of existing private hospitals currently regulated under Cap. 165 may apply to the Director for a licence under the Ordinance in reliance on section 125, and such application shall be made between T1 and 31 December 2019. Operators of new private hospitals, which have not yet commenced operation and are thus not registered under Cap. 165 at present, may submit their application for a licence under the Ordinance on or after T1. Hospital licences issued under the Ordinance will take effect on 1 January 2021 (T3). By then, the regulation of private hospitals will have migrated to the new regime under the Ordinance and the repeal¹ of Cap. 165 will take effect on the same date. Consequential amendments are also made to other legislation that makes reference to Cap. 165. Any person who operates a private hospital without a licence under the Ordinance on or after T3 commits an offence under section 10 of the Ordinance.

¹ See section 148 of the Ordinance.

Arrangements for Day Procedure Centres

5. Applications for licences for day procedure centres will commence on 2 January 2020 (T2). Operators who were operating day procedure centres on 30 November 2018² may apply to the Director for a day procedure centre licence (i.e. a full licence for a day procedure centre) between T2 and 30 April 2020 if they wish to be eligible for a provisional licence under section 135(2) of the Ordinance.³ The provisional licence allows the day procedure centre to continue to operate during the transitional period under the new regulatory regime before being qualified for a full licence. Operators of other day procedure centres⁴ may submit their application on or after T2 for a full licence. The first batch of day procedure centre licences (including both full and provisional licences) is anticipated to take effect on T3. The relevant offence provisions in respect of operating a day procedure centre without licence, which will not be included in the current exercise, will be effective on a date to be confirmed, when we consider that both the public and stakeholders are ready for the regulation pertaining to day procedure centres.

Arrangements for Scheduled Nursing Homes

6. The current registration of scheduled nursing homes⁵ under Cap. 165 would cease to be in effect when Cap. 165 is repealed on T3. Operators of scheduled nursing homes may, depending on their plan on future operation, apply for –

² Under the Private Healthcare Facilities Ordinance (Specification of Date for Section 135(1)(a)) Notice (L.N. 261 of 2018), the Director has specified 30 November 2018 as the date on which a person operates a day procedure centre could be eligible for a provisional licence. The Notice will come into operation on the day on which section 135 of the Ordinance comes into operation, i.e. T2.

³ The Director must, on receiving an application for a full licence from these operators, issue a provisional licence to the operators if satisfied that certain conditions are met. Such conditions include – (a) the applicant is a fit and proper person to operate or exercise control over the day procedure centre; (b) the chief medical executive to be appointed is a fit and proper person to administer the centre; and (c) the operation of the centre by the applicant would not be contrary to the public interest.

⁴ That is, operators who commenced operation of day procedure centres after 30 November 2018 or who are planning to commence operation of day procedure centres.

⁵ Nursing homes listed in Schedule 10 to the Ordinance.

- (a) a licence in respect of a residential care home under the Residential Care Homes (Elderly Persons) Ordinance (Cap. 459)⁶;
- (b) a licence in respect of a residential care home for persons with disabilities under the Residential Care Homes (Persons with Disabilities) Ordinance (Cap. 613); or
- (c) a licence for a PHF under the Ordinance.⁷

7. As part of the transitional arrangements, if the operator of a scheduled nursing home has applied for, but has not been granted, any of the licences mentioned in paragraph 6, the operator may apply to the Director under section 128 of the Ordinance between T2 and 30 April 2020 for an exemption. An exemption permits the operator to operate the scheduled nursing home on the premises concerned without a licence under the Ordinance. The Department of Health and the Social Welfare Department have been providing assistance to the operators of scheduled nursing homes to facilitate their smooth transition under the new regulatory regime.

Provision of Radiotherapy Services in Ambulatory Setting

8. In Hong Kong, radiotherapy services are provided in public and private settings for treatment of cancer and certain benign conditions. In the private sector, while most (if not all) radiotherapy services are currently performed in hospital settings, it is anticipated that there would be increasing prevalence of radiotherapy services provided in private stand-alone ambulatory facilities, which calls for the need to set up relevant regulatory standards.

⁶ As the Ordinance is designed to replace Cap. 165, the regulatory regime for nursing homes for elderly persons originally registered under Cap. 165 would need to be transferred to Cap. 459 and its subsidiary legislation. Cap. 459, which currently regulates three types of residential care homes (namely care and attention home, aged home and self-care hostel), would be expanded to cover nursing homes. Amendments to Cap. 459 and the Residential Care Homes (Elderly Persons) Regulation (Cap. 459A) are set out in Part 11 of the Ordinance and will take effect on T2.

⁷ If the operators of scheduled nursing homes intend to apply for a licence to operate a private hospital under the Ordinance, the application may be made in reliance on section 126 and such application shall be made between T1 and 31 December 2019, i.e. the same application period for existing private hospitals (see paragraph 4 above).

