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Panel on Health Services

Background brief prepared by the Legislative Council Secretariat for the meeting on 28 February 2017

Legislative proposals for regulation of private healthcare facilities

Purpose

This paper provides background information 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, and highlights the views expressed by members of the Panel on Health Services ("the Panel") on the proposals.

Background

2. At present, private hospitals, nursing homes and maternity homes are regulated under the Hospital, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165), whereas non-profit-making medical clinics are regulated under the Medical Clinics Ordinance (Cap. 343). These private healthcare institutions are required to register with the Department of Health ("DH") and subject to DH's regulations on accommodation, staffing and equipment. In this regard, 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 institutions.

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. 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 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,[1] the Government established a Steering Committee on Review of the Regulation of Private Healthcare Facilities ("the Steering Committee")[2] in October 2012 to conduct a holistic review of the regulation of private healthcare facilities. In view of the findings and recommendations of the review, the Administration launched in December 2014 a three-month public consultation exercise to gauge the public's views on the following proposals put forth in the Consultation Document to revamp the existing regulatory regime for private healthcare facilities:

(a) to enact a new piece of legislation to replace the Hospital, Nursing Homes and Maternity Homes Registration Ordinance and the Medical Clinics Ordinance;

(b) to regulate facilities providing high-risk medical procedures in ambulatory setting[3] and facilities providing medical services under the management of incorporated bodies;

(c) to define "hospital" more accurately so that community-based centres such as nursing homes providing care without or with minimal medical involvement will no longer be caught under regulation targeting medical facilities;

(d) to adopt 19 regulatory aspects encompassing five key areas, namely corporate governance, standard of facilities, clinical quality, price transparency and sanctions as essential regulatory requirements for private hospitals, with suitable adaptation commensurate with the lower degree of complexity and risks of medical services provided in other private healthcare facilities; and

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1 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.

2 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.

3 According to the Consultation Document, ambulatory setting means (a) the patient is discharged in the same calendar day of admission; and (b) the expected total duration of procedure and recovery requiring continuous confinement within the facility does not exceed 12 hours.

(e) to confer the regulatory authority with enhanced regulatory powers for regulating private healthcare facilities.

4. The Administration published the Consultation Report on Regulation of Private Healthcare Facilities ("the Consultation Report") in April 2016. According to the Administration, there was broad support for the proposals. It would take forward the proposals along the general direction set out in the Consultation Document, with refinements to some specific proposals having taken into account the views received in the consultation exercise. These included, among others, the renaming of the second and third categories of private healthcare facilities to be regulated as referred to in paragraph 4(b) above as day procedure centres and clinics under the management of incorporated bodies respectively.

Deliberations of the Panel

5. The Panel discussed the Administration's review of the private healthcare facilities, the Consultation Document and the Consultation Report at a number of meetings in the Fifth Legislative Council, and received views from about 130 deputations on various issues of concerns. It also discussed the directorate staffing proposal for the new Office for Regulation of Private Healthcare Facilities to be set up under DH at a meeting in December 2015. The deliberations and concerns of members are summarized in the following paragraphs.

Timetable for legislative amendments

6. Members were generally of the view that the existing regulatory regime for private healthcare facilities was far from effective in ensuring the safety and quality of private healthcare services and protecting consumer rights. Agreeing with the need to modernize the regulatory regime, they urged the Administration to expeditiously introduce the relevant legislative proposals so as to better safeguard the interest of patients. 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.

7. Members were advised that with broad support from the community to strengthen the regulation over private healthcare facilities during the public consultation exercise, the Administration would implement the proposals for revamping the existing regulatory regime through replacing the Hospital, Nursing Homes and Maternity Homes Registration Ordinance and the Medical

Clinics Ordinance by a new piece of legislation. Before the enactment of the proposed new legislation, DH would 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. As regards day procedure centres, it was proposed that an administrative listing system for these facilities would be introduced as an interim measure to monitor them before the statutory registration came into effect.

8. Members noted that the original target of the Administration as set out in the Consultation Document was to introduce the legislative proposal into the Legislative Council ("LegCo") in 2015-2016. At the meeting on 21 December 2015, members were advised that the latest plan of the Administration was to introduce the bill into LegCo in the 2016-2017 legislative session. In view of the wide spectrum of professional responsibilities relating to the regulation of private healthcare facilities as well as the complexity and sensitivity of the legislation exercise for revamping the regulatory framework, a new Office for Regulation of Private Healthcare Facilities was proposed to be set up in DH on a time-limited basis for three years, and the existing Office for Registration of Healthcare Institutions in DH would subsume under the new office.

