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Panel on Health Services

Background brief prepared by the Legislative Council Secretariat for the meeting on 21 July 2014

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 ("the Code") 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, an adverse incident in early October 2012 causing casualties resulting from the performance of high-risk invasive procedures offered by a beauty service company ("the adverse incident") has 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 which are respectively responsible for (a) differentiation between medical procedures and beauty services; (b) defining high-risk medical procedures/practices performed in an ambulatory setting; (c) regulation of premises processing health products for advanced therapy; and (d) regulation of private hospitals.

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. The deliberations and concerns of members are summarized below.

<u>The review of the Steering Committee</u>

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. There was a view that the Steering Committee should engage the trade and the public in the review process.

6. The Administration advised that given the wide range and complexity of issues to be examined by the Steering Committee, the review was expected to take about a year to complete. The plan of the Administration was to consult the public on the recommendations put forward by the Steering Committee. It would then proceed to the legislative procedures as and when necessary.

Differentiation between medical procedures and beauty services

7. At the meeting on 18 November 2013, members were advised of the recommendations put forth by the Working Group on Differentiation between Medical Procedures and Beauty Services ("the Working Group") 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 also 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 the Administration's original proposal was to restrict the operation of Class 3B and Class 4 high-power medical laser to statutorily registered healthcare professionals; and allow only trained personnel who had passed the intense pulsed light trade test run by authorized institutes to operate intense pulsed light equipment if they were not statutorily registered healthcare professionals. Taking on board the Working Group's recommendation, the Administration would now 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. Noting that the study would aim to develop a set of criteria for determining the type of personnel and the level of competence required to operate specified

types of devices, some members suggested that beauticians fulfilling a set of skills and competency requirements should be allowed to operate these devices 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.

11. According to the Administration, the Steering Committee would, among others, review the scope of regulation of private healthcare facilities, including whether to cover private healthcare facilities other than private hospitals, nursing homes and non-profit-making medical clinics in the regulatory regime, and also study whether to place any premises which conduct high-risk medical treatments/procedures under regulatory control. It could not be ruled out that these premises would be subject to licensing control in the future.

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. 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.

Regulation of private hospitals

Price transparency

14. 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.

15. The Administration stressed that it had no intention of regulating the level of charges of private hospitals. It was also not appropriate for it to regulate the level of charges of profit-making hospitals developed on land acquired through land sale under the free market principle. At present, the Code required private hospitals to, among other things, have a schedule of charges for reference by the public. DH would ensure compliance of private hospitals with the Code and that private hospitals would publish and update their pricing information for information of the public and patients. Private hospitals were also required to submit audited financial report information to DH under the Code.

16. Members considered that the requirement of listing out 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 while it understood the call of members of the public to enhance price transparency of private hospitals, it noted the concern of some private hospitals that packaged pricing was not feasible for all hospital admissions or procedures and their difficulty to ensure the provision of a specific percentage of inpatient bed days taken up in a year for services provided at packaged charge. In their views, packaged pricing was only possible where a certain treatment or procedure was performed at a sufficiently high frequency allowing the variation in costs to be averaged out among different cases. That said, the Administration would continue to discuss with the private hospitals to explore the introduction of packaged charging for

specific treatments or procedures, thereby providing greater certainty and higher transparency in terms of medical costs.

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.

Penalty for offences under the Ordinance

20. Members noted with 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 advised that the review would cover, among other things, the penalty system.

<u>Regulation of healthcare intermediary service providers</u>

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.

Recent developments

23. In June 2014, a woman died shortly after undergoing a surgical procedure called liposuction at a hair transplant centre. The incident has aroused public concern over the lack of regulation of high-risk medical procedures performed in community-based private healthcare facilities, and the outcome of the review conducted by the Steering Committee in this regard.

24. The Administration will report to the Panel on the recommendations on review of regulation of private healthcare facilities at the meeting on 21 July 2014.

Relevant papers

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

Council Business Division 2
Legislative Council Secretariat
18 July 2014

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
	16.6.2014 (Item IV)	Agenda CB(2)2025/13-14(01)

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