#### LEGISLATIVE COUNCIL BRIEF

## REVIEW ON REGULATION OF PRIVATE HEALTHCARE FACILITIES

#### **INTRODUCTION**

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At the meeting of the Executive Council on 2 December 2014, the Council ADVISED and the Chief Executive ORDERED that a public consultation should be launched on the proposal to revamp the existing regulatory regime for private healthcare facilities (PHFs) on 15 December 2014 for three months by putting forward the following proposals in the form of a consultation document (draft executive summary at **Annex A**) –

- (a) To **enact a new legislation** to replace the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance, Cap. 165 and the Medical Clinics Ordinance, Cap. 343;
- (b) To broaden the types of PHFs to be regulated beyond private hospitals and non-profit-sharing medical clinics to encompass 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 as high-risk inpatient setting requiring continuous medical care and/or Chinese medicine service with continuous medical support and lodging 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 nineteen regulatory aspects encompassing 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 PHFs; and
- (e) To confer the **regulatory authority with enhanced regulatory powers** for regulating PHFs.

#### **JUSTIFICATIONS**

#### Existing Regulatory Regime for Private Healthcare Facilities

Hong Kong's healthcare system runs on a dual-track basis comprising both the public and private sectors, with roughly equal share of expenditure but different emphasis and positioning<sup>2</sup>. By improving the transparency and accountability of private healthcare services and better assuring the public of their quality and reliability, there would be greater incentive for those who could afford it to make use of private healthcare services, thus relieving the public hospital system so that it could focus on serving those in need. Coupling with the proposed Voluntary Health Insurance Scheme, we consider that revamping and modernizing the regulatory regime for PHFs, including private hospitals, ambulatory medical centres and clinics, will better safeguard public interest and help enhance the long term sustainability of our healthcare system. While the scale of operation, complexity in management and range of services vary significantly across PHFs, there are common threads of issues and concerns broadly applicable to them all. They are usually regulated by comprehensive legislation in overseas jurisdictions such as Singapore and Australia. Regulation of PHFs in Hong Kong, however, is limited to a narrow set of facilities drawn up decades ago mainly covering private hospitals (Cap. 165) and non-profit-sharing medical clinics (Cap. 343).

## Need for Change

3. Both Cap. 165 and Cap. 343 are outdated and have outlived their usefulness. Major revamping is required to better regulate private healthcare services amid the evolving landscape of healthcare services. With the advancement in medical technology and rapid changes in medical practices, high-risk medical procedures/practices once confined to hospitals are increasingly performed in ambulatory setting. The practice hitherto of relying solely on the ethics and self-discipline of doctors coupled with sanctions against those breaching professional conduct via the Medical Council under the Medical Registration Ordinance ("Cap. 161") has been found wanting as any registered doctor with a valid practice certificate could offer and undergo high-risk medical

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According to the definition of 'Health Expenditure' under the Domestic Health Accounts of Hong Kong, health spending consists of health and health-related expenditures. Expenditures are defined on the basis of their primary or predominant purpose of improving health, regardless of the primary function or activity of the entity providing or paying for the associated health services.

The public sector is predominantly hospital-oriented providing highly subsidized inpatient and ambulatory services for the community covering around 88% of hospital demands on account of bed days (and 80% by admission), as well as limited outpatient services mainly for chronic diseases and the underprivileged. Private healthcare, as an essential component of our healthcare system, is a major provider (more than 70%) of outpatient services and provides more personalized inpatient and same-day ambulatory services for those who could afford it and are willing to pay.

procedures in ambulatory setting in whatever way and form he/she deems appropriate. There are calls to tighten up regulation through facilities-based regulation in line with international common practices. The need for such a change is made ever more urgent and necessary following medical incidents causing a number of casualties resulting from high-risk medical procedures performed in ambulatory setting. Outpatient clinics in the community used to be run by solo medical practitioners or a group of doctors working in partnership has increasingly given way to incorporated clinics, where ownership and the delivery of medical services are severed. There is a need to go beyond professional regulation and institute facilities-based regulation for these incorporated clinics.

4. In the light of the above, there is a genuine need to conduct a root-and-branch review of PHFs regulation and introduce a robust and comprehensive regulatory regime for PHFs so that other facets essential to PHFs regulation such as corporate governance, clinical governance and price transparency could be adequately provided for.

## Review by the Steering Committee on Review of Regulation of Private Healthcare Facilities

- 5. In October 2012, the Food and Health Bureau established the Steering Committee on Review of Regulation of Private Healthcare Facilities ("Steering Committee") to conduct a root-and-branch review on the regulation of PHFs. The Steering Committee set up four working groups to conduct reviews on four priority areas, namely,
  - (i) Differentiation between Medical Procedures and Beauty Services;
  - (ii) Defining High-risk Medical Procedures/Practices Performed in Ambulatory Setting;
  - (iii) Regulation of Premises Processing Health Products for Advanced Therapies; and
  - (iv) Regulation of Private Hospitals.

The reviews of the working groups have been completed and their recommendations have been endorsed by the Steering Committee. In view of the findings and recommendations of the Steering Committee and its working groups, we consider that effort should be focused on introducing a new regulatory regime covering three classes of PHFs, namely, (a) hospitals, (b) facilities providing high-risk medical procedures in ambulatory setting and

(c) facilities providing medical services under the management of incorporated bodies.

### A. Hospitals

- 6. We propose to define 'hospital' as 'any healthcare facility primarily for the provision of medical care and/or Chinese medicine practice with continuous medical support and lodging'.
- 7. For the sake of clarity, 'healthcare facility' does not include that under the control of the Government, the Hospital Authority ("HA") (under the Hospital Authority Ordinance, ("Cap. 113")), or the Garrison. The term 'medical' in this context refers to professional care and practice of registered medical practitioners (under Cap. 161) or registered dentists (under the Dentists Registration Ordinance, Cap. 156). The term 'Chinese medicine practice' refers to that defined under section 2 of the Chinese Medicine Ordinance ("Cap. 549"). 'Lodging' is defined as 'a setting where a patient may not be discharged on the same calendar day of admission; or the expected total duration of the procedure, recovery, treatment and care requiring continuous confinement within the facility may exceed 12 hours'. Consequentially, we propose that maternity homes should no longer be separately licensed and should be subsumed under 'hospital' as part of the facility. Besides, 'nursing home', the applicability and interpretation of which have been ambiguous in the existing regulatory regime, should no longer be treated as a separate class of PHFs in the new regime. Instead, PHFs currently registered as 'nursing homes' under Cap. 165 should either be (i) registered as 'hospitals' or 'facilities providing high-risk medical procedures in ambulatory setting' in the new legislation depending on the type and nature of service provided, or (ii) left out from the new legislation if they only provide welfare service with no or minimal medical elements.