Proposed requirements on price transparency

9. Members expressed grave concern about the high level of charges of private hospitals. Some members were of the view that the listing out of the charges for individual service items could not provide certainty and predictability in terms of the medical costs to be borne by the patients, as the need to utilize the services, and thereby the actual charges, depended on the outcomes of consultation and investigation. They considered that the Administration should encourage doctors to reach an understanding with individual patients on the medical costs involved before the performance of treatments and procedures. There was a view that the Administration should set up an independent mechanism for handling medical disputes over the excessive service charges of doctors.

10. Members noted from the Consultation Document that private hospitals were required under the proposed new regulatory regime for private healthcare facilities to enhance their price transparency on four regulatory aspects, namely, (a) making the fee schedules covering all chargeable items publicly available; (b) ensuring that patients were provided with the estimated total charges for the whole course of investigative procedures or elective, non-emergency therapeutic operations or procedures for known diseases on or before admission;

(c) voluntarily providing recognized service packages which were identically and clearly defined standard services provided at packaged charge; and (d) publishing key historical statistics on their actual bill sizes for common treatments or procedures as prescribed by the regulatory authority.

11. Members in general expressed support to the proposed requirements to enhance price transparency of private hospitals so as to enable prospective patients to be better informed. However, there was a concern that there was no mechanism to regulate the price setting of the private hospitals. The charges of private hospital services might still 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 introduction of the proposed Voluntary Health Insurance Scheme ("VHIS") which aimed at enhancing the accessibility, quality and transparency of health insurance products and encouraging a greater use of private healthcare services. The Administration advised that there would be no direct regulation of price setting for hospital services. It was expected that the gradual enhancement in private hospital capacity, together with the proposed regulatory requirements on price transparency would help promote market competition and contain medical cost.

12. At the Panel meeting on 21 November 2016, members were advised that a pilot programme for enhancing price transparency for private hospitals ("the pilot programme") had been rolled out on 1 October 2016 to try out the price transparency measures before they were implemented under the new regulatory regime for private healthcare facilities. All the 11 private hospitals had participated in the pilot programme and would (a) provide budget estimates on 24 common and non-emergency operations/procedures as recommended by DH[4] for patients concerned before hospital admission; (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

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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.

12 common operations/procedures as recommended by DH[6].

13. 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/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 to patients. There was also a suggestion that a webpage should be set up by DH to enable patients to have convenient access to the up-to-date fee schedules, recognized service packages and historical bill sizes statistics released by private hospitals.

Complaints management

14. Noting that private hospitals were currently required to develop their own policies and mechanisms to identify, report and manage sentinel events, members 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.

15. Members were advised of the Administration's proposal of establishing a two-tier complaints handling system, under which private hospitals were required to set up the first-tier complaints management at the service delivery level to manage complaints at source according to a standardized complaints handling mechanism prescribed by the regulatory authority. An Independent Committee on Complaints against Private Hospitals ("the Independent Committee") would be established to handle unresolved complaint cases at the second-tier through a centralized and independent mechanism.

16. On members' concern about the power of the Independent Committee, the Administration advised that the Independent Committee would be empowered to investigate and review all appeal cases and make recommendations to the regulatory authority for consideration and follow-up actions. Some members considered that the Independent Committee should introduce mediation as an

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[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.

option to handle complaints. There was also a view that non-hospital private healthcare facilities should also be subject to a similar complaints handling system; otherwise, protection for consumers in this regard might be undermined.

17. The Administration explained that a two-tier complaints handling mechanism would incur considerable amount of administrative workload and compliance costs for non-hospital private healthcare facilities which had a much smaller scale of operation. The burden of complying with such a comprehensive mechanism would unavoidably drive up cost of service which would eventually be borne by consumers. A simplified mechanism was therefore proposed for non-hospital private healthcare facilities. Having taking into account the views received during the public consultation exercise, the Administration would explore the feasibility of establishing an Independent Committee on Complaints against Private Healthcare Facilities which would be empowered to look into complaints unresolved at service delivery level by private hospitals, day procedure centres and clinics under the management of incorporate bodies.

Penalties for private healthcare facilities

18. Members had long expressed concern that at present, private hospital which was found guilty of an offence under the Hospital, 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.

19. The Administration agreed that increasing the sanctions for private hospitals were necessary and justified. A set of sanctions commensurated with the severity of offences, covering unregistered operation and non-compliance of other provisions in the legislation, would be imposed under the new regulatory regime. Having considered the views received during the public consultation exercise, the Administration would critically review the scope and level of penalties of the proposed sanctions in the legislative exercise. Acts which might be considered offences included private healthcare facilities without licence, willfully obstructing public officers in performing duties, failing to comply with orders of suspension, etc. There was a view that other than the person appointed as person-in-charge of the private healthcare facilities concerned, the owner(s) should also be liable for the default.

