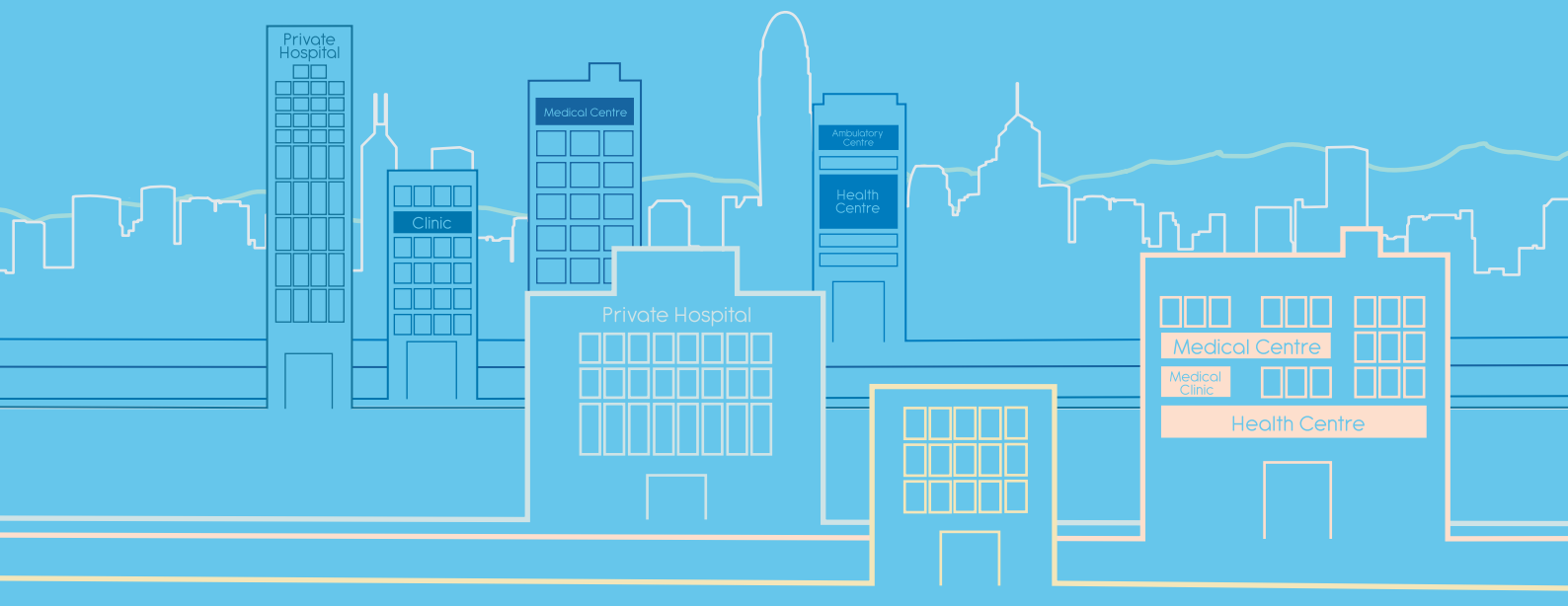




Regulation of Private Healthcare Facilities

Consultation Document



Food and Health Bureau
Hong Kong Special Administrative Region Government

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MESSAGE FROM DR KO WING-MAN, BBS, JP, SECRETARY FOR FOOD AND HEALTH



Dear Citizens,

Over the years, our healthcare system has evolved into its present shape and characteristics through changes and development that were in keeping with the needs and aspirations of the community. The dual-track system encompassing both public and private elements has served us well. Our strong and efficient public healthcare serves as a safety net for the general public. This is complemented by an adaptive and vibrant private healthcare sector providing more personalized and accessible services to those who are willing and could afford to make use of it.

The dual-track healthcare system functions well and will continue to have the backing of the Government. But we cannot rest on our laurels. We must respond to the challenges facing our healthcare system. Our population is aging. And the community's demand for healthcare services is ever increasing. We have been investing heavily in our public healthcare so that it will remain the bedrock of our healthcare system. The Government's commitment to public healthcare is beyond doubt. However, reliance on public healthcare alone cannot be a total solution to the problems in front of us.

To take on these challenges, we believe that promoting the development of private healthcare at a steady pace is equally important. Striking a balance between the public and private healthcare sectors with better collaboration will contribute to the sustainable development of our healthcare system. It is in the public interest to actively engage the private healthcare sector as our partners for safeguarding public health and fostering diversity in healthcare service.

In order to meet the public demand and better safeguard public health, we have undertaken to conduct a root-and-branch review of the regulatory regime for private healthcare facilities with a view to strengthening regulation and enhancing standards. Through the review, we have sought to align our regulatory regime with international best practices while recognising the need for local adaptation in view of our unique circumstances. I hope we can all seize the opportunity to build a consensus on how to make the best out of our private healthcare for the benefit of the community at large.

Finally, I would like to express my sincere gratitude to members of the Steering Committee on Review of Regulation of Private Healthcare Facilities and its working groups for their unfailing support and valuable comments. Their contributions are essential for us to come up with the recommendations.



Dr KO Wing-man
Secretary for Food and Health
December 2014

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 expenditure¹ 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 facilities (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 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.

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 **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 **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	✓	✓	✓

Chapter 1

Existing Regulatory Regime for Private Healthcare Facilities

1.1 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. 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. Revamping and modernizing the regulatory regime for private healthcare facilities (PHFs) will better safeguard public interest and help enhance the long term sustainability of our healthcare system.