### Residential Homes for Elders as 'Nursing Homes'

8. Among the 53 institutions registered as 'nursing homes', 33 are residential homes for the elderly<sup>3</sup>. 26 out of the 33 nursing homes for the elderly are providing both nursing home and care and attention ("C&A") home places and are at present concurrently registered under the Residential Care Homes (Elderly Persons) (RCHE) Ordinance ("Cap. 459") as C&A homes. For the remaining seven nursing homes for the elderly, they provide purely

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The remaining 20 institutions registered as nursing homes provide rather diverse spectrum of services which include centres for renal dialysis, eye surgery, termination of pregnancy, cancer patients, disabled children or drug dependents. They can be classified either as hospitals or facilities providing high-risk medical procedures in ambulatory setting as discussed in section B below.

nursing home places and are registered under Cap. 165 only. Unlike hospitals, most of these nursing homes for the elderly have no, among others, resident doctors essential for the provision of 'continuous medical support' as required in the proposed definition of hospital. These facilities, therefore, should not be regulated under the proposed definition. We propose that all nursing homes for the elderly should be registered under the regulatory regime provided by Cap. 459.

9. In this regard, consequential amendments to Cap. 459 and/or its Regulations will be included in the new legislation for PHFs to transfer the regulatory regime for nursing homes for the elderly from Cap. 165 to Cap. 459 necessitated by the revamp of the regulatory regime for PHFs. The amendments are technical and there will not be any substantial changes to the existing level of regulatory requirements for the nursing homes and C&A homes for the elderly.

#### B. Facilities Providing High-Risk Medical Procedures in Ambulatory Setting

- 10. A PHF would be regulated as 'facilities providing high-risk medical procedures in ambulatory setting' if it provides high-risk medical procedures in ambulatory setting. A medical procedure is classified as high-risk if the
  - (a) risk of procedure is high (a list of procedures that could be considered as high-risk is at **Annex B**); or
  - (b) risk of anaesthesia involved is high; or

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(c) patient's condition is classified as Class 3 - severe systemic disease – unstable (acute exacerbation) or worse according to the American Society of Anaesthesiologists ("ASA") Physical Status Classification System.

The proposed regulatory regime aims to cover medical procedures provided/performed by registered medical practitioners or registered dentists. It would not cover procedures conducted under alternative medicines unless they intrude into the purview of high-risk medical procedures under the disguise of alternative medicines. Barring unforeseen circumstances, Chinese medicine practitioners offering outpatient services in the community would not be caught within the ambit of high-risk medical procedures defined based on the principles in paragraph 10 (a) - (c) above. For the sake of clarity, 'ambulatory setting' means -

- (i) the patient is discharged in the same calendar day of admission; and
- (ii) the expected total duration of procedure and recovery requiring continuous confinement within the facility does not exceed 12 hours.

Similar to 'hospitals', facilities controlled by the Government, HA and the Garrison would be exempt from regulation. Besides, facilities already regulated as 'hospitals' would require no separate regulation under this part.

# C. Facilities Providing Medical Services under the Management of Incorporated Bodies

11. The provision of medical service could take a variety of organizational Among them, there have long been concerns over 'medical groups' or 'managed care organizations' operated in the form of incorporated bodies (including statutory bodies, registered societies and incorporated companies) in which non-medical investors or managers may take part in the operation of Registered medical practitioners practicing there do not have full control of the PHFs concerned in ensuring effective governance and maintaining high service quality. We consider it necessary to introduce facilities-based regulation in addition to professional self-regulation for these PHFs. Exemption will be granted to PHFs owned, managed, operated and serviced solely by identical registered medical practitioners that are not providing high-risk medical procedures because there would not be similarly perceived operational risk. Chinese medicine clinics and, similar to the two other classes of PHFs, facilities controlled by the Government, HA and the Garrison will be exempt from regulation. With the proposed new legislation, we would repeal Cap. 343 and regulate clinics currently registered under that ordinance, which are all 'non-profit-sharing medical clinics', as facilities providing medical services under the management of incorporated bodies in the new legislation. To avoid duplicate regulation, all PHFs which are already regulated as 'hospitals' or 'facilities providing high-risk medical procedures in ambulatory setting' should automatically be exempt from regulation as this class of PHFs.

### Proposed Nineteen Regulatory Aspects

12. We propose to constitute nineteen regulatory aspects as essential regulatory requirements of the regulatory regime for private hospitals, with suitable adaptation commensurate with the lower degree of complexity and risks of medical services provided in other PHFs. The list of the nineteen regulatory aspects are presented as follows under five broad categories of control:

#### A. Corporate Governance

- (A1) Appointment of Person-in-charge;
- (A2) Establishment of Medical Advisory Committee;
- (A3) Complaints Management System;
- (A4) Establishment of an Information System Connectable with the Electronic Health Record Sharing System ("eHRSS"); and
- (A5) Maintenance of Hospital Accreditation Status.

#### B. Standard of Facilities

- (**B6**) Premises Management effective premises management hinges on proper management and maintenance of physical assets such as buildings, equipment, power and water supply with a view to ensuring the quality of services provided;
- (B7) Physical Conditions include but not limited to the state of repair, ventilation, lighting, and periodical maintenance of a PHF; and
- **(B8)** Infection Control.

