

**For discussion on  
26 October 2012**

**Legislative Council Panel on Health Services**

**Review on the Regulation of Private Healthcare Facilities  
and the Performance of High-risk Medical Treatments/Procedures**

**PURPOSE**

This paper briefs Members on the existing regulatory framework of private healthcare services, the review on the regulation of private healthcare facilities to enhance regulation of private hospitals and the performance of high-risk medical treatments/procedures, as well as the interim measures adopted now or soon to be put in place, including drawing up a guideline to differentiate low-risk, non-invasive cosmetic procedures from high-risk procedures for reference by the beauty industry and the medical profession to enhance protection for consumers/patients before the completion of the review and the amendment of the legislation.

**CURRENT SITUATION**

2. Provision of healthcare services involves a combination of different aspects, including healthcare professionals, drugs, devices, premises, procedures, advertisement/sales practice etc. Currently there are a number of legislations regulating the above key and distinct aspects (a list of major laws or regulations is at **Annex A**). Under the Medical Registration Ordinance (Cap. 161) and the Nurses Registration Ordinance (Cap. 164), medical practitioners and nurses are required to register with their respective statutory boards/councils and observe requirements on professional conduct. Medical practitioner who commits a criminal offence or a professional misconduct could be disciplined by the Medical Council of Hong Kong. Conducting medical procedures by any person other than a registered medical practitioner would constitute a crime. The Dangerous Drugs Ordinance (Cap. 134) and the Pharmacy and Poisons Ordinance (Cap. 138) stipulate requirements concerning the

control of drugs and drug traders; the Radiation Ordinance (Cap. 303) prescribes the use and safe management of radioactive substance and irradiating apparatus; performance of certain medical procedures, such as human organ transplant, is restrained under the Human Organ Transplant Ordinance (Cap. 465); and certain advertisements relating to medicines and treatments are restricted by the Undesirable Medical Advertisements Ordinance (Cap. 231).

3. As for the regulation of premises for the provision of private healthcare services, private hospitals, nursing homes and maternity homes are regulated under the Hospital, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165), while non-profit-making medical clinics are regulated under the Medical Clinics Ordinance (Cap. 343). Under the two ordinances, prescribed private healthcare facilities are required to register with Department of Health (“DH”) and hence subject to DH’s regulations on conditions relating to accommodation, staffing and equipment.

## **THE NEED FOR REVIEW**

4. Cap. 165 and Cap. 343 have undergone no substantive amendments since 1960s. Private healthcare premises are regulated on rather limited scope under the two ordinances. Ambulatory medical centres and non-clinical facilities where high-risk and complicated medical treatments/procedures are performed are not covered in the existing regulatory regime. Moreover, the regulatory conditions of registered healthcare institutions are confined to a few aspects, namely accommodation, staffing and equipment. In response to this situation, DH issued a Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes in 2003 to set out the standards of good practice regarding governance, quality management, patient care, risk management, clinical standards and so forth. Compliance with the requirements is a condition for the registration and re-registration of private healthcare institutions.

5. Over the past few years, there have been concerns over safety, quality and fee transparency of private hospitals. There are calls for revamping the regulation of private hospitals in keeping with the modern-day requirements and strengthening the role of DH as their regulator to better ensure patient safety, practice standard and consumer rights (including charging transparency and reasonableness). We consider that there is a genuine and pressing need to review the regulation of private healthcare facilities, having regard to public concerns, development in medical practice and technology, as well as international best practices applicable to local circumstances.

## **RECENT DEVELOPMENT**

6. The recent incident causing one death and serious sickness of three other patients resulting from high-risk medical procedures involving a beauty services company and laboratory processing health products for advanced therapies has aroused public concern about the regulation of high-risk medical procedure advertised as “medical beauty services”. While there are regulations over professional conduct of medical practitioners and practice of drug traders, we will examine in the review whether there is a need to introduce a more comprehensive regulatory framework to regulate the performance of high-risk medical procedures/treatments. Specifically, we will differentiate between high-risk medical procedures and low-risk, non-invasive beauty services, so that the delivery of the former would be restricted to qualified medical practitioners at regulated premises.