1.2 Healthcare services consist of a variety of things, including healthcare professionals, drugs, devices, premises, procedures, advertisement/sales practice etc. Each aspect is regulated separately under different ordinances. Under the Medical Registration Ordinance (Cap. 161), the Dentists Registration Ordinance (Cap. 156), the Chinese Medicine Ordinance (Cap. 549), the Nurses Registration Ordinance (Cap. 164) and the Supplementary Medical Professions Ordinance (Cap. 359), medical practitioners, dentists, Chinese medicine practitioners, nurses and allied health professionals are required to register with their respective statutory boards/councils and observe requirements on professional conduct stipulated in their professional codes of conduct. The registration systems ensure that the practice and conduct of these healthcare professionals are up to standard, and practice without registration would constitute an offence. The Dangerous Drugs Ordinance (Cap. 134) and the Pharmacy and Poisons Ordinance (Cap. 138) stipulate requirements concerning the control of drugs and drug traders; the Radiation Ordinance (Cap. 303) prescribes the use and safe management of radioactive substance and irradiating apparatus; performance of certain medical procedures, such as human organ transplant, is restrained under the Human Organ Transplant Ordinance (Cap. 465); and certain advertisements relating to medicines and treatments are restricted by the Undesirable Medical Advertisements Ordinance (Cap. 231).

1.3 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. However, regulation of PHFs in Hong Kong is limited to a narrow set of facilities drawn up in 1960s mainly covering private hospitals and non-profit-sharing medical clinics. The Hospital, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) and the Medical Clinics Ordinance (Cap. 343) set out the regulatory framework for private hospitals, nursing homes and maternity homes; and non-profit-sharing medical clinics, respectively. 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 any statutory control beyond regulation of individuals' professional practice.

Private Healthcare Facilities in Hong Kong

(A) Private hospitals, nursing homes and maternity homes

1.4 Private hospitals, nursing homes and maternity homes are regulated under Cap. 165. Exemption is granted to facilities that are maintained by the Government, the Hospital Authority and the Garrison. As at July 2014, there were 11 institutions registered as private hospitals, 53 as nursing homes and 10 as maternity homes. All existing 10 institutions registered as maternity homes are concurrently registered as private hospitals. As the scope of nursing home is not specified in law, institutions registered as nursing homes provide rather diverse spectrum of medical and nursing services which include residential homes for the elderly, renal dialysis centres, and centres for eye surgery, termination of pregnancy, cancer patients, disabled children or drug dependents.

1.5 Under Cap. 165, the Department of Health (DH) could impose conditions relating to accommodation, staffing or equipment with the registration and is empowered to cancel the registration at any time if the conditions imposed have been contravened. Registration shall be valid until the end of the year and annual re-registration is required for continuous operation.

1.6 With the advancement of medical technology and rising community aspirations for quality services, there is growing public expectation for health care institutions to provide quality services and DH, as the regulator, to keep a close monitor on the registered institutions. To enable institutions to understand the requirements and standards of good practice, DH issued the Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes (Cap. 165 CoP) in 2003 which sets out the standards

of good practice for private hospitals to adopt, including requirements on the human resources management, management of premises and services, protection of the rights of patients and their right to know, the setting up of a system to deal with complaints, as well as management of medical incidents/ sentinel events, etc. Cap. 165 CoP also includes requirements for specific types of clinical and support services, such as laboratory services, outpatient services, pharmacy services, imaging services, sterilization services and maintenance services. Compliance with Cap. 165 CoP is a condition for the registration and re-registration of the facilities. However, Cap. 165 CoP is promulgated administratively and does not form part of Cap. 165.

(B) Non-profit-sharing clinics

1.7 Cap. 343 was enacted in 1963 to provide for the registration of non-profit-sharing medical clinics. Exemption is granted to facilities that are operated by government or certain healthcare professionals¹ registered under other legislation, who are subject to control by the professional code of conduct of their respective professions. Private consultation rooms of registered medical practitioners and dentists are exempt as long as these rooms do not bear any title or description which includes the word “clinic” or “polyclinic”. As at July 2014, there were 113 clinics registered under Cap. 343.

1.8 Under Cap. 343, DH could impose conditions relating to accommodation, staffing or equipment with the registration and is empowered to cancel the registration at any time if the conditions imposed have been contravened. Registration shall be valid for one year and re-registration is required for continuous operation.

1.9 To facilitate these clinics to meet the standards of good practice, DH issued the Code of Practice for Clinics Registered under the Medical Clinics Ordinance (Cap. 343 CoP), setting out the standards of various aspects including registration, human resources management, accommodation and equipment, medical record keeping, patients care and rights, drug records and dispensing, infection control and complaints handling procedures. Compliance with the requirements in Cap. 343 CoP is a condition for the registration and annual re-registration of clinics.

(C) Other PHFs

1.10 Apart from private hospitals and non-profit-sharing clinics, 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 any specific regulation. These PHFs are not required to be registered as long as they do not bear any title

¹ As stipulated in the definition of “clinic” under section 2 of Cap. 343, these professionals include medical practitioners, dentists, Chinese medicine practitioners, pharmacists, physiotherapists, chiropractors and optometrists.

or description that includes the word 'clinic', in which case such facilities would be regulated under Cap. 343 and must be non-profit-sharing. The organization, physical set-up and operation of these facilities are not subject to any direct control or oversight. There are also no statistics as to the numbers of ambulatory medical centres and clinics in Hong Kong.