#### C. Clinical Quality

- (C9) Service Delivery and Care Process;
- (C10) Resuscitation and Contingency standards on the essential resuscitation equipment (such as monitoring device and defibrillator) and contingency planning;
- (C11) Standards Specific to Procedures Performed standards embracing requirements on the premises, equipment and staffing for high-risk procedures the administration of which is confined to regulated premises;
- (C12) Credentialing of Visiting Doctors hospitals should have in place policies and mechanisms to ensure the competence of visiting doctors;

- (C13) Establishment of Clinical Audit System; and
- (C14) Sentinel Events Management a sentinel event is an unexpected occurrence involving death or serious physical or psychosocial injury, or the risk thereof. Hospitals should establish a comprehensive sentinel events management system for quality assurance.

#### D. Price Transparency

- (D15) Provision of Fee Schedule an up-to-date fee schedule setting out all charges that may be levied in a standardized format and terminology should be readily available at all regulated PHFs;
- (D16) Provision of Quotation patients should be informed of the estimated total charges for the whole course of investigative procedures or elective, non-emergency therapeutic operations/procedures for known diseases on or before admission;
- (**D17**) Provision of Recognized Service Packages encouraging all PHFs to provide Recognized Service Packages which are identically and clearly defined standard services provided at packaged charge; and
- (D18) Disclosure of Historical Bill Sizes Statistics mandatorily requiring hospitals to publish key historical statistics on their actual bill sizes for common treatments/procedures as prescribed by the regulatory authority. The statistics should be made available through the common electronic platform for public consumption.

#### E. Sanctions (E19)

13. At present, the maximum penalty for carrying on a hospital without being duly registered is \$2,000, while penalties for other non-compliance and the daily fine of continuous contravention are set at \$2,000 and \$50 respectively. This is ineffective to have any deterrent effect in today's standard. We consider that regulated PHFs that fail to comply regulatory requirements should be subject to sanctions commensurate with the seriousness of the offence. We propose the following **maximum penalties** for hospitals (and the Person-in-charge in respect of imprisonment) and other regulated PHFs respectively –

### (1) <u>Unlawful Operation (hospitals)</u>:

- a fine of **\$5,000,000**
- imprisonment for **two years**

#### (2) Unlawful Operation (other regulated PHFs):

- a fine of **\$100,000**
- imprisonment for three months

### (3) Non-compliance of other provisions of the legislation (hospitals):

- a fine of **\$1,000,000**
- a daily fine of \$10,000 for continuous contravention

# (4) <u>Non-compliance of other provisions of the legislation (other regulated PHFs)</u>:

- a fine of \$25,000
- a daily fine of \$2,000 for continuous contravention

#### Powers of the Regulatory Authority

- 14. For effective enforcement and operation of the revamped regulatory regimes for PHFs, the regulatory authority should be provided with appropriate regulatory powers necessary to ensure proper oversight on regulated PHFs to safeguard the safety and interest of the public. We propose that the regulatory authority/the Government should be vested with powers to
  - (a) Issue and amend regulations/code of practice;
  - (b) Inspect, collect and publish information;
  - (c) Suspend a facility/service/use of equipment;
  - (d) Appoint committees (to deal with matters relevant to the regulation of PHFs, including an Independent Review Committee on Regulatory Actions and an Independent Committee on Complaints against Private Hospitals); and
  - (e) Devise, review and update the scope and standards of regulation for high-risk medical procedures/practices.

## Introducing a New Regulatory Regime

15. To implement the aforesaid proposals, we propose replacing the two existing ordinances (i.e. Cap. 165 and Cap. 343) by a new single legislation

regulating all three classes of PHFs. We also propose that the Director of Health be empowered to enforce the regulatory requirements under the new regime.

#### Interim Measures

16. We recommend that certain short to medium term administrative measures could be introduced to supplement the existing regulatory regime before the new regime is put in place, including (a) reviewing the existing administrative Codes of Practices for the two ordinances to enhance existing regulatory requirements in the regulatory regime for PHFs, (b) conducting a survey to assess the number and types of private healthcare facilities that might be affected by the new regulatory regime, as well as range of their services and (c) introducing an administrative listing system for ambulatory facilities providing high-risk medical procedures in ambulatory settings to monitor such facilities before the introduction of statutory registration. The regulatory authority will also 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 will be promulgated to the profession as guidance before incorporated into the future legislation as part of the statutory requirements.

#### **OTHER OPTIONS**

17. We considered two alternative opinions and found both of them infeasible, the two alternatives are (a) amending the two existing ordinances i.e. Cap. 165 and Cap. 343 and (b) strengthening the two Codes of Practices issued by the DH without introducing amendments to Cap. 165 and Cap. 343. For option (a), we considered the possibility of amending the two enabling ordinances i.e. Cap. 165 and Cap. 343 to provide for a revamped regulatory for PHFs. However, we noted that this would require major overhaul in the scope, regulatory aspects, operational arrangements and sanctions, etc. of the existing ordinances which essentially amount to re-writing the entire ordinance. Making exceedingly extensive amendments to an ordinance is not a desirable The effect of the amendments would be difficult to drafting approach. appreciate. There will also be inconsistencies in drafting style between the new provisions and the existing ones. In addition, such approach would continue to regulate PHFs under two separate ordinances which fail to regulate PHFs under a unified regulatory framework. We have also explored option (b), i.e. amending 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 only instead of the two ordinances. We found this

approach ineffective as the Codes of Practices lack legal backing, and the regulatory authority cannot take enforcement actions as the existing legislation confine to three aspects of regulation, i.e. staffing, equipment and accommodation only. Besides, no appropriate sanctions would be imposed for non-compliance of the Codes of Practices. Furthermore, given the large numbers and variety of PHFs, a large number of PHFs would not be covered if only the two Codes of Practices are amended. In the light of the above considerations, we consider that a new single legislation must be enacted to replace Cap. 165 and Cap. 343 for effectively providing a revamped regulatory regime for PHFs.

#### IMPLICATIONS OF THE PROPOSAL

18. The proposal to release the consultation paper with the above recommendations is in conformity with the Basic Law, including the provisions concerning human rights. Depending on the outcome of the public consultation, the recommendations would be further considered in detail to ensure that the finalized measures are in conformity with the Basic Law, including the human rights provisions. They have no environmental, productivity or family implications. The proposal has financial and civil service, economic and sustainability implications as set out in **Annex C**.