9. In view of the above trend, the Project Steering Committee on Standards for Ambulatory Facilities (the Project Steering Committee)⁸ reviewed the issue in January 2019 and considered that some of the radiotherapy services might be conducted in day procedure centres provided there were appropriate regulatory measures and standards in place, while others should be conducted only in hospital settings. Schedule 3 to the Ordinance is amended so that certain radiotherapy services will be regarded as scheduled medical procedures under the Ordinance. Premises providing such services in an ambulatory setting will have to obtain a day procedure centre licence and comply with relevant regulatory standards.

10. Given the evolving mode of delivery in healthcare services and the advancement in medical technology, we will continue to review the need to amend Schedule 3 regularly.

THE NOTICES

11. To give effect to the implementation arrangements mentioned in paragraphs 4 to 7 above, the following Notices have been made by the Secretary/the Director -

Notice	Purpose
Private Healthcare Facilities Ordinance (Commencement) Notice 2019 (at Annex A)	To bring the relevant provisions for private hospitals, day procedure centres and scheduled nursing homes into operation. The Notice will also cover provisions in relation to the repeal of Cap. 165 and corresponding consequential amendments to other legislation, as well as the offence of operating private hospitals without licence.

⁸ The Project Steering Committee, chaired by Professor Raymond Liang, was set up by the Department of Health and the Hong Kong Academy of Medicine in mid-2015 to draw up standards for day procedure centres and to give advice on the standards for clinics under the new regime.

Notice	Purpose
Private Healthcare Facilities Ordinance (Specification of Period for Section 125(1)(c)) Notice (at Annex B)	To specify the period (i.e. from 2 July 2019 to 31 December 2019) during which operators of existing private hospitals currently registered under Cap. 165 may apply to the Director for a licence for a hospital under the Ordinance in reliance on section 125.
Private Healthcare Facilities Ordinance (Specification of Period for Section 126(1)(c)) Notice (at Annex C)	To specify the period (i.e. from 2 July 2019 to 31 December 2019) during which operators of scheduled nursing homes may apply to the Director for a licence for a hospital under the Ordinance in reliance on section 126.
Private Healthcare Facilities Ordinance (Specification of Period for Section 128(3)(a)) Notice (at Annex D)	To specify the period (i.e. from 2 January 2020 to 30 April 2020) during which operators of scheduled nursing homes may apply to the Director for an exemption in reliance on section 128.
Private Healthcare Facilities Ordinance (Specification of Period for Section 135(1)(b)) Notice (at Annex E)	To specify the period (i.e. from 2 January 2020 to 30 April 2020) during which operators of existing day procedure centres being operated by the operators on 30 November 2018 may apply to the Director for a day procedure centre licence, and the Director must issue a provisional licence to the operators if the Director is satisfied that certain conditions are met.

12. In addition, to take forward the Project Steering Committee's recommendations set out in paragraph 9, the Private Healthcare Facilities Ordinance (Amendment of Schedule 3) Notice 2019 (at **Annex F**) has been made by the Secretary to include certain radiotherapy services (i.e. external beam radiotherapy, brachytherapy and radionuclide therapy) in Schedule 3 to the Ordinance.

13. Separate subsidiary legislation would be made at a later stage in relation to the commencement of regulatory regimes for clinics and health services establishments, as well as a number of penalty provisions, etc.

LEGISLATIVE TIMETABLE

14. The legislative timetable will be –

Publication in the Gazette	28 June 2019
Tabling at Legislative Council	3 July 2019

ENQUIRY

15. Enquiries on this brief may be directed to Mr Michael Li, Assistant Secretary for Food and Health (Health) 4B, Food and Health Bureau, at 3509 8939.

Food and Health Bureau
26 June 2019

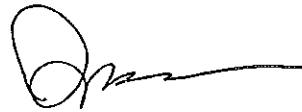
Private Healthcare Facilities Ordinance (Commencement) Notice 2019

Under section 1(2) of the Private Healthcare Facilities Ordinance (Cap. 633), I appoint—

- (a) 2 July 2019 as the day on which the following provisions of the Ordinance come into operation—
 - (i) Part 1;
 - (ii) section 11 (except subsection (2)(b));
 - (iii) sections 13(1), (2)(a) and (3)(a), 14(1), 16, 17 (except subsection (2)(a), (b) and (c)), 18 and 19(1);
 - (iv) Divisions 2, 3 (except section 24), 4, 5 (except sections 32, 34(2)(b), 35(2)(b), (3)(b) and (5)(b) and 36), 6 (except section 38(1)(b), (c) and (d)(ii), (2)(b)(i), (ii) and (v) and (d) and (3)(a), (b) and (e)) and 7 (except section 39(1)(g) and (h)) of Part 3;
 - (v) Divisions 1, 2 (except sections 49(5)(b), 50, 53 and 54), 3 (except sections 56(2) and 57(5)(a)) and 4 of Part 5;
 - (vi) sections 64 and 65 (in so far as it relates to a private healthcare facility that is a hospital);
 - (vii) Division 6 of Part 5 (except sections 66(2)(a), 67(2)(a) and 68);
 - (viii) Part 6 (in so far as it relates to a private healthcare facility that is a hospital);
 - (ix) Part 7 (except section 92);
 - (x) Part 8 (except section 107(1)(b) and (3)(b));
 - (xi) Divisions 1 and 2 of Part 9;

