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Bills Committee on Private Healthcare Facilities Bill

Background brief prepared by the Legislative Council Secretariat

Purpose

This paper provides background information on the Private Healthcare Facilities Bill ("the Bill") and gives a brief account of the discussions by the Panel on Health Services ("the Panel") on the Administration's proposals to strengthen regulation of private healthcare facilities.

Background

2. At present, private hospitals, nursing homes and maternity homes are regulated under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165), whereas non-profit-sharing medical clinics are regulated under the Medical Clinics Ordinance (Cap. 343)[1]. These private healthcare facilities are required to register with the Department of Health ("DH"). DH has issued a Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes and a Code of Practice for Clinics Registered under the Medical Clinics Ordinance to set out the respective standards of good practice. Compliance with the relevant requirements is a condition for registration and renewal of registration of these private healthcare facilities.

3. The above two Ordinances were enacted in 1936 and 1963 respectively, to which no substantive amendments have been introduced since 1966 albeit changing landscape of the healthcare market. Separately, the Audit Commission has conducted a review of DH's regulatory control of private hospitals in 2012 and made a number of recommendations in Report No. 59 of

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[1] Under the Medical Clinics Ordinance, clinics do not include, among others, facilities that are managed by any department of the Government and the Hospital Authority, or operated by certain healthcare professionals who have duly registered under other legislation.

the Director of Audit. In the light of the above and to address the increasing public concern over the regulation of high-risk medical procedures performed in ambulatory setting,[2] the Administration established a Steering Committee on Review of the Regulation of Private Healthcare Facilities ("the Steering Committee")[3] in October 2012 to conduct a holistic review of the regulation of private healthcare facilities. The Administration launched in December 2014 a three-month public consultation exercise to gauge the public's views on the proposals put forth in the Consultation Document on Regulation of Private Healthcare Facilities ("the Consultation Document") to revamp the existing regulatory regime for private healthcare facilities. In April 2016, the Administration published the Consultation Report on Regulation of Private Healthcare Facilities ("the Consultation Report") which set out the consultation outcomes and the way forward for putting in place the new regulatory regime.

The Bill

4. The Administration introduced the Bill into the Legislative Council ("LegCo") on 23 June 2017 to provide for the new regulatory regime for four types of private healthcare facilities, namely hospitals, day procedure centres, clinics and health services establishments, which will replace the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance, and the Medical Clinics Ordinance and its subsidiary legislation currently in force. The Bill covers, among others, the licensing scheme; exemption arrangement for small practice clinics; regulatory requirements; mechanism on managing complaints against private healthcare facilities; and incidental and related matters. The key features of the Bill are set out in paragraphs 5 to 23 of the LegCo Brief issued by the Food and Health Bureau on 14 June 2017 (File Ref: FH CR 3/3231/16).

Deliberations of the Panel

5. The Panel discussed the Administration's review of the private healthcare facilities, the Consultation Document, the Consultation Report and related issues

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[2] Two adverse incidents took place in October 2012 and June 2014 causing casualties resulting from the performance of high-risk invasive procedures offered by a beauty service company and a surgical procedure called liposuction provided by a hair transplant centre respectively.

[3] The Steering Committee is underpinned by four working groups, namely (a) Working Group on Differentiation between Medical Procedures and Beauty Services; (b) Working Group on Defining High-risk Medical Procedures/Practices Performed in Ambulatory Setting; (c) Working Group on Regulation of Premises Processing Health Products for Advanced Therapies; and (d) Working Group on Regulation of Private Hospitals.

at a number of meetings in the Fifth and Sixth Legislative Council, and received views from about 130 deputations on various issues of concerns. The Panel was consulted on the legislative proposals on 28 February 2017. The deliberations and concerns of members are summarized in the following paragraphs.

Types of private healthcare facilities to be regulated

6. Members expressed support for the direction of strengthening regulation of private healthcare facilities. They noted that of the four types of private healthcare facilities to be regulated under the new regulatory regime, health services establishments and day procedure centres were two new types of facilities to be subject to statutory regulation. There was a question about whether beauty centres would fall into any of these types of private healthcare facilities. Referring to the Administration's intention to have the regulatory control on clinics be focused on those under the management of incorporated bodies, some members raised concern on the proposed exemption arrangement for those clinics which involved only solo or small group practice, which would in effect exempt about 70% of the medical and/or dental clinics from regulation.