#### **PUBLIC CONSULTATION**

19. We are launching a three-month public consultation on the proposals on regulation of PHFs on 15 December 2014. We will conduct open consultation forums for the public in general, and arrange targeted consultation sessions with specific groups of relevant sectors, professions and stakeholders. Polling will be conducted to gauge public views on key issues of the proposal.

#### **PUBLICITY**

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20. We will brief the Legislative Council Panel on Health Services on 15 December 2014. We will organize a press conference and issue a press release to launch the consultation. More detailed briefings for editors and commentators will be arranged. Announcement in the Public Interest on TV and radio will be issued on the consultation. A line-to-take will be prepared and a government spokesman will be available to answer enquiries. A media plan will be developed to co-ordinate attendance of specific media events, publication of op-ed articles, and any other publicity and media responses during the consultation period.

## **ENQUIRY**

21. Enquiries on this brief may be directed to Mr Sheung-yuen LEE, Deputy Head, Healthcare Planning and Development Office, Food and Health Bureau, at 3509 8929.

Food and Health Bureau 15 December 2014

#### **Executive Summary**

#### **Existing Regulatory Regime for Private Healthcare Facilities (Chapter 1)**

Hong Kong's healthcare system runs on a dual-track basis comprising both the public and private sectors, with roughly equal share of expenditure but different emphasis and positioning. The public sector is predominantly hospital-oriented providing highly-subsidized inpatient and ambulatory services for the community covering around 88% of hospital demands on account of bed days (and 80% by admission), as well as limited outpatient services mainly for chronic diseases and the underprivileged. Private healthcare, as an essential component of our healthcare system, is a major provider (more than 70%) of outpatient services and provides more personalized inpatient and same-day ambulatory services for those who could afford it and are willing to pay. improving the transparency and accountability of private healthcare service and better assuring the public of their quality and reliability, there would be greater incentive for those who could afford it to make use of private healthcare services, thus relieving the public hospital system so that it could focus on serving those in need. Coupling with the proposed Voluntary Health Insurance Scheme, we consider that revamping and modernizing the regulatory regime for private healthcare facilities (PHFs) will better safeguard public interest and help improve the long term sustainability of our healthcare system.

2. PHFs, including private hospitals, ambulatory medical centres and clinics, embrace a wide range of privately-owned facilities providing medical While the scale of operation, complexity in diagnosis and treatment. management and range of services vary significantly across PHFs, there are common threads of issues and concerns broadly applicable to them all. They are usually regulated by comprehensive legislation in overseas jurisdictions such as Singapore and Australia. Regulation of PHFs in Hong Kong, however, is limited to a narrow set of facilities drawn up decades ago mainly covering private hospitals and non-profit-sharing medical clinics. The Hospital, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) and the Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes (Cap. 165 CoP) set out the regulatory framework for private hospitals, nursing homes and maternity homes. The Medical Clinics Ordinance (Cap. 343) and the Code of Practice for Clinics Registered under Medical Clinics Ordinance (Cap. 343 CoP), on the other hand, set out the regulatory framework for non-profit-sharing medical clinics.

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According to the definition of 'Health Expenditure' under the Domestic Health Accounts of Hong Kong, health spending consists of health and health-related expenditures. Expenditures are defined on the basis of their primary or predominant purpose of improving health, regardless of the primary function or activity of the entity providing or paying for the associated health services.

3. Other PHFs, such as ambulatory medical centres and clinics operated by medical groups or individual (or jointly by several) medical practitioners, are not subject to direct statutory control beyond regulation of individuals' Regulatory oversight is achieved indirectly through professional practice. generic regulations applicable to aspects such as healthcare professionals, the use and handling of dangerous drugs as well as the instalment and operation of For example, the professional codes of conduct irradiating equipment. promulgated by the Medical Council and the Dental Council of Hong Kong regulate medical practitioners and dentists, respectively, who may practise in PHFs. Other ordinances regulate specific activities that may take place in PHFs, such as the Pharmacy and Poisons Ordinance (Cap. 138) (on manufacture, wholesale, retail, sale or supply, etc. of poisons and pharmaceutical products), the Radiation Ordinance (Cap. 303) (on import, export, possession and use of radioactive substances and irradiating apparatus) and the Dangerous Drugs Ordinance (Cap. 134) (on import/export, transit, manufacture, wholesale, etc. of dangerous drugs).

### Need for Change

- Both Cap. 165 and Cap. 343 are outdated and have outlived their usefulness. Major revamping is required to better regulate private healthcare services amid the evolving landscape of healthcare services. advancement in medical technology and rapid changes in medical practices, high-risk medical procedures/practices once confined to hospitals increasingly performed in ambulatory setting. The practice hitherto of relying solely on the ethic and self-discipline of doctors coupled with sanctions against those breaching professional conduct via the Medical Council under the Medical Registration Ordinance (Cap. 161) has been found wanting as any registered doctor with a valid practice certificate could offer and undergo high-risk medical procedures in ambulatory setting in whatever way and form he/she deems There are calls to tighten up regulatory oversight through facilities -based regulation in line with international common practices. The need for such a change is made ever more urgent and necessary following medical incidents causing a number of casualties resulting from high-risk medical procedures performed in ambulatory setting.
- 5. In the light of the above, there is a **genuine need to conduct a root-and-branch review of PHFs regulation and introduce a robust and comprehensive regulatory regime for PHFs** so that other facets essential to PHFs regulation such as corporate governance, clinical quality and price transparency could be adequately provided for.

### **Review on Regulation of Private Healthcare Facilities (Chapter 2)**

- 6. The **Department of Health (DH) and** the **Audit Commission, reviewed the existing regulatory regime** of PHFs in 2000 and 2012 respectively, which identified, inter alia, the follow aspects that an effective regulatory regime should bear
  - (a) **appropriate standards** should be set for core services and individual disciplines;
  - (b) regulated PHFs should undertake quality assurance activities;
  - (c) the regulatory authority should be empowered **to add or change licensing conditions** as and when necessary;
  - (d) to enhance the powers of the regulatory authority in the **inspection** and collection of data from registered PHFs for monitoring purposes; and
  - (e) to enhance **price transparency** of PHFs.

