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Panel on Health Services

Updated background brief prepared by the Legislative Council Secretariat for the special meeting on 13 January 2015

Regulation of private healthcare facilities

Purpose

This paper summarizes the concerns of the members of the Panel on Health Services ("the Panel") on issues relating to the regulation of private healthcare facilities.

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.

Separately, there were two adverse incidents 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 ("the adverse incidents"). The incidents have aroused wide public concern over the regulation of high-risk medical procedures. To address public concerns as well as further enhance the safety and quality of private healthcare services, the Government established a Steering Committee on Review of the Regulation of Private Healthcare Facilities ("the Steering Committee") on 11 October 2012 to conduct a holistic review of the regulation of private healthcare facilities. The Steering Committee is underpinned by four working groups, namely (a) Working Group on Differentiation between Medical Procedures and Beauty Services ("Working Group 1"); (b) Working Group on Defining High-risk Medical Procedures/Practices Performed in Ambulatory Setting ("Working Group 2"); (c) Working Group on Regulation of Premises Processing Health Products for Advanced Therapies ("Working Group 3"); and (d) Working Group on Regulation of Private Hospitals ("Working Group 4").

Deliberations of the Panel

4. The Panel held a number of meetings between 2009 and 2014 to discuss issues relating to the regulation of different types of private healthcare facilities, and receive views of deputations at five of these meetings. At the meeting on 21 July 2014, the Administration briefed members on the key recommendations on review of regulation of private healthcare facilities proposed by the four Working Groups and endorsed by the Steering Committee. The deliberations and concerns of members are summarized below.

Timetable for legislative amendments

5. 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 review and modernize the regulatory regime, they urged the Administration to expeditiously complete the review and 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.

6. The Administration advised that a public consultation exercise on the revamped regulatory regime for private healthcare facilities would be launched by the end of 2014. Subject to the outcome of the public consultation, the

Administration planned to proceed to the relevant legislative procedures in the 2015-2016 legislative session. 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 ambulatory facilities providing high-risk medical procedures, it was proposed that an administrative listing system for facilities providing high-risk medical procedures would be introduced as an interim measure to monitor these facilities before the statutory registration came into effect.

Differentiation between medical procedures and beauty services

7. At the meeting on 18 November 2013, members were advised of the recommendations put forth by Working Group 1 as endorsed by the Steering Committee that procedures involving injections, mechanical or chemical exfoliation of the skin below the epidermis and hyperbaric oxygen therapy should be performed by registered medical practitioners; and that dental bleaching should be performed by registered dentists. Members in general agreed that beauty service providers who were not themselves registered medical practitioners or registered dentists should refrain from performing these procedures in view of their inherent risks. Some members drew to the Administration's attention that the adverse incident was caused by professional misconduct on the part of the medical practitioner concerned, and enforcement actions against persons who practised medicine/surgery or dentistry without registration should be stepped up. They urged the Administration to ensure that registered medical practitioners and registered dentists, in particular those associating with beauty service companies, would act in the patients' best interests when performing the aforesaid procedures.

8. According to the Administration, DH would strengthen market surveillance and collaborate with the Consumer Council to identify suspected violation of the Medical Registration Ordinance (Cap. 161) and the Dentists Registration Ordinance (Cap. 156). DH would also issue letters to registered medical practitioners and registered dentists reminding them to strictly observe the Code of Professional Conduct issued by their Councils when they provided cosmetic procedures in their professional practice, and issue an advisory note to beauty service providers to remind them to refrain from these procedures.

9. For those cosmetic procedures involving the use of medical devices, particularly energy-emitting devices, members noted in the context of discussing the latest development of the proposed regulatory framework for medical devices at the meeting on 16 June 2014 that, as recommended by Working

Group 1, the Administration would engage an external consultant to conduct a more detailed study to examine overseas experience and practices of, and the scope of control on the use of, these medical devices. Some members were of the view that beauticians fulfilling a set of skills and competency requirements should be allowed to operate these medical devices, such as intense pulsed light equipment, when certain conditions were satisfied, say, they were working under the supervision of registered medical practitioners.

Regulation of ambulatory facilities providing high-risk medical procedures

10. 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.

11. At the meeting on 21 July 2014, members noted the recommendations made by Working Group 2, among others, 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. It was proposed that ambulatory facilities where high-risk medical procedures were performed should be regulated by a statutory registration system and subject to a set of core facility standards and requirements. As an interim measure, DH would work with the Hong Kong Academy of Medicine to establish a mechanism for setting standards required of facilities providing specific classes of high-risk procedures. These procedure-specific standards would be promulgated to the profession as guidance before they became mandatory when the statutory registration system was in place. An administrative listing system for facilities providing high-risk medical procedures in ambulatory setting would also be put in place before the introduction of the mandatory registration system.

Regulation of premises processing health products for advanced therapy

12. 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.

13. 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.

14. Members subsequently noted that Working Group 3 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. 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.

