**For discussion**
**on 21 July 2014**

**Legislative Council Panel on Health Services**

**Review on the Regulation of Private Healthcare Facilities**

## PURPOSE

This paper reports on the progress of the work and the major recommendations on review of regulation of private healthcare facilities.

## BACKGROUND

2. Currently, regulation of private healthcare facilities is limited to a narrow set of premises drawn up decades ago mainly covering private hospitals and non-profit-making medical clinics. The two enabling ordinances, namely the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) and the Medical Clinics Ordinance (Cap. 343), have undergone no substantive amendments since 1960s and require major revamping to better regulate private healthcare services amid the changing landscape of the healthcare sector. There is a need to broaden the regulatory scope beyond accommodation, staffing and equipment so that other facets essential to healthcare facility regulation such as corporate and clinical governance and price transparency could be adequately provided for. There is also a need to extend the regulatory sphere to cover ambulatory setting where outpatient surgeries or high-risk medical services are performed. It is therefore necessary for the Government to conduct a holistic review of the regulation of private healthcare facilities to modernize the regulatory regime so as to better safeguard patient safety and consumer rights.

## THE REVIEW

3. Against this backdrop, the Steering Committee on Review of Regulation of Private Healthcare Facilities (Steering Committee) was established in October 2012 to oversee the review. Four working groups have been set up under the Steering Committee to conduct in-depth study on four priority areas –

(i) Working Group on Differentiation between Medical Procedures and Beauty Services;

(ii) Working Group on Defining High-risk Medical Procedures/ Practices Performed in Ambulatory Setting;

(iii) Working Group on Regulation of Premises Processing Health Products for Advanced Therapies; and

(iv) Working Group on Regulation of Private Hospitals.

4. The terms of reference and membership lists of the Steering Committee and its Working Groups are enclosed at **Annex I**.

## KEY RECOMMENDATIONS

5. All four Working Groups have completed reviews on their respective priority areas and their findings and recommendations are endorsed by the Steering Committee. The key recommendations proposed by the Working Groups are summarised in the ensuing paragraphs.

### Working Group on Differentiation between Medical Procedures and Beauty Services (Working Group 1)

6. Working Group 1 identified a total of 35 cosmetic procedures with potential safety concerns and recommended that 15, among the 35, cosmetic services should be performed by registered medical

practitioners/ dentists because of the risks involved (**Annex II**). These procedures include those involving injections, mechanical/chemical exfoliation of the skin below the epidermis, hyperbaric oxygen therapy[1] and dental bleaching. With the endorsement of the Steering Committee, the Department of Health (DH) issued advisory notes in November 2013 to both the beauty industry and medical profession to remind practitioners of these requirements when providing cosmetic services. Enforcement action would be taken as necessary under the Medical Registration Ordinance (Cap. 161) and the Dentists Registration Ordinance (Cap. 156). Moreover, DH also enhanced publicity to raise public awareness of the risks of cosmetic services.

7. For cosmetic procedures involving the use of medical devices, particularly energy-emitting devices, the Steering Committee agreed that the regulatory approach to these procedures should be deliberated within the regulatory framework for medical devices currently under review. We plan to introduce a regulatory regime for the control of the use of specified high-risk medical devices through the new medical device legislation. A consultant will be engaged to conduct an in-depth study into the subject and consult stakeholders, including the beauty industry and medical profession.

## Working Group on Defining High-risk Medical Procedures/Practices Performed in Ambulatory Setting (Working Group 2)

8. Working Group 2 established five Expert Groups to deliberate on the scope of regulation and regulatory approach for five areas, namely (1) surgical procedures, (2) endoscopic procedures, (3) dental and maxillofacial procedures, (4) chemotherapy, diagnostic/interventional radiological procedures; and (5) renal dialysis, cardiac catheterisation, lithotripsy. Major health professional groups were consulted in writing from December 2013 to February 2014 so that their views and suggestions were taken into account when drawing up the recommendations.

[1] The Working Group recommended that this procedure should only be performed by registered medical practitioners on patients with clinical need and not as a form of beauty procedure.

9. Working Group 2 recommended defining high-risk procedures by criteria set out in respect of –

(i) risk of procedures;

(ii) risk of anaesthesia involved; and

(iii) patient's conditions.

Any procedure defined as high-risk by any one of these three factors will be regarded as high-risk medical procedure. A schematic illustration on the interaction among these three dimensions is at **Annex III**.