Need for Change

1.11 Currently, PHFs in Hong Kong are not regulated in a way commensurate with their comprehensiveness of services and level of clinical and operational risk involved. Instead of being regulated by a single comprehensive legislation, they are subject to scattered regulatory regimes for various specific aspects. Cap. 165 and Cap. 343 regulate only private hospitals and non-profit-sharing medical clinics leaving out other PHFs such as ambulatory medical centres and clinics operated by medical groups or individual (or jointly by several) medical practitioners. Cap. 165, enacted in 1936, and Cap. 343, enacted in 1963, have undergone no substantive amendments throughout the years except for very minor technical updates. The regulatory standards prescribed in both ordinances are confined to limited aspects of healthcare services, namely accommodation, staffing and equipment.

1.12 Both Cap. 165 and Cap. 343 are outdated and ineffective in providing adequate regulation for PHFs. There is a need to broaden the regulatory scope beyond accommodation, staffing and equipment so that other facets essential to PHFs regulation such as corporate governance, clinical quality and price transparency could be adequately provided for. 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 Cap. 161 has been found wanting as any registered doctor with a valid practising 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 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.

1.13 In the light of the above, we consider that there is a genuine need to introduce a more robust and comprehensive regulatory regime for PHFs. In devising the new regulatory regime, it is necessary to identify key regulating aspects crucial to

the regulation of PHFs. To start with, we have made reference to previous reviews conducted by different parties including DH, the Audit Commission and the Public Accounts Committee of the Legislative Council. We have drawn heavily on the findings and recommendations of the recently completed review overseen by the Steering Committee on Review of Regulation of Private Healthcare Facilities (the Steering Committee). The recommendations of this Consultation Document are the same as those deliberated and recommended by the Steering Committee for the three classes of PHFs proposed to be regulated under the new regime.

Chapter 2

Review of Regulation of Private Healthcare Facilities

2.1 This Chapter gives a brief account of the reviews on the regulations of private healthcare facilities (PHFs), including the findings and recommendations of the Department of Health (DH)'s review in 2000, and also the review of the Audit Commission (Audit) and the subsequent Public Accounts Committee Report in 2012/13. An overview would also be provided for the latest review of the Steering Committee on Review of Regulation of Private Healthcare Facilities (the Steering Committee), the recommendations of which form the basis of the proposals of this Consultation Document.

Review of Legislation for the Regulation of Health Facilities

2.2 In October 2000, DH conducted a Review of Legislation for the Regulation of Health Facilities (the 2000 review) in order to improve the regulatory regime for PHFs. Having regard to the views of stakeholders and the then latest development in the regulatory framework in overseas countries, the 2000 review recommended a number of recommendations including —

- (a) Strengthen the regulatory regime for private hospitals with a focus on the regulatory standards and mechanism to ensure quality of patient care, safety, and service quality;
- (b) Extend the scope of the existing legislation to cover healthcare institutions conducting high-risk medical procedures;
- (c) Institute a more comprehensive and systematic complaint-handling system to deal with complaints arising from the practice of healthcare institutions;
- (d) Provide flexibility for the regulatory authority to add or change licensing conditions expeditiously at times of urgency; and
- (e) Enhance the role of the regulatory authority in monitoring healthcare institutions, such as the power to inspect and collect information, and the power to suspend facilities/services/equipment which are endangering the safety of patients.

2.3 Subsequent to the 2000 review, DH supplemented the regulatory regime through issuing the Code of Practice (CoP) for private hospitals and medical clinics setting out the standards of good practice and quality of healthcare services; and established a dedicated unit, the Office for Registration of Healthcare Institutions (ORHI), to undertake the licensing of private hospitals, nursing homes, maternity homes and medical clinics. Compliance with CoP and other registration conditions by regulated PHFs are monitored by ORHI through inspections and investigation into complaints, sentinel events and other incidents.

Reports of the Audit Commission and the Public Accounts Committee of the Legislative Council on Regulatory Control of Private Hospitals

2.4 In October 2012, Audit published a value-for-money report on the regulatory control of private hospitals (Audit report). The Audit report revealed room for improvement in the regulatory control of private hospitals and urged the Government to review the existing regulatory regime to effectively regulate private hospitals, particularly in the areas of service standards, mechanism for handling sentinel events and complaints, transparency of medical charges, and penalty for non-compliance. The Audit report proposed, among others, the following recommendations to strengthen the regulatory control of private hospitals —

- (a) the regulatory authority should take a proactive role and implement effective monitoring mechanisms in regulating the services provided by private hospitals;
- (b) the sentinel event reporting system and complaint handling mechanism for private hospitals should be enhanced;
- (c) information should be made available to the public in a timely manner when serious irregularities concerning the operation and management of the private hospitals are detected;
- (d) the regulatory authority should take measures to enhance the price transparency of private hospitals; and
- (e) a review on the regulatory regime for PHFs within set timeframe should be conducted, followed by public consultation and legislative process as early as practicable.

2.5 In February 2013, the Public Accounts Committee (PAC) issued a report corresponded to the findings and recommendations of the Audit reports, and expressed

concerns on the insufficient manpower in ORHI for carrying out its regulatory and monitoring functions effectively.