## Review by the Steering Committee on Review of Regulation of Private Healthcare Facilities

- 7. In October 2012, the Food and Health Bureau established the Steering Committee on Review of Regulation of Private Healthcare Facilities (Steering Committee) to conduct a root-and-branch review on the regulation of PHFs. The Steering Committee set up four working groups to conduct **reviews on four priority areas**, namely,
  - (i) Differentiation between Medical Procedures and Beauty Services;
  - (ii) Defining High-risk Medical Procedures/Practices Performed in Ambulatory Setting;
  - (iii) Regulation of Premises Processing Health Products for Advanced Therapies; and
  - (iv) Regulation of Private Hospitals.

The reviews of the working groups have been completed and their recommendations have been endorsed by the Steering Committee. The progress in taking forward the working groups' recommendations are as follows

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- (i) Working Group on Differentiation between Medical Procedures and Beauty Services (WGI) the Working Group considered that certain cosmetic services should be performed by registered medical practitioners/dentists because of the risks involved. It was also agreed that for cosmetic procedures involving the use of medical devices, particularly energy-emitting devices, the regulatory approach to these procedures should be deliberated within the regulatory framework for medical devices currently under review. With the endorsement of the Steering Committee, 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 Cap. 161 and the Dentists Registration Ordinance (Cap. 156). The progress of the implementation of the Working Group's recommendations would be reviewed from time to time.
- (ii) Working Group on Regulation of Premises Processing Health Products for Advanced Therapies (WG3) the Working Group 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. Since the subject involved cutting edge and quickly evolving sector in healthcare technology, 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, as a separate exercise, in future to regulate cells, tissues and health products for advanced therapies.
- (iii) Working Group on Defining High-risk Medical Procedures/Practices Performed in Ambulatory Setting (WG2) and Working Group on Regulation of Private Hospitals (WG4) both Working Groups reviewed the regulation of PHFs providing direct medical services to the public. WG2 was tasked 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. WG4 was tasked 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. WG4 also deliberated on the regulation of facilities providing outpatient medical services in the form of incorporated companies. The key components of the proposed new

**regulatory regime for PHFs** put up for public consultation in this document are formulated **based on the recommendations** of these two Working Groups.

8. In view of the findings and recommendations of the aforementioned reviews, particularly the findings of the Steering Committee and its working groups, we consider that **effort should be focused on introducing a new regulatory regime covering three classes of PHFs**, namely, (a) hospitals, (b) facilities providing high-risk medical procedures in ambulatory setting and (c) facilities providing medical services under the management of incorporated bodies.

#### **Private Healthcare Facilities to be Regulated (Chapter 3)**

#### A. Hospitals

- 9. We propose to **define 'hospital'** as 'any healthcare facility primarily for the provision of medical care and/or Chinese medicine practice with continuous medical support and lodging'.
- 10. For the sake of clarity, 'healthcare facility' does not include that under the control of the Government, the Hospital Authority (HA) (under the Hospital Authority Ordinance, Cap. 113) or the Garrison. The term 'medical' in this context refers to professional care and practice of registered medical practitioners (under Cap. 161) or registered dentists (under Cap. 156). The term 'Chinese medicine practice' refers to that defined under section 2 of the Chinese Medicine Ordinance (Cap. 549). 'Lodging' is defined as 'a setting where a patient may not be discharged on the same calendar day of admission; or the expected total duration of the procedure, recovery, treatment and care requiring continuous confinement within the facility may exceed 12 hours'.
- 11. Under the new regime, maternity homes should no longer be separately licensed and should be subsumed under 'hospital' as part of the facility. Besides, 'nursing home', the applicability and interpretation of which have been ambiguous in the existing regulatory regime, should no longer be treated as a separate class of PHFs in the new regime. Instead, PHFs currently registered as 'nursing homes' under Cap. 165 should either be (i) registered as 'hospitals' or 'facilities providing high-risk medical procedures in ambulatory setting' in the new legislation depending on the type and nature of service provided, or (ii) left out from the new legislation if they only provide welfare service with no or minimal medical elements. For nursing homes providing mainly residential service with no or limited medical care, they should be

regulated as welfare/rehabilitative institutions under existing regulatory regimes, depending on the nature of service provided.

# B. Facilities Providing High-Risk Medical Procedures in Ambulatory Setting

- 12. We propose that **facilities providing high-risk medical procedures** in ambulatory setting should be regulated.
- 13. A medical procedure is classified as high-risk if the
  - (a) risk of procedure is high; or
  - (b) risk of anaesthesia involved is high; or
  - (c) patient's condition is classified as Class 3 severe systemic disease unstable (acute exacerbation) or worse according to the American Society of Anaesthesiologists (ASA) Physical Status Classification System.

'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.

Similar to 'hospitals', facilities controlled by the Government, HA and the Garrison would be exempt from regulation. Barring unforeseen circumstances, Chinese medicine practitioners offering outpatient services in the community would not be caught within the ambit of high-risk medical procedures defined based on the principles set out above. Besides, facilities already regulated as 'hospitals' would require no separate regulation under this part.

14. We also propose introducing a mechanism to regularly review and update the lists of high-risk procedures. The mechanism should involve seeking expert advice from the Hong Kong Academy of Medicine (HKAM).

# C. Facilities Providing Medical Services under the Management of Incorporated Bodies

- 15. We propose that facilities providing medical services under the management of incorporated bodies should be regulated.
- 16. The provision of medical service could take a variety of organizational forms. Among them, there have long been concerns over 'medical groups' or

'managed care organizations' operated in the form of incorporated bodies, including statutory bodies and registered societies and incorporated companies in which non-medical investors or managers would take part in the operation of PHFs. We consider it necessary to introduce facilities-based regulation in addition to professional self-regulation for these PHFs. This is because registered medical practitioners practising there do not have full control of the PHFs concerned in ensuring effective governance and maintaining high service quality. Exemption will be granted to PHFs **owned, managed, operated and serviced solely by identical registered medical practitioners** because there would not be similarly perceived operational risk. These practising registered medical practitioners could be held solely accountable for their own practice. Any matters arising from these PHFs could be followed up by existing established mechanism governing the professional practice of registered medical practitioners.