10. Working Group 2 further recommended that –

(i) ambulatory facilities where high-risk medical procedures are performed should be regulated by a statutory registration system;

(ii) high-risk procedures should be performed only in regulated ambulatory facilities or hospitals by qualified health professionals.

(iii) regulated ambulatory facilities should be subject to a set of core facility standards and requirements that cover – (a) management of the facility, (b) physical condition, (c) service delivery and care process, (d) infection control, and (e) resuscitation and contingency. Further facility standards that are specific to the procedures, e.g. haemodialysis, cytotoxic chemotherapy and anaesthesia[2], would be imposed.

(iv) a mechanism should be established to devise, review and update the scope of regulation and standards with regard to the expert advice of the Hong Kong Academy of Medicine (HKAM).

[2] The "Guidelines on Procedural Sedation" promulgated by the Hong Kong Academy of Medicine is recommended to be the regulatory standards on anesthetic safety.

11. Working Group 2 recommended that a survey should be conducted to assess the number and types of private healthcare facilities that might be affected by the proposed regulatory measures and requirements, as well as the range of their services, and an administrative listing system might be implemented before the introduction of statutory registration. As an interim measure, DH will work with the HKAM to establish a mechanism for setting standards required of facilities providing specific classes of high-risk procedures. These procedure-specific standards will be promulgated to the profession as guidance.

**Working Group on Regulation of Premises Processing Health Products for Advanced Therapies (Working Group 3)**

12. Working Group 3 recommended introducing a new legislation with an overarching authority to regulate cells, tissues and health products for advanced therapies through a comprehensive set of regulatory controls including licensing requirements for premises, accreditation of premises, compliance with guidelines, adverse event reporting, designation of Person-in-Charge, staffing requirement and training, import and export control, and registration of health products for advanced therapies.

13. Since the subject involved cutting edge and quickly evolving sector in healthcare technology, we consider a prudent approach should be adopted in carrying forward the recommendations of the Working Group 3 to ensure public safety would be adequately safeguarded on the one hand, the development and adoption of technological advancement would not be unnecessarily hindered on the other. More time and efforts are required to look into each aspect of the proposed regulation so that details of implementation could be worked out in consultation with stakeholders concerned. Subject to further studies and deliberation with parties concerned, we envisage that a new and standalone legislative framework suitable to the unique circumstances of Hong Kong would be drawn up in future to regulate cells, tissues and health products for advanced therapies. Meanwhile, we will implement interim measures in particular educational campaign to increase the awareness of the trade and public on the potential risk associated with health products for

advanced therapies. DH will also continue to regulate, under existing regulatory regimes, those health products for advanced therapies that fall under the definition of pharmaceutical products, including the registration of products, licensing of facilities, and import/export controls.

**Working Group on Regulation of Private Hospitals (Working Group 4)**

14. Working Group 4 put forward a list of recommendations to enhance the regulatory regime for private hospitals covering the following areas of concerns:

(i) **Corporate governance** – enhancing the corporate management of private hospitals by requiring the appointment of a Person-in-Charge and establishment of a Medical Advisory Committee, introducing complaints handling system and promoting hospital accreditation;

(ii) **Clinical governance** – improving service quality through the implementation of clinical risk management, clinical audit, collection of clinical indicators and sentinel events reporting system; and

(iii) **Price transparency** – recommendations in enhancing price transparency for the sake of protecting consumer right are further divided into four areas:

(a) **Disclosure of price information**: private hospitals should prepare a fee schedule setting out all charges that may be levied. The fee schedule should be readily available where appropriate for public's reference. Any change in price levels could only take effect after the schedule has been updated to reflect the changes;

(b) **Implementing a uniform quotation system**: patients having investigative procedures or elective, non-emergency therapeutic operations/ procedures for

known diseases should be informed of the estimated total charges on or before admission to private hospitals. In case there is any material change to the estimates, patients should be informed of and consent to the latest estimates before any operation will be conducted.

(c) **Adopting 'Recognized Service Packages' for common operations**: private hospitals are encouraged to offer Recognized Service Packages (RSP), which are identically and clearly defined standard services provided at packaged charge for common operations/ procedures on known diagnosis, for easy consumption of the public. Private hospitals should specify how and to what extent treatment for complications directly arising from the operations/ procedures concerned would be covered by RSP, as well as the cap on the aggregate expenditure. It should also state clearly what arrangements would be available for patients if treatment for complications is not completely covered.