2.6 Based on the findings and recommendations of Audit and PAC, the Government had taken actions with a view to strengthening regulatory control of private hospitals including enhancing the private hospital inspection programme, improving the sentinel event reporting and management system, stepping up regulatory actions in identifying and monitoring the rectification of irregularities, etc. Additional manpower has also been provided to ORHI to strengthen its regulatory work. Besides, the Government set up the Steering Committee to conduct a review on the regulatory regime for PHFs.

Steering Committee on Review of Regulation of Private Healthcare Facilities

2.7 The Steering Committee, chaired by the Secretary for Food and Health with members from the medical sector, academia and civil society, was established in October 2012 to conduct a root-and-branch review of the regulation of PHFs. Taking into account the findings of previous reviews, the latest development in the regulatory models of PHFs in overseas jurisdictions, the unique circumstances of the local healthcare sector, and views from stakeholders and general public on the regulation of PHFs, the review aims to (a) identify areas of the current legislative regime, including the Hospital, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) and the Medical Clinics Ordinance (Cap. 343), requiring enhancement and improvement, (b) examine the scope of regulation (whether to extend to other healthcare facilities) and to formulate options and examine the pros and cons of each approach, as well as (c) advise on the strategies on public consultation for the way forward.

2.8 Four Working Groups under the auspices of the Steering Committee have been set up to conduct in-depth study on four priority areas –

- (i) Working Group on Differentiation between Medical Procedures and Beauty Services;
- (ii) Working Group on Defining High-risk Medical Procedures/Practices Performed in Ambulatory Setting;
- (iii) Working Group on Regulation of Premises Processing Health Products for Advanced Therapies; and
- (iv) Working Group on Regulation of Private Hospitals.

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

2.10 The review was completed in June 2014 and the Steering Committee has endorsed the findings and recommendations proposed by the four Working Groups. The ensuing paragraphs set out the key recommendations proposed by the Working Groups and the progress in taking forward the recommendations.

Working Group on Differentiation between Medical Procedures and Beauty Services (WG1)

2.11 WG1 was tasked to differentiate between medical treatments and ordinary beauty services and making recommendations on the regulatory approach. WG1 considered that certain cosmetic services should be performed by registered medical practitioners/ dentists because of the risks involved. These procedures include those involving injections, mechanical/chemical exfoliation of the skin below the epidermis, hyperbaric oxygen therapy¹ and dental bleaching. WG1 identified a total of 35 cosmetic procedures with potential safety concerns and recommended that 15, among the 35, cosmetic services should be performed by registered medical practitioners/ dentists because of the risks involved. For the remaining 20 procedures, most of them are cosmetic procedures involving the use of medical devices, particularly energy-emitting devices, the Steering Committee agreed that the regulatory approach to these procedures should be deliberated within the regulatory framework for medical devices currently under review. We plan to introduce a regulatory regime for the control of the use of specified high-risk medical devices through the new medical device legislation. A consultant will be engaged to conduct an in-depth study into the subject and consult stakeholders, including the beauty industry and medical profession. The full report of WG1 is at http://www.dh.gov.hk/english/useful/useful_medical_beauty/files/WG_report_eng.pdf.

Working Group on Defining High-risk Medical Procedures/Practices Performed in Ambulatory Setting (WG2)

2.12 WG2 established five Expert Groups to deliberate on the scope of regulation and regulatory approach for five areas, namely (1) surgical procedures, (2) endoscopic procedures, (3) dental and maxillofacial procedures, (4) chemotherapy, diagnostic/interventional radiological procedures; and (5) renal dialysis, cardiac catheterisation, lithotripsy. Major health professional groups were consulted in writing from December

1 WG1 recommended that this procedure should only be performed by registered medical practitioners on patients with clinical need and not as a form of beauty procedure.

2013 to February 2014 so that their views and suggestions were taken into account when drawing up the recommendations.

2.13 WG2 recommended defining high-risk procedures by criteria set out in respect of –

- (i) risk of procedures;
- (ii) risk of anaesthesia involved; and
- (iii) patient’s conditions.

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

General Principles for Defining High-risk Medical Procedures

		<ul style="list-style-type: none"> • Risk of procedure and • Risk of anaesthesia } Whichever is higher		
		Low	High	Hospital-only
Patient's condition ¹ using ASA Classification ²	Class 1	Any healthcare facilities	Regulated ambulatory facilities or hospitals	Hospitals only
	Class 2			
	Class 3 - stable			
	Class 3 - unstable	Regulated ambulatory facilities or hospitals		
	Class 4	Hospitals only		
	Class 5	Hospitals only		

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

2 American Society Anaesthesiologists Physical Status Classification System:

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

2.14 WG2 further recommended that –

- (i) ambulatory facilities where high-risk medical procedures are performed should be regulated by a statutory registration system;
- (ii) high-risk procedures should be performed only in regulated ambulatory facilities or hospitals by qualified health professionals;

- (iii) regulated ambulatory facilities should be subject to a set of core facility standards and requirements that cover – (a) management of the facility, (b) physical condition, (c) service delivery and care process, (d) infection control, and (e) resuscitation and contingency. Further facility standards that are specific to the procedures, e.g. haemodialysis, cytotoxic chemotherapy and anaesthesia, would be imposed; and
- (iv) a mechanism should be established to devise, review and update the scope of regulation and standards with regard to the expert advice of the Hong Kong Academy of Medicine (HKAM).