- 17. Given their current mode of organizations, "Non-profit-sharing medical clinics" currently registered under Cap. 343 will all be registered under this category under the new regulatory regime. Chinese medicine clinics and, similar to the two other classes of PHFs, facilities controlled by the Government, HA and the Garrison will be exempt from regulation.
- 18. To avoid duplicate regulation, all PHFs which are already regulated as 'hospitals' or 'facilities providing high-risk medical procedures in ambulatory setting' should automatically be exempt from regulation as this class of PHFs.

## **Schematic Outline of Proposed Regulatory Aspects (Chapter 4)**

19. The essential regulatory requirements under the new regime are expressed in modular form. There are all together nineteen regulatory aspects (under five broad categories of control). Their **proposed applicability** to the three classes of PHFs is at **Appendix**.

## **Corporate Governance (Chapter 5)**

- 20. Corporate governance refers to the system of rules, practices and processes by which a company/organization is directed and controlled. The following five regulatory aspects aim at enhancing corporate governance of PHFs:
- (A1) Appointment of Person-in-charge we propose mandatorily requiring the appointment of a person-in-charge for each regulated PHF;

- (A2) Establishment of Medical Advisory Committee we propose mandatorily requiring the establishment of medical advisory committee for hospitals;
- (A3) Complaints Management System we propose establishing a two-tier complaints management system for hospitals; and a streamlined complaints management system for other regulated PHFs;
- (A4) Establishment of an Information System Connectable with the Electronic Health Record Sharing System (eHRSS) we propose that hospitals should, in time, establish an information system connectable with eHRSS; and
- (A5) Maintenance of Hospital Accreditation Status we propose that consideration should be made to require any established hospitals to participate in hospital accreditation and keep the regulatory authority informed of any change in the accreditation status.

#### **Standard of Facilities (Chapter 6)**

- 21. We propose that the following three regulatory aspects should be included in the regulatory regime for enhancing standard of premises of all regulated PHFs –
- (B6) Premises Management effective premises management hinges on proper management and maintenance of physical assets such as buildings, equipment, power and water supply with a view to ensuring the quality of services provided;
- (B7) Physical Conditions include but not limited to the state of repair, ventilation, lighting, and periodical maintenance of a PHF;
- (B8) Infection Control PHFs should devise mechanism regarding infection control on diagnosis, treatments, operations and other medical procedures, etc. performed in regulated premises (for example, documentation procedures to ensure staff have complied with relevant protocols)

## **Clinical Quality (Chapter 7)**

22. Effective monitoring of the quality of clinical practice is essential to improving the quality of medical service, minimising clinical risk and increasing

effectiveness in service delivery. We consider the following six regulatory aspects are indispensable in ensuring clinical quality of PHFs:

- (C9) Service Delivery and Care Process we propose prescribing standards on service delivery and care process for compliance of all PHFs;
- (C10) Resuscitation and Contingency we propose hospitals and facilities providing high-risk medical procedures in ambulatory setting should comply with standards on the availability and readiness of essential resuscitation equipment (such as monitoring device and defibrillator) and guidelines as well as contingency planning;
- (C11) Standards Specific to Procedures Performed we propose prescribing standards embracing requirements on the premises, equipment and staffing for high-risk procedures the administration of which is confined to regulated facilities;
- (C12) Credentialing of Visiting Doctors we propose mandatorily requiring hospitals to implement policies in relation to the credentialing of visiting doctors;
- (C13) Establishment of Clinical Audit System we propose mandatorily requiring hospitals to conduct clinical audits (by standing clinical audit committee); and
- (C14) Sentinel Events Management we propose hospitals should establish a comprehensive sentinel events management system to strengthen internal quality assurance and enable the regulatory authority to gain access to relevant information for regulatory purposes. However, a dedicated and full-fledged mechanism might be too onerous and beyond the capability of other classes of PHFs given their limited scale of operation. Further deliberation is necessary before deciding whether this aspect should be applied to all regulated PHFs.

## **Price Transparency (Chapter 8)**

23. A high level of price transparency allows the public to be better informed before making decisions in meeting their medical needs and making necessary financial arrangements in advance. Consumer rights would also be better protected under a more transparent disclosure regime.

- 24. The regulatory regime for PHFs should therefore include the following four regulatory aspects relating to price transparency:
- (D15) Provision of Fee Schedule we propose that fee schedules, covering all chargeable items, should be publicly available at all regulated PHFs:
- (D16) Provision of Quotation we propose that hospitals should inform patients of the estimated total charges for the whole course of investigative procedures or elective, non-emergency therapeutic operations/procedures for known diseases on or before admission;
- (D17) Provision of Recognized Service Packages we propose encouraging all PHFs to provide Recognized Service Packages which are identically and clearly defined standard services provided at packaged charge; and
- (D18) Disclosure of Historical Bill Sizes Statistics we propose mandatorily requiring hospitals to publish key historical statistics on their actual bill sizes for common treatments/procedures as prescribed by the regulatory authority.

## **Sanctions (Chapter 9)**

25. Regulated PHFs that fail to comply with the above regulatory requirements should be subject to sanctions commensurate with the seriousness of the offence. We propose the following **maximum penalties** for hospitals (and the Person-in-charge in respect of imprisonment) and other regulated PHFs

## (1) <u>Unlawful Operation (hospitals)</u>:

- a fine of **\$5,000,000**
- imprisonment for **two years**

## (2) Unlawful Operation (other regulated PHFs):

- a fine of **\$100,000**
- imprisonment for **three months**

## (3) Non-compliance of other provisions of the legislation (hospitals):

- a fine of **\$1,000,000**
- a daily fine of \$10,000 for continuous contravention

- (4) <u>Non-compliance of other provisions of the legislation (other regulated PHFs)</u>:
  - a fine of \$25,000
  - a daily fine of \$2,000 for continuous contravention