Standards for day procedures

20. Members were gravely concerned that with the evolution of medical technology, some high-risk and complicated medical treatments/procedures

which were previously performed in the hospital setting were currently performed at ambulatory medical centres and non-clinical facilities. However, these premises were not covered in the existing regulatory framework of private healthcare premises. They urged the Administration to introduce a statutory registration system for these premises. There was another suggestion that DH should make available a list of these premises for public inspection.

21. Members noted the latest proposal of the Administration was that any medical procedure defined as high risk in respect of (a) risk of procedures, (b) risk of anaesthesia involved, and (c) patients' conditions should be performed only in regulated ambulatory facilities or hospitals by qualified health professionals or personnel under their supervision. Day procedure centres should be regulated by a statutory registration system and subject to a set of core facility standards and requirements that covered the management of the facility, physical conditions, service delivery and care process, infection control and resuscitation and contingency. At the meeting on 18 April 2016, members were advised that DH had, in cooperation with the Hong Kong Academy of Medicine ("HKAM"), established a Project Steering Committee on Standards for Ambulatory Facilities in April 2015 to steer the development and promulgation of facility standards for day procedure centres. Seven tasks force had been set up to formulate standards on service areas of services which included anaesthesia and sedation; surgery; endoscopy; dental procedures; chemotherapy; haemodialysis; and interventional radiology and lithotripsy. These standards would provide guidance to the profession and facility operators before the statutory registration system was in place. An administrative listing system for day procedure centres would also be put in place before the introduction of the mandatory registration system.

22. There was 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.

Regulation of clinics under the management of incorporated bodies

23. Members were advised that as there had long been concerns over "medical groups" or "managed care organizations" operated in form of incorporated bodies, in which non-medical investors or managers would take part in the operations of private healthcare facilities, it was proposed that clinics under the management of incorporated bodies (including incorporated companies, registered societies and statutory bodies in which non-medical investors or managers would take part in the operation of these facilities) should be subject to regulation. Under the proposed regulatory regime, a

person-in-charge should be appointed for each regulated private healthcare facilities. The person-in-charge would be held accountable for breaches or non-compliance of the private healthcare facilities concerned.

Regulation of premises processing health products for advanced therapy

24. Members were concerned about the potential risk associated with health products for advanced therapies. Question was raised about the existing regulatory control on private medical and clinical laboratories for processing cells, tissues and health products for advanced therapies, in particular those which undertook aseptic work, to safeguard the health of patients.

25. The Administration advised that laboratories within private hospitals were subject to regulation under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance and the Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes. Pathology services of these hospitals had to have a pathology specialist appointed to be in charge of the laboratory services and a Part I medical laboratory technologist ("MLT") assigned to take charge of the day-to-day operation. For private laboratories operating outside hospital setting, they were subject to the relevant provisions under the Supplementary Medical Professions Ordinance (Cap. 359) and its subsidiary legislation. Under the Ordinance, MLTs had to practice his 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.

26. Members subsequently noted that the Working Group on Regulation of Premises Processing Health Products for Advanced Therapies had recommended introducing a new piece of legislation with an overarching authority to regulate cells, tissues and health products for advanced therapies through a comprehensive set of regulatory controls. Given that the regulation of premises processing health products for advanced therapies involved cutting edge and quickly evolving sector in healthcare technology, more time and efforts were required to look into each aspect of the proposed regulation. Subject to further studies and deliberation with parties concerned, a new and standalone legislative framework would be drawn up, as a separate exercise, in future. In the meantime, DH would step up its efforts to increase the awareness of the trade and public on the potential risk associated with health products for advanced therapies. DH would also continue to regulate, under existing regulatory regimes, those health products for advanced therapies that fell under the definition of pharmaceutical products, including the registration of products, licensing of facilities, and import/export controls.

Recent developments

27. In November 2016, DH and the HKAM promulgated a set of core standards for day procedure centres.[7] These standards will serve as guidance for operators of the day procedure centres as well as the medical and dental professions.

28. The Administration will brief the Panel on the details of the legislative proposals for regulation of private healthcare facilities on 28 February 2017.

Relevant papers

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

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[7] The set of core standards for day procedure centres, which is in English version only, can be assessed at the website of DH (http://www.dh.gov.hk/english/main/main_orphf/files/CS_DPC.pdf) and the website of HKAM (http://www.hkam.org.hk/announcement/Core_Standards_for_Day_Procedure_Centres.pdf).

Appendix

Relevant papers on the legislative proposal for regulation of private healthcare facilities

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

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