(d) **Introducing requirements on disclosure of statistics of historical bill sizes:** private hospitals should develop a database of key historical statistics on their actual bill sizes for common treatments/ procedures that are reportable as prescribed by the regulatory authority. The statistics should include annual number of discharges, average length of stay, selected percentiles (e.g. 50th percentile and 90th percentile) of bill sizes for each reportable treatment/ procedure. Each hospital should publish its own statistics where appropriate for public reference. Statistics of all private hospitals will also be available through the common electronic platform provided by the regulatory authority for public consumption.

15. Working Group 4 further recommended enhancing the statutory power of the regulatory authority with a view to strengthening the effectiveness in enforcing the regulatory standards, such as the power

to issue code of practice, the power to conduct inspection, the power to collect and publish information from private hospitals, the power to suspend facility/ equipment/ service, the power to appoint committees as well as the power to impose penalties commensurate with the severity of offence. The findings and recommendations in these areas would serve as a common foundation for other private healthcare facilities to be regulated because of their similarities in the provision of medical services, with suitable adaptation commensurate with the lower degree of complexity and risks of medical services provided in ambulatory setting.

16. Working Group 4 also deliberated on the regulation of premises providing outpatient medical services in the form of incorporated company, and considered measures to better control risks that may arise where the persons bearing the ownership, management, operation and the provision of medical service do not align. The Steering Committee is of the view that there is a need to regulate these premises in addition to private hospitals and ambulatory medical centres conducting high-risk procedures.

## WAY FORWARD

17. The Steering Committee has endorsed the findings and recommendations of the review of the working groups as outlined in the previous paragraphs. The Government is considering the findings and recommendations of the Steering Committee and aims to conduct a public consultation exercise in the second half of 2014 on the revamped regulatory regime for private healthcare facilities encompassing private hospitals, ambulatory medical centres conducting high-risk procedures and premises providing outpatient medical services in the form of incorporated company. Subject to the outcome of the public consultation, we plan to proceed to legislative procedures to enhance the regulation of private healthcare facilities in the 2015/16 legislative year.

**Food and Health Bureau**
**Department of Health**
**July 2014**

**Annex I**

# Steering Committee on Review of Regulation of Private Healthcare Facilities

## Terms of Reference and Membership

### Terms of Reference

- To –

  (i) identify the areas of the current legislations, including Cap. 165 and Cap. 343, requiring enhancement and improvement;

  (ii) examine the scope of regulation (whether to extend to other healthcare facilities) and to formulate options and examine the pros and cons of each approach; and

  having regard to –

  (a) the latest developments in the regulatory framework and standards of private healthcare facilities in overseas countries and making reference with local needs and environment; and

  (b) the views from stakeholders and general public on the regulation of private healthcare facilities,

- To advise on the strategies on public consultation for the way forward.

### Membership

Chairman

Secretary for Food and Health

Members

Professor Francis CHAN Ka-leung *(from 17 September 2013)*
Ms CHEUNG Jasminia Kristine

Professor FOK Tai-fai *(until 16 September 2013)*
Dr Samuel KWOK Po-yin
Mr Andy LAU Kwok-fai
Ms Connie LAU Yin-hing *(until 14 March 2014)*
Professor Joseph LAU Wan-yee
Dr Anthony LEE Kai-yiu
Professor LEE Sum-ping *(until 16 September 2013)*
Professor Gabriel LEUNG *(from 17 September 2013)*
Dr Sigmund LEUNG Sai-man
Professor Raymond LIANG Hin-suen
Dr Susie LUM Shun-sui
Professor Samantha PANG Mei-che
Dr TSE Hung-hing
Dr Homer TSO Wei-kwok
Ms Gilly WONG Fung-han *(from 24 March 2014)*
Ms Sandy WONG Hang-yee
Dr YEUNG Chiu-fat

Ex-officio Members
Permanent Secretary for Food & Health (Health)
Director of Health (or representative)
Chief Executive, Hospital Authority (or representative)
Head of Healthcare Planning and Development Office, Food and Health Bureau

Secretary
Deputy Head of Healthcare Planning and Development Office, Food and Health Bureau

# Working Group on Differentiation between Medical Procedures and Beauty Services

## Terms of Reference and Membership

### Terms of Reference

- To differentiate between medical treatments and ordinary beauty services currently available in the market