- (xii) Part 10;
- (xiii) Schedules 1, 2, 3, 4, 5, 6, 7, 9 and 10;
- (b) 2 January 2020 as the day on which the following provisions of the Ordinance come into operation—
 - (i) sections 11(2)(b), 13(2)(b) and (3)(b), 14(3), 15, 17(2)(a) and (b), 19(2), 24, 32 (except subsection (2)(b)), 34(2)(b), 35(2)(b), (3)(b) and (5)(b), 36, 38(1)(b), (c) and (d)(ii), (2)(b)(i), (ii) and (v) and (d) and (3)(a), (b) and (e) and 39(1)(g) and (h);
 - (ii) sections 49(5)(b), 53 (except subsections (2), (4)(b) and (c) and (5)), 54, 65 (in so far as it relates to a private healthcare facility that is a day procedure centre) and 68 (except subsection (1)(b) and (c));
 - (iii) Part 6 (in so far as it relates to a private healthcare facility that is a day procedure centre);
 - (iv) Division 3 of Part 9;
 - (v) sections 135, 137 (in so far as it relates to a provisional day procedure centre licence) and 139;
 - (vi) Part 11; and
- (c) 1 January 2021 as the day on which the following provisions of the Ordinance come into operation—
 - (i) section 10(1) (in so far as it relates to a private healthcare facility that is a hospital) and (3)(a);
 - (ii) Division 1 of Part 12;
 - (iii) Divisions 1, 2, 3 and 4 of Part 13;
 - (iv) section 159 (except subsection (2));
 - (v) Division 8 of Part 13;
 - (vi) sections 162 and 163(1);
 - (vii) Divisions 10, 11, 12 and 13 of Part 13;

- (viii) sections 175(1) and (2), 176(1), (2) and (3) (in so far as it relates to items 8 and 9), 177(1), (2), (3), (4) and (5) (in so far as it relates to items 5 and 6), 178(1), (2), (3), (4) and (5) (in so far as it relates to items 8 and 9) and 179(1), (2), (3), (4) and (5) (in so far as it relates to items 7 and 8);
- (ix) Divisions 19, 20, 21, 23, 24 and 26 of Part 13;
- (x) sections 189 (except subsection (3)) and 190(2);
- (xi) Divisions 29, 30 and 31 of Part 13;
- (xii) section 196(1).



Secretary for Food and Health

25 April 2019

**Private Healthcare Facilities Ordinance (Specification
of Period for Section 125(1)(c)) Notice**

(Made by the Director of Health under section 125(7) of the Private
Healthcare Facilities Ordinance (Cap. 633))

1. Commencement

This Notice comes into operation on the day on which section 125
of the Private Healthcare Facilities Ordinance (Cap. 633) comes
into operation.

2. Specification of period for section 125(1)(c) of Ordinance

The period beginning on 2 July 2019 and ending on 31 December
2019 is specified for the purpose of section 125(1)(c) of the
Ordinance.



Director of Health

25 April 2019

Explanatory Note

Section 125(1)(c) of the Private Healthcare Facilities Ordinance
(Cap. 633) (*PHF Ordinance*) refers to a period to be specified by
the Director of Health under section 125(7) of the PHF Ordinance.
If a person holding a valid certificate of registration of a hospital
issued under section 3 of the Hospitals, Nursing Homes and
Maternity Homes Registration Ordinance (Cap. 165) applies for a
licence for a hospital under the PHF Ordinance within the period—

- (a) the person may only apply for a single licence to include
certain premises associated with the main hospital that
are covered by the certificate, treating the main hospital
and the associated premises as one single private
healthcare facility; and
 - (b) the application fee will be the same as the fee for
renewing a licence for a hospital under the PHF
Ordinance.
2. This Notice specifies that the period begins on 2 July 2019 and ends
on 31 December 2019.

**Private Healthcare Facilities Ordinance (Specification
of Period for Section 126(1)(c)) Notice**

(Made by the Director of Health under section 126(3) of the Private
Healthcare Facilities Ordinance (Cap. 633))

1. Commencement

This Notice comes into operation on the day on which section 126
of the Private Healthcare Facilities Ordinance (Cap. 633) comes
into operation.