2.15 WG2 recommended that a survey should be conducted to assess the number and types of PHFs that might be affected by the proposed regulatory measures and requirements, as well as the range of their services, and an administrative listing system might be implemented before the introduction of statutory registration. As an interim measure, DH will work with 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 they become mandatory when the statutory registration system comes into effect. The full report of WG2 is at <http://www.hpdo.gov.hk/en/fhsdrelevantpapers.html>

Working Group on Regulation of Premises Processing Health Products for Advanced Therapies (WG3)

2.16 WG3 was tasked to recommend regulatory control on premises where cells, tissues and health products for advanced therapies are stored and processed in Hong Kong. WG3 recommended introducing a new legislation with an overarching authority to regulate cells, tissues and health products for advanced therapies through a comprehensive set of regulatory controls including licensing requirements for premises, accreditation of premises, compliance with guidelines, adverse event reporting, designation of Person-in-charge, staffing requirement and training, import and export control, and registration of health products for advanced therapies. The full report of WG3 is at <http://www.hpdo.gov.hk/en/fhsdrelevantpapers.html>

Working Group on Regulation of Private Hospitals (WG4)

2.17 WG4 was tasked to review the regulatory regime for private hospitals, and to formulate recommendations aiming for better control of different aspects related to the provision of healthcare services by private hospitals. WG4 recommended ways to enhance corporate governance, clinical governance, price transparency, management of complaints and sentinel event reporting system for private hospitals. It also

recommended enhancing the statutory power of the regulatory authority with a view to strengthening the effectiveness in enforcing regulatory standards. The full report of WG4 is at <http://www.hpdo.gov.hk/en/fhsdrelevantpapers.html>

Facilities providing medical services under the management of incorporated bodies

2.18 Apart from private hospitals and ambulatory centres providing high-risk medical procedures, there are facilities in Hong Kong providing medical services in the form of incorporated bodies (including statutory bodies, registered societies and incorporation companies) where persons bearing the ownership, management, operation and the provision of medical service do not always align. Such facilities usually operate as outpatient clinics mainly providing primary care to the public. Therefore, they would not fall within the remit of the proposed regulatory framework for private hospitals and ambulatory centres providing high-risk medical procedures. The protection of patient safety and assurance of the professional standard in these facilities rely solely on the regulation of individual medical practitioners. Because of their increased prevalence in the market and the operational risks pertinent to this mode of organization, the Steering Committee considered that there might be a need to regulate these facilities in addition to the abovementioned two other classes of PHFs.

Progress in taking forward the Working Groups' recommendations

2.19 With the endorsement of WG1's recommendations by the Steering Committee, DH had issued advisory notes in November 2013 to both the beauty industry and medical profession to remind practitioners that certain cosmetic procedures should be performed by registered medical practitioners/ dentists when providing these cosmetic services. Depending on the facts and evidence of each case, if the aforementioned cosmetic procedures are carried out not in accordance with the recommendations endorsed by the Steering Committee, enforcement action might be taken under the Medical Registration Ordinance (Cap. 161) and the Dentists Registration Ordinance (Cap. 156). Moreover, DH had also enhanced publicity to raise public awareness of the risks of cosmetic services.

2.20 For WG3, since the subject involved cutting edge and quickly evolving sector in healthcare technology, we consider a prudent approach should be adopted in taking forward the recommendations of WG3 to ensure that public safety would be adequately safeguarded while the development and adoption of technological advancement would not be unnecessarily hindered. 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. Meanwhile, DH would implement interim measures in particular educational campaign to increase the awareness of the trade and public on the potential risk associated with health products for advanced therapies. DH would also continue to regulate, under existing regulatory regimes, those health products for advanced therapies that fall under the definition of pharmaceutical products, including the registration of products, licensing of facilities, and import/export controls.

2.21 Albeit the proposed regulatory arrangements for private hospitals, facilities providing high-risk medical procedures and facilities providing medical services in the form of incorporated bodies were separately considered and formulated, these PHFs should be subject to a common core of regulatory requirements because of their similarities in the manner they provide medical services to the public. The recommendations of WG2 (an extract at **Annex B**) and WG4 (an extract at **Annex C**) serve as the foundation for drawing up the common core of regulatory requirements. The regulatory aspects constituting the common core are elaborated in Chapters 5 to 9.

2.22 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. The proposed scope of regulation for each of the three classes is elaborated in Chapter 3.

Chapter 3

Private Healthcare Facilities To Be Regulated

3.1 In devising the scope of regulation of the new regulatory regime (i.e. which private healthcare facilities (PHFs) should be regulated), we adopted a risk-based approach (including risk of procedures and operational risk) to identify the classes of PHFs that should be regulated.

3.2 Among all PHFs, private **hospitals** provide the widest range of medical services and entail the highest level of risks. The regulatory control on hospitals should therefore be the most stringent. To safeguard public safety, medical procedures that are too risky to be performed outside hospital setting should be classified as ‘hospitals-only procedures’.

3.3 Ambulatory medical centres (at which patients would be discharged on the day of admission and would not stay overnight) providing ‘high-risk’ medical procedures are commonly seen nowadays. We have categorised this class of PHFs as **facilities providing high-risk medical procedures in ambulatory setting** given the high risk level of the services provided and its ambulatory nature. Such ambulatory medical centres might provide any medical procedures, including those prescribed as ‘high-risk’, other than those classified as ‘hospitals-only procedures’ unless they are already regulated as hospitals.