7. The Administration advised that under the legislative proposals, health services establishments were meant to encompass new modes of operation or delivery of medical services that entailed a significant level of risk, such as facilities for conducting clinical trials, whereas day procedure centres were referring to premises that were used for carrying out those medical procedures of higher risks (to be listed in a schedule to the Bill) on patients in an ambulatory setting. There was a view that any amendments to these scheduled medical procedures should be subject to the positive vetting procedure under section 35 of the Interpretation and General Clauses Ordinance (Cap. 1) such that LegCo would have sufficient time to examine the amendments. According to the Administration, its intention was for the amendments be subject to the negative vetting procedure under section 34 of the General Clauses Ordinance. This would facilitate amendments more efficiently when regulatory need arose so as to safeguard public health. That said, it would consider any views that Members might have during the scrutiny of the Bill.

8. Members were concerned about the regulatory control on private medical and clinical laboratories operated outside hospital setting for processing cells, tissues and health products for advanced therapies, in particular those which undertook aseptic work. The Administration advised that under the Supplementary Medical Professions Ordinance (Cap. 359) and its subsidiary legislation, medical laboratory technologists ("MLTs") had to practice their profession in premises which were considered to be suitable for practice by the MLT Board. In addition, a corporation carrying on the business of practicing

the MLT profession should have at least one professionally qualified director, and all employees practicing the MLT profession had to be registered in respect of the profession. The Working Group on Regulation of Premises Processing Health Products for Advanced Therapies under the Steering Committee had recommended introducing a new piece of legislation with an overarching authority to regulate cells, tissues and health products for advanced therapies. Subject to further studies and deliberation with the parties concerned, a new and standalone legislative framework would be drawn up, as a separate exercise, in future. In the meantime, DH would continue to regulate, under the existing regulatory regimes, those health products for advanced therapies that fell under the definition of pharmaceutical products.

9. Concern was raised as to the reason for transferring nursing homes for elderly persons, which were currently regulated under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance, to the ambit of the Residential Care Homes (Elderly Persons) Ordinance (Cap. 549). The Administration advised that residents of these registered nursing homes did not require continuous and round-the-clock medical care. The great majority of them received treatment from visiting medical practitioners and/or dentists when needed. Hence, these nursing homes were not medical facilities and should not be regarded as such under the new regulatory regime.

Proposed requirements on price transparency

10. Members expressed grave concern about the high level of charges of some private clinics and hospitals. There was a view that the Administration should set up an independent mechanism for handling medical disputes over the excessive service charges of doctors. Concern was also raised that in the absence of a mechanism to regulate the price setting of the private hospitals, charges of private hospital services would continuously be set at a high level given the limited supply of private hospital beds and the current medical manpower constraint. In addition, there might be a rise in the medical cost following the future introduction of the Voluntary Health Insurance Scheme which aimed at enhancing the accessibility, quality and transparency of health insurance products and encouraging a greater use of private healthcare services.

11. The Administration advised that there would be no direct regulation of price setting for hospital services. Under the proposed regulatory regime, the private healthcare facilities had to make available to the public information about the prices of specified chargeable items and services provided in the private healthcare facility. In particular, private hospitals would be required to put in place a budget estimate system, and to publish historical statistics on fees and charges in respect of the specified treatments and procedures. It was expected that the gradual enhancement in private hospital capacity, together

with these proposed regulatory requirements on price transparency would help promote market competition and contain medical cost. A pilot programme for enhancing price transparency for private hospitals ("the Pilot Programme") had already been rolled out on 1 October 2016 to try out the price transparency measures before they were implemented after the passage of the Bill. All the 11 private hospitals had participated in the Pilot Programme and would (a) provide budget estimates on 24 common and non-emergency operations or procedures as recommended by DH for the patients concerned before hospital admission;[4] (b) publicize on the hospitals' websites the fee schedules of six major chargeable items as recommended by DH;[5] and (c) publicize on the hospitals' websites the historical bill sizes of 12 common operations or procedures as recommended by DH.[6]

12. Members in general were in support of the Pilot Programme. However, there were views that the historical bill sizes statistics provided by private hospitals should cover all the 24 operations or procedures recommended for the provision of budget estimates. In addition, a mechanism should be put in place to monitor the profit margin of private hospitals so as to prevent excessive pricing, and patients should be provided with estimates on both doctor's fees and hospital charges in order to offer better budget certainty to patients covered by private hospital insurance. For the latter, private hospitals should set up an electronic platform with pricing information on the major chargeable items to facilitate private doctors to provide the relevant budget estimates for patients. Subsequently, the Administration advised that at the suggestion of members, DH was developing a webpage to provide the list of common operations or procedures for provision of budget estimates, as well as enabling patients to have convenient access to the historical bill sizes statistics released by private hospitals on their respective websites.