#### **Powers of the Regulatory Authority (Chapter 10)**

- 26. For effective enforcement and operation of the revamped regulatory regimes for PHFs, the regulatory authority should be provided with appropriate regulatory powers necessary to ensure proper oversight of regulated PHFs to safeguard the safety and interest of the public. We propose that the regulatory authority/Government should be vested with powers to
  - (a) Issue and amend regulations/code of practice the regulations and/or code of practice should set out the principles, procedures, guidelines and standards for the operation and management of PHFs and provide practical guidance;
  - (b) Inspect, collect and publish information to inspect, collect and publish information from PHFs for regulatory purposes and public scrutiny;
  - (c) Suspend a facility/service/use of equipment to suspend the use of all or part of a facility/service/use of equipment to enable a proportionate response to manage an immediate and serious risk to patient safety;
  - (d) Appoint committees to appoint committees advising on the regulation of PHFs, including but not limited to the followings:
    - (i) <u>Advisory Committee on Regulation of Private Healthcare Facilities</u> to advise on issues in respect of registration, compliance and other matters of concern that relate to regulation of PHFs;
    - (ii) <u>Independent Review Committee on Regulatory Actions</u> to handle appeals lodged by regulated PHFs or any person who is aggrieved by regulatory decisions (e.g. refusal of registration) or enforcement actions (e.g. order of service suspension) taken by the regulatory authority; and
    - (iii) <u>Independent Committee on Complaints against Private Hospitals</u> to handle complaints lodged by the public against the service of private hospitals or against how complaints are handled by private hospitals.

(e) Devise, Review and Update the Scope and Standards of Regulation for High-risk Medical Procedures/Practices – to devise, review and update the scope and standards of regulation of high-risk medical procedures/practices so that the regulatory regime can keep up with the advancement in technology and medical services.

### **Introducing a New Regulatory Regime (Chapter 11)**

27. To implement the aforesaid proposals, we propose replacing the two existing ordinances (i.e. Cap. 165 and Cap. 343) by a new single legislation regulating all three proposed classes of PHFs. The Director of Health will be empowered to enforce the regulatory requirements under the new regime.

#### **Interim Measures (Chapter 12)**

- We recommend that short to medium term administrative measures should be introduced to supplement the existing regulatory regime before enactment of the new regime by legislation, including (a) **reviewing Cap. 165 CoP** to enhance existing regulatory requirements in the regulatory regime for PHFs, (b) conducting a survey to **assess the number and types of private healthcare facilities** that might be affected by the new regulatory regime, as well as their range of services and (c) introducing an **administrative listing system for ambulatory facilities providing high-risk medical procedures** to monitor such facilities before the introduction of statutory registration.
- 29. The regulatory authority will also work with 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 before incorporated into the future legislation as part of the statutory requirements.

#### We Need Your Views

- 30. Your view and comments on the proposals for revamping the existing regulatory regime for PHFs are much appreciated. We would like to invite you to focus on and share with us how you feel about the following issues set out in this Consultation Document
  - (1) the proposed three classes of PHFs to be regulated and their respective definitions:

- hospitals
- facilities providing high-risk medical procedures in ambulatory setting
- facilities providing medical services under the management of incorporated bodies
- (2) the proposed **nineteen regulatory aspects and their applicability** under the revamped regulatory regime (as shown in Appendix); and
- (3) the proposed **powers to be conferred on the regulatory authority**.
- 31. We will consolidate and analyses the views received for this public consultation exercise before deciding on the way forward. With community support for the proposals in this Consultation Document, we plan to proceed to implement the proposals through replacing Cap. 165 and Cap. 343 by a new legislation regulating PHFs subject to the findings of the public consultation exercise. We aim to introduce the legislative proposal to the Legislative Council in 2015/16.
- 32. Please send us your views on the Consultation Document on or before 16 March 2015 through the contact below. Please indicate if you do not want your views to be published or if you wish to remain anonymous when your views are published. Unless otherwise specified, all responses will be treated as public information and may be published in the future.

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## **Appendix**

## **Proposed Nineteen Regulatory Aspects and Their Applicability**

	Regulatory Aspects	Private Hospitals	Facilities Providing High-Risk Medical Procedures in Ambulatory Setting	Facilities Providing Medical Services under the Management of Incorporated Bodies
A. Corporate Governance				
A1	Appointment of Person-in-charge	✓	✓	✓
A2	Establishing Medical Advisory Committee	✓	N/A	N/A
<b>A3</b>	Complaints Management System	<b>✓</b>	Modified	Modified
A4	Information System Connectable with eHRSS	✓	N/A	N/A
A5	Maintenance of Accreditation Status	✓	N/A	N/A
B. Standard of Facilities				
<b>B6</b>	Premises Management	✓	<b>✓</b>	✓
<b>B7</b>	Physical Conditions	<b>√</b>	<b>✓</b>	✓
B8	Infection Control	<b>√</b>	<b>✓</b>	✓
C. Clinical Quality				
С9	Service Delivery and Care Process	<b>√</b>	✓	✓
C10	Resuscitation and Contingency	<b>√</b>	✓	N/A
C11	Standards Specific to Procedures Performed	<b>√</b>	✓	N/A
C12	Credentialing of Visiting Doctors	✓	N/A	N/A
C13	Clinical Audit System	✓	N/A	N/A
C14	Sentinel Events Management	<b>√</b>	Not now; could be considered in future	Not now; could be considered in future
D. Price Transparency				
D15	Provision of Fee Schedule	✓	✓	✓
D16	Provision of Quotation	<b>✓</b>	N/A	N/A
D17	Recognized Service Packages	Voluntary	Voluntary	Voluntary
D18	Disclosure of Statistics	✓	N/A	N/A
E. Sanctions				
E19	Sanctions	✓	✓	✓

#### List of Procedures That Could Be Considered As High-Risk

Established under the Steering Committee on Review of Regulation of Private Healthcare Facilities, the Working Group on Defining High-risk Medical Procedures/Practices Performed in Ambulatory Setting studied different methodologies and made reference to standards adopted overseas in attempting to define a range of high-risk medical procedures. The Working Group proposed that the following procedures could be considered as high-risk.