3.4 In addition to the risk of procedures, some medical service providers are subject to operational risks which may affect patients’ well-being and consumers’ rights. These PHFs are usually managed by incorporated bodies, and the management/directors of which may not be medical practitioners. Doctors providing medical services in these PHFs might be subject to influence by the management due to cost/management considerations, causing concerns that the rights of patients/consumers might be compromised. We identified this class of PHF as ‘facilities providing medical services under the management of incorporated bodies’.

A. Hospitals

3.5 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’**.

Definition

3.6 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 the Medical Registration Ordinance (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 may exceed 12 hours'.

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

3.7 We propose that **facilities providing high-risk medical procedures in ambulatory setting** should be regulated.

Definition

3.8 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 Section A of Annex B(1)); **or**
- (b) **risk of anaesthesia** involved is high (a list of high-risk anaesthetic procedures is at Section B of Annex B(1)); **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.

3.9 **'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. We also consider that certain high-risk procedures

should be explicitly prohibited from being performed in this category of facilities because these procedures (namely ‘hospitals-only procedures’) should be confined to hospitals in view of its risk (a preliminary list of hospital-only procedures is at Section D of Annex B(1) for reference).

3.10 We also propose introducing a mechanism to regularly review and update the list of high-risk procedures. The mechanism should involve seeking expert advice from the **Hong Kong Academy of Medicine** on, among others, –

- (a) the range of high-risk procedures; and
- (b) the relevant procedure-specific facility standards.

‘Single-licence’ Principle

3.11 Separate licences as this class of PHFs are not required for PHFs already regulated as ‘hospitals’ to **avoid duplicate regulation**.

C. Facilities Providing Medical Services Under the Management of Incorporated Bodies

3.12 We propose that **facilities providing medical services under the management of incorporated bodies** should be regulated.

Background

3.13 Evolution in the provisions of medical service gives rise to a type of organisations, operated in the form of incorporated bodies (also commonly known as ‘Medical Groups’ or ‘Managed Care Organisations’), in which non-medical investors or managers may take part in the operation of PHFs. We accept that regulation is necessary for PHFs under the management of this type of organisations in which the practicing medical practitioners do not have full control of the PHFs concerned in ensuring effective governance and maintaining high service quality. Conventional PHFs **owned, managed, operated and serviced solely by identical registered medical practitioners should be exempt** from regulation because there would not be similarly perceived operational risk. The practising medical practitioner, in these conventional PHFs, 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 the registered medical practitioners concerned.

'Single-licence' Principle

3.14 Separate licences as this class of PHFs are not required for PHFs already regulated as either 'hospitals' or 'facilities providing high-risk medical procedures in ambulatory setting'.

Implications to PHFs Currently Regulated under the Hospitals, Nursing Homes and Maternity Home Registration Ordinance (Cap. 165) and the Medical Clinics Ordinance (Cap. 343)

3.15 Under the proposed definitions for the three classes of PHFs mentioned in the preceding paragraphs, existing PHFs will be regulated under the new regime as long as they fall under any of the three definitions. Implications of the new definitions on existing PHFs are set out in the ensuing paragraphs.

Hospitals, Maternity Homes and Nursing Homes Currently Registered under Cap. 165

3.16 At present, there are three types of licences under the regulatory regime of Cap. 165 - hospitals, maternity homes and nursing homes.

3.17 The existing 11 hospitals registered under Cap. 165 will continue to be regulated as 'hospitals' under the new definitions. Regarding the existing 10 maternity homes, which are already part of the existing hospitals, should have already been regulated as 'hospitals'. Separate licences for maternity homes will not be necessary.

3.18 There are 53 institutions currently registered under Cap. 165 as 'nursing homes'. These institutions are currently providing a diverse range of service and will be regulated in accordance with the nature of their services under the new regime as appropriate as follows –

- (a) **three** residential centres for cancer patients and disabled children would be registered as '**hospitals**' as they should be providing both "continuous medical support" and "lodging" which falls under the new definition of 'hospital';
- (b) **10** renal dialysis centres and **two** centres for minor operations would be registered as '**facilities providing high-risk medical procedures in ambulatory setting**' as the services provided by these institutions falls under the definition of 'high-risk medical procedures' as discussed in paragraph 3.8 above;

- (c) **five** residential centres for treatment of drug dependents would not be caught in the proposed regime if they provide little or no medical treatment. It should be noted that these institutions are **already licenced** under the Drug Dependent Persons Treatment and Rehabilitation Centres (Licensing) Ordinance (Cap. 566); and

the remaining 33 institutions are residential homes for the elderly. These 33 residential homes for the elderly have no, among others, around-the-clock resident doctors essential for the provision of ‘continuous medical support’ as required in the proposed definition of hospital and, therefore, they will not be regulated as such under the new regime. With a view to unify the regulation of residential homes for the elderly, we propose that all of these 33 institutions should be registered as residential homes for the elderly under the regulatory regime provided by the Residential Care Homes (Elderly Persons) Ordinance (Cap. 459). 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 residential homes for the elderly from Cap. 165 to Cap. 459. The amendments are technical and there will not be any substantial changes to the existing level of regulatory requirements for the residential homes and Care and Attention homes for the elderly.