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4 The operations/procedures recommended for the provision of budget estimates included hernia repair; herniotomy; thyroidectomy; haemorrhoidectomy; cholecystectomy; colectomy; breast lump excision; colposcopy; hysterectomy; dilation and curettage; ovarian cystectomy; gastroscopy and colonoscopy with or without polypectomy; cystoscopy with or without biopsy; bronchoscopy with or without biopsy; tonsillectomy; direct laryngoscopy with or without vocal cord polyp biopsy; micro-laryngoscopy; LASIK; knee arthroscopy; laminectomy; spine fusion; open reduction and internal fixation of various fractures; carpal tunnel release; and trigger finger release.

5 The categories of chargeable items recommended for the publication of fee schedules included charges on ward accommodation; operating theatre charges; charges for common nursing procedures' charges for outpatient and/or specialist clinics consultations; charges for investigative and treatment procedure; and charges for medical reports and photocopies of medical records.

6 The operations/procedures recommended for the publication of historical bill sizes statistics included circumcision; hernia repair; vaginal delivery; caesarean section; colposcopy; gastroscopy with or without polypectomy; colonoscopy with or without polypectomy; gastroscopy and colonoscopy with or without polypectomy; tonsillectomy; phacoemulsification and intraocular lens implantation; LASIK; and Knee arthroscopy.

Sentinel events and complaints management

13. Noting that private hospitals were currently required to develop their own policies and mechanisms to identify, report and manage sentinel events, members had long urged the Administration to devise a uniform mechanism for all private hospitals to follow. There should also be a regulatory mechanism for investigating complaints and medical incidents relating to private hospitals. Members noted that it was proposed in the Consultation Document that private hospitals should establish a comprehensive sentinel events management system to strengthen internal quality assurance and enable the regulatory authority to gain access to relevant information for regulatory purposes. This apart, a two-tier complaints handling system was proposed to be set up for the handling of complaints against private hospitals. Some members held the view that the proposal should be applied on other types of private healthcare facilities.

14. According to the Administration, having taken into account members' views and the views received during the public consultation exercise, it would propose under the Bill the setting up of a two-tier complaints management system to handle complaints against all the four types of private healthcare facilities. The first-tier would be at the service delivery level where private healthcare facilities should manage complaints at source. At the second-tier, an independent Commission on Complaints against Private Healthcare Facilities ("Complaints Committee") would be established as a centralized mechanism to look into complaints unresolved at service delivery level by the private healthcare facilities concerned. In response to a member's suggestion of putting in place an appeal mechanism under the complaints management system, the Administration advised that the second-tier Complaints Committee could provide an appropriate check and balance in this regard.

15. Members noted that under the legislative proposals, the chairperson and all members of the Complaint Committee (in the range of not less than 24 and not more than 48 members) would be appointed by the Secretary for Food and Health, with at least half of the members being lay persons. Some members expressed concern about whether representatives from the beauty sector could serve as lay members therein. According to the Administration, its initial thought was that these lay members might include representatives from patients groups and the Consumer Council, as well as members of other professions or business sectors.

Penalties for private healthcare facilities

16. Members had long expressed concern that at present, a private hospital which was found guilty of an offence under the Hospitals, Nursing Homes and

Maternity Homes Registration Ordinance would in respect of each offence only be liable on summary conviction to a fine of $1,000. They considered it necessary to increase the penalty for offences under the Ordinance to enhance the deterrent effect. The Administration advised that the Bill would provide for the regulatory measures, such as empowering DoH to suspend a service in a private healthcare facility or even suspend or cancel a licence for a private healthcare facility, to tackle breaches of the law and the licensing requirements including relevant codes of practice. The Bill would also provide for offences for serious and intentional non-compliance with the proposed requirements. Licensees and chief medical executives, who played significant roles in managing the private healthcare facilities concerned, could be subject to sanctions for certain contraventions.[7]

Standards for clinics and day procedure centres

17. Noting that different types of private healthcare facilities under the new regulatory regime would each be subject to a set of regulatory standards which would be promulgated in the form of codes of practice, some members called on the Administration to ensure that the regulatory standards for clinics would not be pitched at such a high level that clinics of small and medium sizes would find it difficult, if not impossible, to comply with. There was also a view that the Administration should gauge the view of the beauty industry and those frontline medical practitioners who engaged in cosmetic procedures in formulating the regulatory framework for high-risk cosmetic procedures.