## **REVIEW OF REGULATION OF PRIVATE HEALTHCARE FACILITIES**

7. We have established a Steering Committee on Review of the Regulation of Private Healthcare Facilities (“Steering Committee”) to conduct a review on the regulatory regime for private healthcare facilities. The Steering Committee will put forward recommendations on the regulatory approach and scheme for private healthcare facilities, taking into account views from various sectors of community. The Steering

Committee is chaired by the Secretary for Food and Health and comprises 16 non-official members and four ex-officio members. Non-official members comprise personalities from a wide range of backgrounds and interests, including healthcare professions, academia, regulatory bodies and patient and consumer rights groups. The membership of the Steering Committee is at **Annex B**.

8. In conducting the review, reference will be made to regulatory frameworks in overseas jurisdictions and the international trend for safeguarding patient interests, while taking into account the local circumstances of private healthcare services and the demands and expectations of the public at large. In particular, the Steering Committee will review the scope of regulation which is currently restricted to private hospitals, nursing homes and maternity homes, and having regard to the evolution of medical technology and the increasing trend for ambulatory surgery procedures to be performed outside the hospital setting. The guiding principles in any medical treatments/procedures must be that it is effective and there is due cognizance given to patient safety. Hence, the Steering Committee will also identify, as a matter of priority, high-risk medical procedures/practices being advertised and disguised as “medical beauty services” and recommend regulation of such procedures so that they can only be performed properly by qualified medical practitioners and the patients are fully informed of the risks involved.

9. The Steering Committee will be underpinned by working groups to conduct in-depth research and work out options of way forward on task-based topics. The first working group to be set up would be tasked to differentiate between high-risk medical treatments and low-risk, non-invasive beauty services, and formulate guidelines as interim measures pending legislative enactment. The working group will be chaired by the Director of Health and include representatives from relevant medical specialties, the beauty industry and consumer groups. We will explore the possibility of setting up dedicated working groups to review other priority areas, such as regulation of premises involved in processing health products for advanced therapies.

10. The review on the regulatory regime for private healthcare facilities is expected to complete within a year, after which we would consult the public on the proposals put forward by the Steering Committee. We would then proceed to legislative process as and when necessary.

## **INTERIM MEASURES**

11. In the meantime, DH, the Customs and Excise Department and the Consumer Council will step up their efforts within their respective purviews to protect consumer interests and enhance public education on how to select safe beauty services. DH will enhance screening of advertisement of beauty services and work with the Consumer Council to analyse complaints, conduct inquiries and take proactive inspection and where necessary, enforcement actions against beauty services companies suspected of involving in the provision of high-risk medical treatments/procedures to customers. A separate exercise is being carried out in parallel to regulate the safety, performance and quality of medical device through legislation. Beauty equipment falling within the definition of “medical device” will also be regulated under the proposed legislation. Separately, in the last legislative term, a new piece of legislation (Trade Descriptions (Unfair Trade Practices) (Amendment) Ordinance 2012) has been enacted, which seeks to tackle specified unfair trade practices that may be deployed against consumers, such as false trade descriptions of services and the practice of wrongly accepting payment. The legislation will apply to the provision of services (including beauty services). As the principal enforcement agency, the Customs and Excise Department is gearing up for the implementation of the new legislation. It is the intention of the Commerce and Economic Development Bureau to bring the legislation into operation in 2013.

**Food and Health Bureau**  
**Department of Health**  
**October 2012**

**Existing Legislations on Provision of Healthcare Services**

Healthcare professionals

*Cap. 138 Pharmacy and Poisons Ordinance:*

To provide for the registration and disciplinary control of pharmacists and for purposes connected therewith.

*Cap. 156 Dentists Registration Ordinance:*

To provide for the registration and disciplinary control of dentists and for purposes connected therewith.

*Cap. 161 Medical Registration Ordinance:*

To provide for the registration and disciplinary control of medical practitioners in medicine and surgery and for purposes connected therewith.