Clinics Currently Registered under Cap. 343

3.19 The Medical Clinics Ordinance (Cap. 343) provides for registration of medical clinics that are operated on a non-profit-sharing basis. The existing 113 clinics registered under Cap. 343 are owned and managed by the following three types of organisations respectively – (i) incorporated companies, (ii) registered societies and (iii) statutory bodies. Since the medical practitioners providing medical services in these clinics are not in full control of the facilities concerned, these medical clinics (and other similar organisations) will be regulated as ‘facilities providing medical services under the management of incorporated bodies’ under the new regulatory regime.

Chapter 4

Schematic Outline of Proposed Regulatory Requirements

4.1 The findings and recommendations of the reviews on regulation of private healthcare facilities (PHFs) reveal that PHF regulation can be dissected into separate and distinct building blocks each targeting an essential area of regulatory need. There are 19 regulatory aspects which, putting together, constitute the essential regulatory requirements under the new regulatory regime for PHFs.

4.2 Adopting a building-block approach allows greater flexibility to fine tune the level and content of each regulatory aspect having regard to risk, scale and complexity of services pertaining to different classes of PHFs. It also enhances consistency and uniformity in regulation, while providing room for adjustments to cater for variations (e.g. scale of business, complexity in management, available resources and mode of operation) in different types of PHFs. For each of the three classes of PHFs proposed to be regulated (see Chapter 3), we have examined the 19 regulatory aspects one by one, by first determining whether it is applicable to a class of PHF and, if yes, how and to what extent it should be imposed on that class of PHFs having regard to a basket of considerations including –

- (a) Calibrating control measures commensurate with risks to patients;
- (b) Striking a balance between professional autonomy and proper risk control;
- (c) Improving accountability having regard to scale of operation and complexity of operation;
- (d) Keeping compliance cost in check without compromising regulatory effectiveness; and
- (e) Facilitating the sustainable development of private healthcare services in the long-term.

4.3 The 19 aspects are categorized into five groups according to their target regulatory areas –

(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)

(A5) Maintenance of Hospital Accreditation Status

(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

(C11) Standards Specific to Procedures Performed

(C12) Credentialing of Visiting Doctors

(C13) Establishment of Clinical Audit System

(C14) Sentinel Events Management

(D) Price Transparency

(D15) Provision of Fee Schedule

(D16) Provision of Quotation

(D17) Provision of Recognized Service Packages

(D18) Disclosure of Historical Bill Sizes Statistics

(E) Sanctions

(E19) Sanctions

Details of the 19 regulatory requirements are set out in the ensuing Chapters.

Chapter 5

Corporate Governance

5.1 Corporate governance refers to the system of rules, practices and processes by which a company/organization is directed and controlled. Good corporate governance helps ensure service quality, efficiency and safety of private healthcare facilities (PHFs). PHFs should operate in accordance with a comprehensive set of rules, supported by an effective and accountable organization, in its day-to-day operation, management and service delivery. Among the 19 regulatory aspects proposed for PHFs, five of them aim at enhancing 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.**

(A1) Appointment of Person-in-charge

Existing Requirements

5.2 The Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) stipulates that the Director of Health (Director) may refuse an application for registration by a private hospital if it is not under the charge of a person who is either a duly qualified medical practitioner or a registered nurse and who is resident in the hospital.

5.3 The Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes (Cap. 165 CoP) stipulates that a person-in-charge (PIC) shall be of integrity and good character, be physically and mentally fit to operate the establishment and possess the qualifications, skills and experience necessary.

5.4 The Medical Clinics Ordinance (Cap. 343) stipulates that every person registered in respect of a clinic shall appoint and maintain a registered medical practitioner who shall be responsible for the medical management of the clinic concerned.

5.5 The Code of Practice for Clinics Registered under the Medical Clinics Ordinance (Cap. 343 CoP) requires that a clinic should be under the continuous personal supervision of a registered medical practitioner (who is called “Medical In-charge” in Cap. 343 CoP). Where there is any change in the Medical In-charge, prior approval from the Director shall be sought.

Observations

5.6 Having a PIC to oversee the management, day-to-day operation and service delivery is essential to a PHF's good corporate governance as there would be clear accountability for all matters happened within a PHF. As the sole representative of a PHF, the PIC would become the point of contact between the PHF and the regulatory authority/the public. The current requirements of the two Codes of Practices on the appointment of PIC are framed in broad terms. We consider that more detailed requirements about the appointment and functions of a PIC would be desirable to enhance organizational accountability.

Overseas Practices

The Private Hospitals and Medical Clinics Act and Regulations in Singapore and the Private Healthcare Facilities and Services Act in Malaysia require private hospitals to appoint a Person-in-Charge who shall take charge of the administration and management of the hospital. The Person-in-charge is also held accountable for breaches or non-compliance that would seriously affect the safety or integrity of hospital services.

Proposal

5.7 We propose **mandatorily requiring the appointment of a person-in-charge for each regulated PHF.**

5.8 The new regulatory regime would provide for the detailed requirements in respect of the appointment of the PIC of a regulated PHF. For example, the PIC should possess the qualifications, skills and experience necessary to manage the establishment, and his/her responsibilities should include overseeing the facilities management and service delivery of the PHFs concerned, etc. Under the new regime, it is also proposed that the PIC will be held accountable (and liable to penalty if the offence is substantiated) for breaches or non-compliance of the PHF concerned that would seriously affect the safety or integrity of healthcare services which he should be in reasonable control when appropriately discharging his responsibilities.