Regulation of private hospitals

Price transparency

15. Members expressed deep concern about the unreasonably high level of charges of the existing private hospitals. They urged the Administration to enhance transparency of charges of private hospitals to safeguard patients' interests. Some members suggested that consideration could be given to requiring private hospitals operating on lands granted at nil or nominal premium to introduce separate pricing for Hong Kong residents and non-Hong Kong residents.

16. Members considered that while private hospitals were currently required to make available a schedule of charges for reference by the public, 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. There was a suggestion 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.

17. The Administration advised that as recommended by Working Group 4, apart from making available a fee schedule setting out all charges that might be levied, private hospitals would be required to implement a uniform quotation system for reference of patients on or before admission to the hospitals, and offer Recognized Service Packages for common operations or procedures on known diagnosis for easy consumption of the public. In addition, it was proposed that private hospitals should develop a database of key historical statistics on their actual bill sizes for common treatments or procedures that were reportable as prescribed by the regulatory authority.

Handling of sentinel events

18. Members were concerned about the different criteria for disclosing sentinel events in public and private hospitals. They urged the Administration to remove the discrepancies whereby the Hospital Authority would consider disclosing a sentinel event in public hospitals if it had an immediate major impact on the public or involved a patient's death, whereas DH would consider disclosing a sentinel event in private hospitals if it had a major impact on the public healthcare system, or if it constituted a persistent public health risk or involved a large number of patients.

19. The Administration advised that efforts had been made by DH to align different descriptions of reported sentinel events between public and private hospitals. Frontline staff members of private hospitals were encouraged to report a medical incident in an open manner, so that lessons could be learnt from the events to prevent similar events from happening in the future. Noting that private hospitals were 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. Members were subsequently advised of the recommendations of the Working Group 4 that private hospitals should establish a comprehensive sentinel events management system and report sentinel events to regulatory authority on a mandatory basis. The regulatory authority should also be empowered to gain access to records and documents in connection with sentinel events for regulatory purposes.

Penalty for offences under the Ordinance

20. 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. The Administration agreed that increasing the sanctions for private hospitals were necessary and justified. It was proposed that a set of sanctions commensurated with the severity of offences, covering unregistered operation and non-compliance of other provisions in the legislation, should be imposed.

Regulation of facilities providing medical services in different organizational forms

21. Members expressed dissatisfaction with the lack of regulation of companies providing healthcare intermediary service. They were gravely concerned that the commercial interests and drive to contain costs among the healthcare intermediary service providers might induce the healthcare service providers to compromise their professional autonomy in the treatment of patients. The Panel passed a motion at its meeting on 20 May 2013, urging the Government to immediately study regulating healthcare intermediaries by legislation, so as to protect the healthcare rights of patients.

22. The Administration advised that doctors were under obligation to ensure that their medical services were up to the professional standards stipulated by the Medical Council of Hong Kong in the Code of Professional Conduct for the Guidance of Registered Medical Practitioners. This obligation would not be affected by the payment arrangement between the doctors and the patients or who paid or settled the fees for the patients. That said, the Steering Committee would look into the modus operandi of medical services offered under different organization forms, including professional partnership, group practice under different ownership and management structure (healthcare intermediary schemes being one of them) to ascertain whether difference in organization forms would pose risks to patient safety and care quality. Members were subsequently advised of the Administration's proposal to regulate facilities providing medical services under the management of incorporated bodies, given that registered medical practitioners practising there did not have full control of these private healthcare facilities in ensuring effective governance and maintaining high service quality.

Recent development

23. On 15 December 2014, the Administration published the Consultation Document on Regulation of Private Healthcare Facilities. The consultation exercise will last for three months until 16 March 2015. The Consultation Document covers the following proposals 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 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

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

Relevant papers

24. A list of the relevant papers on the Legislative Council website is in the **Appendix**.

Council Business Division 2
Legislative Council Secretariat
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Appendix

Relevant papers on regulation of private healthcare facilities

Committee	Date of meeting	Paper
Panel on Health Services	9.11.2009 (Item IV)	Agenda Minutes CB(2)647/09-10(01)
	14.6.2010 (Item IV)	Agenda Minutes CB(2)198/10-11(01)
	14.11.2011 (Item V)	Agenda Minutes
	12.12.2011 (Item VI)	Agenda Minutes CB(2)1027/11-12(01)
	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)
	18.12.2012 (Item I)	Agenda Minutes CB(2)341/13-14(01) CB(2)383/12-13(01) CB(2)888/12-13(01)
	20.5.2013 (Item III)	Agenda Minutes
	18.11.2013 (Item IV)	Agenda Minutes CB(2)532/13-14(01) CB(2)902/13-14(01)

Committee	Date of meeting	Paper
	23.12.2013 (Item I)	Agenda Minutes
	16.6.2014 (Item IV)	Agenda CB(2)2025/13-14(01) *(Circulated to members only)*
	21.7.2014 (Item II)	Agenda

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