*Cap. 162 Midwives Registration Ordinance:*

To provide for the registration and disciplinary control of midwives and for purposes connected therewith.

*Cap. 164 Nurses Registration Ordinance:*

To provide for the registration or enrolment, and disciplinary control of nurses and for purposes connected therewith.

*Cap. 359 Supplementary Medical Professions Ordinance:*

To provide for the registration and disciplinary control of persons engaged in occupations and professions supplementary to medicine and for purposes connected therewith.

*Cap. 428 Chiropractors Registration Ordinance:*

To provide for the registration of chiropractors, the disciplinary control of the professional activities of registered chiropractors, and for matters related to such registration and disciplinary control.

*Cap. 549 Chinese Medicine Ordinance:*

To provide for registration and disciplinary control of Chinese medicine practitioners and for purposes connected therewith.

Drugs

*Cap. 132 Public Health and Municipal Services Ordinance:*

To govern suitability of drugs for human consumption, quality of drugs demanded by the purchaser and prohibit false labelling of drugs.

*Cap. 134 Dangerous Drugs Ordinance:*

To govern the trade on import/export, transit, manufacture, wholesale, etc of dangerous drugs. To prohibit unauthorised possession, supply and usage of dangerous drugs.

*Cap. 137 Antibiotics Ordinance:*

To regulate the sale and supply of antibiotic substances.

*Cap. 138 Pharmacy and Poisons Ordinance:*

To regulate manufacture, wholesale, retail, sale or supply, etc of poisons and pharmaceutical products. To register pharmaceutical products before it is legally sold or distributed in Hong Kong.

Equipments

*Cap. 303 Radiation Ordinance:*

To control the import, export, possession and use of radioactive substances and irradiating apparatus and the prospecting and mining for radioactive minerals and for purposes connected therewith.

Medical Procedures

*Cap. 465 Human Organ Transplant Ordinance:*

To prohibit commercial dealings in human organs intended for transplanting, to restrict the transplanting of human organs between living persons and the transplanting of imported human organs, and for supplementary purposes connected with those matters.

*Cap. 561 Human Reproductive Technology Ordinance:*

To regulate reproductive technology procedures, and the use, for research and other purposes, of embryos and gametes; to confine the provision of reproductive technology procedures to infertile couples subject to any express provision to the contrary in any code; to regulate surrogacy arrangements; to establish a Council on Human Reproductive Technology; and to provide for matters incidental thereto or connected therewith.

Premises

*Cap. 165 Hospitals, Nursing Homes and Maternity Homes Registration Ordinance:*

To provide for the registration and inspection of hospitals, nursing homes and maternity homes and for purposes connected therewith.

*Cap. 343 Medical Clinics Ordinance:*

To provide for the registration, control and inspection of medical clinics and for purposes connected therewith.

Advertisement/ Sales Practice

*Cap. 231 Undesirable Medical Advertisements Ordinance:*

To restrict certain advertisements relating to medicines and treatments.



**Steering Committee on  
Review of Regulation of Private Healthcare Facilities  
Membership**

**Chairman**

Secretary for Food and Health

**Members**

Ms CHEUNG Jasminia Kristine  
Professor FOK Tai-fai, SBS, JP  
Dr Samuel KWOK Po-yin  
Mr Andy LAU Kwok-fai  
Ms Connie LAU, JP  
Professor Joseph LAU Wan-yee  
Dr Anthony LEE Kai-yiu  
Professor LEE Sum-ping  
Dr Sigmund LEUNG Sai-man, JP  
Professor Raymond LIANG  
Dr Susie LUM Shun-sui  
Professor Samantha PANG Mei-che  
Dr TSE Hung-hing  
Dr Homer TSO Wei-kwok, SBS, JP  
Ms Sandy WONG Hang-yee  
Dr YEUNG Chiu-fat

**Ex-officio Members**

Permanent Secretary for Food and Health (Health)  
Director of Health  
Chief Executive, The Hospital Authority  
Head of Healthcare Planning and Development Office, Food and Health  
Bureau