BFAC Paper 1/15

Twenty-eighth Meeting of the Business Facilitation Advisory Committee

Agenda Item 2 : Proposed Regulation of Private Healthcare Facilities

Purpose

The purpose of this paper is to brief members on the public consultation on Regulation of Private Healthcare Facilities.

Background

2. The Food and Health Bureau launched a public consultation 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 (http://www.hpdo.gov.hk/doc/Regulation_of_PHFs_con_doc_e.pdf) with executive summary at **Annex 1** –

(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.

Existing Regulatory Regime for Private Healthcare Facilities

3. Hong Kong's healthcare system runs on a dual-track basis comprising both the public and private sectors, with roughly equal share of expenditure[1] but different emphasis and positioning[2]. 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).

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[1] 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.

[2] 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.

Need for Change

4. 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 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.

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 governance and price transparency could be adequately provided for.

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

6. 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

7. 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'.

8. 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.

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

9. 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 2**); 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.

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 9(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

10. 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, registered societies and incorporated companies) in which non-medical investors or managers may take part in the operation of PHFs. 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

11. 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) Penalties for non-compliance – 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) ***Unlawful Operation (hospitals)***:
- 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) ***<u>Non-compliance of other provisions of the legislation (hospitals)</u>***:
- 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

12. 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

13. 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

14. 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.

Next Steps

15. We have conducted open consultation forums for the public in general, and arranged targeted consultation sessions with specific groups of relevant sectors, professions and stakeholders. Polling has also been conducted to gauge public views on key issues of the proposal.

16. Subject to the views gathered during the consultation period, we will proceed with necessary legislative procedure to implement the proposal.

Way forward

17. Members are invited to note and offer comments on the contents of this paper.

Food and Health Bureau
March 2015

Executive Summary

Chapter 1
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[1] 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. By 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 diagnosis and treatment. 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 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**.

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**

1 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.

to direct statutory control beyond regulation of individuals' professional practice. Regulatory oversight is achieved indirectly through generic regulations applicable to aspects such as healthcare professionals, the use and handling of dangerous drugs as well as the instalment and operation of irradiating equipment. For example, the professional codes of conduct 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

4 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 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 an ambulatory setting in whatever way and form he/she deems appropriate. 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.

Chapter 2
Review on Regulation of Private Healthcare Facilities

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 following 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 is as follows -

(i) ***Working Group on Differentiation between Medical Procedures and Beauty Services (WG1)*** – 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.

Chapter 3
Private Healthcare Facilities to be Regulated

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.

Chapter 4
Schematic Outline of Proposed Regulatory Aspects

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

Chapter 5
Corporate Governance

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.

Chapter 6
Standard of Facilities

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; and

(B8) Infection Control – PHFs should devise mechanism regarding infection control on diagnosis, treatments, operations and other medical procedures, etc. performed in regulated facilites (for example, documentation procedures to ensure staff have complied with relevant protocols).

Chapter 7
Clinical Quality

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 facilites 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.

Chapter 8
Price Transparency

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 ensure that patients are provided with 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.

Chapter 9
Sanctions

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) ***Unlawful Operation (hospitals):***
- 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) ***Non-compliance of other provisions of the legislation (other regulated PHFs):***
- a fine of **$25,000**
- a **daily fine of $2,000** for continuous contravention

Chapter 10
Powers of the Regulatory Authority

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 following:

(i) Advisory Committee on Regulation of Private Healthcare Facilities – to advise on issues in respect of registration, compliance and other matters of concern that relate to regulation of PHFs;

(ii) Independent Review Committee on Regulatory Actions – 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) Independent Committee on Complaints against Private Hospitals – 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.

Chapter 11
Introducing a New Regulatory Regime

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.

Chapter 12
Interim Measures

28 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.

Chapter 13
Invitation of 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 t**hree 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 **19 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 from 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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Proposed 19 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
A3	Complaints Management System	✓	Voluntary	Voluntary
A4	Information System Connectable with eHRSS	✓	N/A	N/A
A5	Maintenance of Accreditation Status	✓	N/A	N/A
B. Standard of Facilities				
B6	Premises Management	✓	✓	✓
B7	Physical Conditions	✓	✓	✓
B8	Infection Control	✓	✓	✓
C. Clinical Quality				
C9	Service Delivery and Care Process	✓	✓	✓
C10	Resuscitation and Contingency	✓	✓	N/A
C11	Standards Specific to Procedures Performed	✓	✓	N/A
C12	Credentialing of Visiting Doctors	✓	N/A	N/A
C13	Clinical Audit System	✓	N/A	N/A
C14	Sentinel Events Management considered in future	✓	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	✓	N/A	N/A
D17	Recognized Service Packages	Voluntary	Voluntary	Voluntary
D18	Disclosure of Statistics	✓	N/A	N/A
E. Sanctions				
E19	Sanctions	✓	✓	✓

Annex 2

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 surgical procedures include the following procedures –

(a) Creation of surgical wound to allow access to major body cavity or viscus[1] (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

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

(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[2]) or skin flap (including face lift) [except small skin graft less than 3 cm in any dimension, conjunctival autograft and transplant procedures which primarily 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 endoscopic 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[3]] 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 dental 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

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[2] Include platelet-rich plasma (PRP)

[3] 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.

(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

(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