2. Specification of period for section 126(1)(c) of Ordinance

The period beginning on 2 July 2019 and ending on 31 December
2019 is specified for the purpose of section 126(1)(c) of the
Ordinance.



Director of Health

25 April 2019

Explanatory Note

Section 126(1)(c) of the Private Healthcare Facilities Ordinance
(Cap. 633) (*PHF Ordinance*) refers to a period to be specified by
the Director of Health under section 126(3) of the PHF Ordinance.
If a person holding a valid certificate of registration—

- (a) that is issued under section 3 of the Hospitals, Nursing
Homes and Maternity Homes Registration Ordinance
(Cap. 165); and
- (b) that relates to a nursing home on the premises listed in
Schedule 10 to the PHF Ordinance,

applies for a licence for a hospital for the premises under the PHF
Ordinance within the period, the application fee will be the same as
the fee for renewing a licence for a hospital under the PHF
Ordinance.

- 2. This Notice specifies that the period begins on 2 July 2019 and ends
on 31 December 2019.

**Private Healthcare Facilities Ordinance (Specification
of Period for Section 128(3)(a)) Notice**

(Made by the Director of Health under section 128(7) of the Private
Healthcare Facilities Ordinance (Cap. 633))

1. Commencement

This Notice comes into operation on the day on which section 128 of the Private Healthcare Facilities Ordinance (Cap. 633) comes into operation.

2. Specification of period for section 128(3)(a) of Ordinance

The period beginning on 2 January 2020 and ending on 30 April 2020 is specified for the purpose of section 128(3)(a) of the Ordinance.



Director of Health

25 April 2019

Explanatory Note

Section 128(3)(a) of the Private Healthcare Facilities Ordinance (Cap. 633) (*PHF Ordinance*) refers to a period to be specified by the Director of Health under section 128(7) of the PHF Ordinance. A person who—

- (a) holds a valid certificate of registration—
 - (i) that is issued under section 3 of the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165); and
 - (ii) that relates to a nursing home on the premises listed in Schedule 10 to the PHF Ordinance; and
- (b) has applied for, but has not been granted, any of the following in relation to all, or a part, of the premises—
 - (i) a licence under the Residential Care Homes (Elderly Persons) Ordinance (Cap. 459);
 - (ii) a licence under the Residential Care Homes (Persons with Disabilities) Ordinance (Cap. 613);
 - (iii) a licence for a private healthcare facility under the PHF Ordinance,

may, within the period, apply to the Director for an exemption permitting the person to operate the nursing home on the premises without a licence.

- 2. This Notice specifies that the period begins on 2 January 2020 and ends on 30 April 2020.

Private Healthcare Facilities Ordinance (Specification of Period for Section 135(1)(b)) Notice

(Made by the Director of Health under section 135(6)(b) of the Private
Healthcare Facilities Ordinance (Cap. 633))

1. Commencement

This Notice comes into operation on the day on which section 135
of the Private Healthcare Facilities Ordinance (Cap. 633) comes
into operation.

2. Specification of period for section 135(1)(b) of Ordinance

The period beginning on 2 January 2020 and ending on 30 April
2020 is specified for the purpose of section 135(1)(b) of the
Ordinance.



Director of Health

25 April 2019

Explanatory Note

Section 135(1)(b) of the Private Healthcare Facilities Ordinance
(Cap. 633) (*Ordinance*) refers to a period to be specified by the
Director of Health under section 135(6)(b) of the Ordinance. If a
person who operates a day procedure centre on 30 November 2018
applies within the period for a licence for a day procedure centre
under the Ordinance, the person must be issued a provisional
licence for the centre if certain conditions are satisfied.

2. This Notice specifies that the period begins on 2 January 2020 and
ends on 30 April 2020.

Private Healthcare Facilities Ordinance (Amendment of Schedule 3) Notice 2019

(Made by the Secretary for Food and Health under section 123 of the Private Healthcare Facilities Ordinance (Cap. 633))

1. Commencement

This Notice comes into operation on the day on which section 123 of the Private Healthcare Facilities Ordinance (Cap. 633) comes into operation.

2. Private Healthcare Facilities Ordinance amended

The Private Healthcare Facilities Ordinance (Cap. 633) is amended as set out in section 3.

3. Schedule 3 amended (classes of specialized services)

Schedule 3—

Add

- “8. Radiotherapy (a) External beam radiotherapy
(b) Brachytherapy
(c) Radionuclide therapy”.



Secretary for Food and Health

25 April 2019

Explanatory Note

Schedule 3 to the Private Healthcare Facilities Ordinance (Cap. 633) sets out different classes of specialized services and the medical procedures corresponding to those classes for determining whether a medical procedure is a scheduled medical procedure for the purposes of a day procedure centre.

2. This Notice amends the Schedule to add radiotherapy as a class of specialized services and certain medical procedures corresponding to the class.