- To make recommendations on procedures which should be performed by registered medical practitioners

### Membership

Chairperson

Director of Health

Members

*Steering Committee members*

Ms Connie LAU Yin-hing *(until 14 March 2014)*
Dr Sigmund LEUNG Sai-man
Dr Susie LUM Shun-sui
Dr TSE Hung-hing
Ms Sandy WONG Hang-yee
Dr YEUNG Chiu-fat
Head of Healthcare Planning and Development Office, Food and Health Bureau (or representative)

*Co-opted members*

Professor Henry CHAN Hin-lee
Ms Rinbo CHAN
Dr HO Chiu-ming
Dr HO King-man

Dr Michael HO Ming-tai
Ms Amy HUI
Mr Nelson IP Sai-hung
Dr Walter KING Wing-keung
Ms Cecilia KUK
Ms Maggie LEUNG
Dr NG Yin-kwok
Ms Quby TANG Mei-yee
Ms Sandra TSOI Lai-ha
Dr David WONG Sau-yan
Dr Hunter YUEN Kwok-lai

## Working Group on Defining High-risk Medical Procedures/Practices Performed in Ambulatory Setting

## Terms of Reference and Membership

### Terms of Reference

- To define the range of high-risk procedures/practices that should be performed in regulated ambulatory facilities only; and

- To recommend appropriate regulatory approaches to the Steering Committee.

### Membership

Chairperson

Professor Raymond LIANG

Members

*Steering Committee members*

Dr Samuel KWOK
Professor Joseph LAU
Dr Anthony LEE
Dr Sigmund LEUNG
Professor Samantha PANG
Dr TSE Hung-hing
Ms Sandy WONG
Director of Health (or representative)
Chief Executive, Hospital Authority (or representative)
Head of Healthcare Planning and Development Office, Food and Health Bureau

*Co-opted members*

Dr Jane CHAN
Dr Billy CHIU
Dr CHOW Yu-fat
Professor LAU Chak-sing
Dr LAW Chun-key
Dr Roch LEE
Dr NG Fook-hong
Mr Peter POON
Dr Gordon SOO
Professor Frances WONG
Dr Andrew YIP
Dr Hunter YUEN

# Working Group on Regulation of Premises Processing Health Products for Advanced Therapies

## Terms of Reference and Membership

### Terms of Reference

- To define and come up with the range of health products for advanced therapies that could be conducted in laboratory/ambulatory setting; and

- To examine whether and how to impose regulatory control on premises where health products for advanced therapies are stored and/or processed having regard to the latest development in medical practice and technology, as well as overseas regulations and international best practices applicable to local circumstances.

### Membership

Chairperson

Dr Homer TSO

Members

*Steering Committee members*

Ms Jasminia Kristine CHEUNG
Mr Andy LAU
Director of Health (or representative)
Chief Executive, Hospital Authority (or representative)
Head of Healthcare Planning and Development Office, Food and Health Bureau (or representative)

*Co-opted members*

Mr CHAN Wing-kwong
Mr CHANG Hsiu-kang
Dr Celine CHENG

Ms Bella HO Shiu-wun
Dr LAM Tak-sum
Mr Arthur LAU
Professor Kenneth LEE Ka-ho
Professor LEE Shui-shan
Dr LEE Cheuk-kwong
Professor Ronald Adolphus LI
Mr Alex LI Wai-chun
Dr Sian NG Chor-shan
Dr Cecilia PANG Wai-bing
Dr Jonathan SHAM Shun-tong
Dr Dominic TSANG Ngai-chong
Professor TSE Hung-fat
Professor Ian WONG Chi-kei
Dr Raymond WONG Siu-ming
Dr WONG Yiu-chung
Professor Albert YU Cheung-hoi

## Working Group on Regulation of Private Hospitals

## Terms of Reference and Membership

### Terms of Reference

- To review the scope of the existing legislation and the regulatory regime for private hospitals; and

- To formulate recommendations for enhanced control of different aspects related to the provision of healthcare services by private hospitals.