- 2. High-risk <u>surgical</u> procedures include the following procedures
  - (a) Creation of surgical wound to allow access to major body cavity or viscus<sup>1</sup> (including access to central large joints) [except peripheral joints distal to knee and elbow (i.e. ankle and below, and wrist and below)]
  - (b) Removal of tissue and/or fluid of a total volume of 500ml or above [except suprapubic tap]
  - (c) Removal of tissue and/or fluid of any volume from deep seated organ in children aged under 12 years old
  - (d) Removal of any volume of fluid and/or tissue from thoracic cavity [except diagnostic pleural tapping]
  - (e) Insertion of any prosthesis (including tissue filler) [except prosthesis in ENT cavity, dental prosthesis and implants, extra-ocular prosthesis and implants, intrauterine or vaginal prosthesis, bulking agents of urethra, prostatic urethral stent, urethral slings, testicular prosthesis]
  - (f) Any core biopsy [except core biopsy of (1) superficial tissue (such as skin, prostate, breast and uterus) but excluding thyroid or salivary glands; (2) superficial muscle; or (3) peripheral muscle]
  - (g) Any biopsy of organ or tissue requiring image guidance
  - (h) Fine needle biopsy of deep-seated organ
  - (i) Lumbar puncture
  - (j) Transplant of any cell, tissue and organ (including autograft, allograft and processed tissue or blood products<sup>2</sup>) or skin flap (including face lift) [except small skin graft less than 3 cm in any dimension, conjunctival autograft and transplant procedures which primarily

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Not including needle injection into joint cavity, intraocular injection with fine needle by ophthalmologists and injection of Botox

<sup>&</sup>lt;sup>2</sup> Include platelet-rich plasma (PRP)

involve dental-alveolar region]

- (k) Termination of pregnancy
- (l) Dilation and curettage
- (m) Circumcision with use of skin sutures in paediatric patients
- 3. High-risk <u>endoscopic</u> procedures include the following
  - (a) Endoscopic procedures requiring image guidance (such as endoscopic retrograde cholangiopancreatography (ERCP))
  - (b) Endoscopic procedures involving invasion of a sterile cavity (such as arthroscopy, laparoscopy and hysteroscopy) [except cystoscopy<sup>3</sup>] or gastrointestinal tract
  - (c) Therapeutic endoscopic procedures (such as endoscopic resection), [except minor therapeutic procedures (such as removal of foreign body)]
  - (d) Bronchoscopy or pleuroscopy
- 4. High-risk <u>dental</u> procedures include the following -

Maxillofacial surgical procedures that extend beyond dento-alveolar process, including but not limited to –

- (a) Maxillary osteotomies and mandibular osteotomies including angle reduction
- (b) Open reduction and fixation of complex maxillofacial fracture
- (c) Surgical treatment of diagnosed malignancies
- (d) Surgical treatment of complex haemangioma
- (e) Surgery involving major salivary glands
- (f) Open surgery of temporomandibular joint except arthrocentesis and arthroscopy
- (g) Harvesting of autogenous bone from outside the oral cavity
- (h) Primary cleft lip and palate surgery
- 5. The following procedures are also classified as high-risk
  - (a) Administration of chemotherapy (cytotoxic) through parenteral routes regardless of therapeutic indication

Cystoscopy does not include cystoscopic procedures such as cystoscopic biopsy, cystoscopic insertion or removal of ureteric catheter or stent, endoscopic urethral dilatation or urethrotomy, cystoscopic removal of stone or foreign body or polyp, cystoscopic injections/diathermy/cautery or haemostasis, cystoscopic lithotripsy, etc.

- (b) Image-guided core biopsy [except breast and superficial lymph node], or image-guided biopsy of deep seated organ
- (c) Haemodialysis
- (d) Transarterial catheterisation or deep venous catheterisation
- (e) Extracorporeal shock wave lithotripsy (ESWL) requiring image guidance
- (f) Injection of sclerosing/embolisation agents into vascular/lymphatic compartment of deep-seated head and neck region

#### Financial and Civil Service, Economic and Sustainability Implications

#### **Financial and Civil Service Implications**

There will be **financial and civil service implications** in implementing the proposal. FHB/DH will endeavor to implement the interim measures set out in paragraph 16 in the main paper and, as far as practicable, absorb additional workload arising from the preparatory work required for introducing relevant legislations into the Legislative Council and developing operational and technical details of the regulatory regime in consultation with stakeholders, etc. within existing resources.

- 2. In the long term, we envisage that there will be additional workload brought by the regulation of more than a thousand PHFs, at least five-fold to the existing number of about 200 PHFs regulated under Cap. 165 and Cap. 343 combined, including handling registration work, conducting inspection and carrying out enforcement actions. However, we are unable to provide a concrete estimate of the full resource implications at this stage. When the implementation details are worked out we will carefully assess the financial and manpower implications of the proposed regulatory regime.
- 3. Licence fees for PHFs registered under the new legislation will be set on a full cost recovery basis. Besides, the fines collected under the proposed regime will be credited to the Government Revenue Account in accordance with the established practice.

#### **Economic Implications**

4. As for **economic implication**, the proposal will increase compliance costs and administrative costs of PHFs, especially for those facilities providing high-risk medical procedures and incorporated companies that are currently unregulated. It is also possible that some service providers might be unable to meet the requirements and be out of business, according to FHB. However, the proposal would help protect patient safety and consumer rights, and improve the quality of private healthcare services, thereby conductive to the long-term sustainability of the healthcare system. These would help reduce the casualty and injury arising from medical malpractice in Hong Kong.

#### **Sustainability Implications**

5. There is also **sustainability implication** as the proposal aims at modernizing and strengthening the regulatory control of PHFs so as to better

safeguard patient safety and consumer rights. This could in turn enhance public confidence in using private healthcare services and facilitate the development of private healthcare market. The proposal is not intended as a total solution to the challenges of our healthcare system, but one of the turning knobs for adjusting the balance of the public-private healthcare sectors. Working together with other turning knobs such as public-private partnerships, the electronic health record platform, and the voluntary health insurance scheme, the proposal is expected to contribute towards the sustainable development of our healthcare system by rationalizing the use of healthcare resources between the public and private sectors in the long run.