18. According to the Administration, a Project Steering Committee on Standards for Ambulatory Facilities had been jointly set up by DH and the Hong Kong Academy of Medicine ("the Academy of Medicine") in mid-2015 to give advice on the standards for clinics and to draw up standards for day procedure centres. The standards for day procedure centres comprised the Core Standards which applied to all day procedure centres, and the Procedure-specific Standards which applied to day procedure centres providing the specific class of procedures to which the standards related. The Core Standards had been promulgated in late 2016, and the Procedure-specific Standards were under preparation. For clinics, DH was consulting stakeholders on the draft version of the Standards for Medical Clinics, which had been drafted with reference to the existing Code of Practice for Clinics Registered under the Medical Clinics Ordinance and relevant standards in overseas jurisdictions. Before the introduction of the statutory licensing system under the new regulatory regime, these Standards would serve as professional guidance for operators and medical and dental professions.

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[7] According to the legislative proposals, the licensee of a private healthcare facility is wholly responsible for the operation of the facility, and must appoint a chief medical executive to take charge of the day-to-day administration of the facility.

Interim measures to be taken before enactment of the Bill

19. Given the lead time required for introducing a new regulatory regime by legislation, question was raised about the short to interim term administrative measures to be taken by the Administration to supplement the existing regulatory regime. According to the Administration, DH would continuously review the Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes and the Code of Practice for Clinics Registered under the Medical Clinics Ordinance, with a view to enhancing existing regulatory requirements in the regulatory regime for these private healthcare facilities. Separately, an administrative listing system for day procedure centres would be introduced to enhance the monitoring of these centres. A new Office for Regulation of Private Healthcare Facilities had been set up in DH in April 2016 on a time-limited basis for three years to, among others, implement the interim measures and undertake preparatory work for a new registration system for private healthcare facilities.[8]

Recent development

20. In May 2017, DH and the Academy of Medicine have updated the Core Standards, and promulgated the Procedure-specific Standards for Day Procedure Centres (Surgery and Anaesthesia & Sedation).[9]

Relevant papers

21. A list of the relevant papers on the LegCo website is in the **Appendix**.

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[8] The Office for Regulation of Private Healthcare Facilities consists of a Licensing Section to oversee the licensing and inspection functions of healthcare institutions registered under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance and the Medical Clinics Ordinance; and a new Planning and Development Section to support the legislative review exercise, implement interim measures and undertake preparatory work for a new registration system for private healthcare facilities, as well as to support the Food and Health Bureau in promoting private hospital development.

[9] The Core Standards for Day Procedure Centres and the Procedure-specific Standards for Day Procedure Centres (Surgery and Anaesthesia & Sedation), which are in in English version only, can be assessed at the website of DH (For Core Standards: http://www.dh.gov.hk/english/main/main_orphf/files/CS_DPC.pdf; for Procedure-specific Standards:http://www.dh.gov.hk/english/main/main_orphf/files/Procedure_Specific_Standards_for_Surgery_and_Anaesthesia.pdf). The two sets of Standards can also be assessed at the website of HKAM (http://www.hkam.org.hk).

Appendix

Relevant papers on the Private Healthcare Facilities Bill

Committee	Date of meeting	Paper
Panel on Health Services	26.10.2012 (Item I)	Agenda Minutes CB(2)143/12-13(01) CB(2)315/12-13(01)
	27.11.2012 (Item I)	Agenda Minutes CB(2)643/12-13(01)
	18.11.2013 (Item IV)	Agenda Minutes CB(2)532/13-14(01) CB(2)902/13-14(01)
	23.12.2013 (Item I)	Agenda Minutes
	21.7.2014 (Item II)	Agenda Mintues
	13.1.2015 (Item I)	Agenda Minutes
	17.2.2015 (Item I)	Agenda Minutes
	21.12.2015 (Item III)	Agenda Minutes
	18.4.2016 (Item V)	Agenda Minutes
	21.11.2016 (Item IV)	Agenda Minutes
	28.2.2017 (Item VI)	Agenda

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