### Membership

Chairman

Permanent Secretary for Food and Health (Health)

Members

*Steering Committee members*

Professor Francis CHAN Ka-leung (from 17 September 2013)
Ms CHEUNG Jasminia Kristine
Professor FOK Tai-fai (until 16 September 2013)
Dr Samuel KWOK Po-yin
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Head, Healthcare Planning and Development Office, Food and Health Bureau

*Co-opted Members*

Ms Elaine CHAN Sau-ho
Dr William HO Shiu-wei
Ms Vera TAM Sau-ngor
Dr Raymond YUNG Wai-hung

**Annex II**

# List of 35 cosmetic procedures with potential safety concerns

| Item | Procedure | Performed by medical practitioners/ dentists | Deliberate within the regulatory framework for medical devices |
|---|---|---|---|
| **Procedures involving skin puncture** | | | |
| **1.** | Dermal filler injection | ✓ | |
| **2.** | Botulinum toxin A injection | ✓ | |
| **3.** | Autologous platelet-rich plasma | ✓ | |
| **4.** | Autologous cellular therapy | ✓ | |
| **5.** | Cryo-crystalised Growth Factor | ✓ | |
| **6.** | Skin whitening injection | ✓ | |
| **7.** | Injection lipolysis | ✓ | |
| **8.** | Mesotherapy | ✓ | |
| **9.** | Microneedle therapy | | ✓ |
| **10.** | Tattooing | Exempted | |
| **11.** | Body piercing | Exempted | |
| **Procedures involving external application of energy** | | | |
| **12.** | Laser (Class 3B and 4) | | ✓ |
| **13.** | Radiofrequency | | ✓ |
| **14.** | Intense pulsed light | | ✓ |
| **15.** | Extracorporeal shock wave | | ✓ |
| **16.** | Ultrasound for lipolysis (high intensity focused ultrasound and nonthermal ultrasound) | | ✓ |
| **17.** | Cryolipolysis | | ✓ |
| **18.** | High voltage pulsed current | | ✓ |
| **19.** | Plasma | | ✓ |
| **20.** | Lighting emitting diode phototherapy | | ✓ |
| **21.** | Infrared light | | ✓ |
| **22.** | Micro-current therapy | | ✓ |
| **23.** | Cryoelectrophoresis | | ✓ |
| **24.** | Electroporation/ Iontophoresis | | ✓ |
| **25.** | Pulsed magnetic field therapy | | ✓ |
| **26.** | Microwave application | | ✓ |
| **Procedures involving mechanical/ chemical exfoliation of the skin below the epidermis** | | | |
| **27.** | Microdermabrasion | ✓ | |
| **28.** | Chemical peel | ✓ | |
| **29.** | JETPEEL | ✓ | |
| **30.** | Water microjet plus vacuum | ✓ | |
| **Other procedures that may pose safety concerns** | | | |
| **31.** | Colon hydrotherapy | | ✓ |
| **32.** | Hyperbaric oxygen therapy | ✓ | |
| **33.** | Jet injector | ✓ | |
| **34.** | Dental bleaching | ✓ | |
| **35.** | Suction massage* | Not required | |

* The risk involved in this procedure is relatively low. This is not a medical treatment if not performed together with other energy applications such as light energy or radiofrequency.

**Annex III**

# General Principles for Defining High-risk Medical Procedures

<table>
<tr><td colspan="2" rowspan="2"></td><td colspan="3">• Risk of procedure<br>• Risk of anaesthesia</td></tr>
<tr><td>Low</td><td>High</td><td>Hospital-only</td></tr>
<tr><td rowspan="6">Patient's condition[1] using ASA Classification[2]</td><td>Class 1</td><td rowspan="3">Any healthcare facilities</td><td rowspan="4"></td><td rowspan="4"></td></tr>
<tr><td>Class 2</td></tr>
<tr><td>Class 3 - stable</td></tr>
<tr><td>Class 3 - unstable</td><td colspan="2">Regulated ambulatory facilities or hospitals</td></tr>
<tr><td>Class 4</td><td colspan="3" rowspan="2">Hospitals only</td></tr>
<tr><td>Class 5</td></tr>
</table>

[1] Age, body size and other physical conditions of the patient should be taken into account when deciding whether the procedure should be performed in ambulatory facility or hospital.

[2] American Society Anaesthesiologists Physical Status Classification System:

- Class 1 - normal healthy patient
- Class 2 - mild systemic disease
- Class 3 - severe systemic disease – stable
- Class 3 - severe systemic disease – unstable (acute exacerbation)
- Class 4 - severe systemic disease that is a constant threat to life
- Class 5 - moribund patient who is not expected to survive without the operation