(A2) Establishment of Medical Advisory Committee (MAC)

Existing Requirements

5.9 Cap. 165, Cap. 343 and Cap. 343 CoP have no requirements regarding the establishment of MAC in PHFs.

5.10 Cap. 165 CoP stipulates that a private hospital should establish governing bodies, including but not limited to MAC. It also sets out that an MAC should comprise specialists from different specialties. The MAC advises the hospital management on matters relating to clinical practice and medical practitioners in the hospital. Among other things, it makes recommendations on eligibility criteria for the granting of practising privileges to medical practitioners, including review, renewal, restriction or withdrawal of practising privileges. It also monitors the clinical work undertaken at the hospital.

Observations

5.11 All registered private hospitals have established MAC in accordance with the requirement of Cap. 165 CoP. However, there is no statutory requirement on the structure, authority and operation of the MAC. Based on the information submitted by private hospitals, there are significant variations regarding the establishment, membership and terms of reference of MAC in private hospitals.

Overseas Practices

In Singapore, the Private Hospitals and Medical Clinics Act and Regulations require private hospitals to establish at least two Quality Assurance Committees (QACs), one on mortality and morbidity and the other on serious reportable events. Members of the QACs shall comprise medical, nursing, administrative and ancillary staff. It is also required by law that the QACs shall submit records/ review reports to the regulatory authority as and when requested.

In New South Wales of Australia, the Private Health Facilities Act stipulates that all private healthcare facilities shall establish MAC which shall comprise at least five medical practitioners, one of whom shall have no pecuniary interest in the private healthcare facility. The responsibilities of the MAC are stipulated in the Act. The regulatory authority may refuse/ suspend a license of a private healthcare facility if the licensee does not appoint an MAC in accordance with the Act.

Proposal

5.12 We propose **mandatorily requiring the establishment of MAC for all private hospitals**, with standardized minimum requirement on their composition, functions and responsibilities. The regulatory authority should also be empowered to, as and when necessary, require private hospitals to submit information concerning the set up and operation of their MAC (please refer to paragraphs 10.7 to 10.9 in Chapter 10).

Applicability to Non-hospital PHFs

5.13 We also propose that the establishment of MAC will not be applicable to ambulatory medical centres and clinics in view of their limited scale, structure and more straightforward services than hospitals. Non-hospital PHFs would have genuine difficulties in establishing and maintaining MACs in a manner similar to that of private hospitals. The cost of operation and manpower requirement would increase significantly if these PHFs were mandated to set up MACs. Besides, there is no known evidence overseas proving the setting up MACs in clinical-scale facilities would bring about marked assurance to better corporate governance of the PHFs concerned. Instead, we consider promulgating clear guidelines on proper management of non-hospital PHFs should be sufficiently adequate and proportionate in achieving similar objectives accomplished by establishing MACs in hospitals.

(A3) Complaints Management System

Existing Requirements

5.14 Cap. 165 CoP requires hospitals to put in place a mechanism for handling complaints made by patients or their representatives, and the mechanism should consist of procedures for receiving, investigating and responding to complaints. It also requires hospitals to display a notice setting out the channels for receiving complaints for patients' information at the admission office, reception counter of each of the individual service, cashier and reception hall. A hospital staff should be assigned as the patient relation officer to handle complaints. Hospitals are also required to provide the Department of Health (DH) with a complaint digest every month. The complaint digest shows a brief description of the complaints received, their nature, the results of investigation, and the action taken by the hospitals.

5.15 Cap. 343 CoP requires that a mechanism should be in place for handling complaints made by a patient or his/her representative. Furthermore, information on the channels for making a complaint shall be readily available to patients (e.g. a written notice should be displayed in the clinic which sets out the designated complaint channel for public reference).

Observations

5.16 Under the existing regulatory regime, hospitals should devise their own complaint handling mechanism based on their operational and administrative arrangements. The existing complaint handling system allows aggrieved parties to

lodge a complaint either with the hospital or DH or simultaneously. The duplication of complaint channel without a clear-cut hierarchy is undesirable, often resulting in overlapping efforts and disgruntled complainants. Setting out explicit arrangements under the new regulatory regime could avoid causing duplication of effort in handling the same matter and confusing the public on the distinct and different roles of the hospitals and regulatory authority.

Overseas Practices

Both the Private Health Facilities Regulation of the New South Wales of Australia and the Private and Voluntary Health Care Regulations of the England of the United Kingdom require private hospitals to have a set of clearly laid down complaints handling procedures available to patients and the public. To ensure consistency of complaints management across private hospitals, the jurisdictions lay down some fundamental requirements for the complaints handling procedures including thorough investigation of complaints, provision of written reply to the complainant and maintaining record of each complaint. In the United Kingdom, the regulations further require private hospitals to submit to the regulatory authority an annual summary of complaints received in the past twelve months and actions taken.

In New South Wales of Australia, the Health Care Complaints Act stipulates the establishment of the Health Care Complaints Commission (HCCC). The HCCC independently deals with complaints against health service providers by assessing and resolving complaints when possible. The powers of the HCCC also include abilities to investigate and seek alternate clinical opinion, to refer to professional registration boards, and to undertake disciplinary actions and prosecutions in case the complaints raise significant public health and safety issues.

In Singapore, healthcare institutions deal with all first-time complaints. The regulatory authority monitors issues related to clinical quality and patient safety, and handles complaints which could not be settled at hospital level.

Proposal

5.17 We propose, with reference to the two-level complaints management system adopted by the Hospital Authority, **establishing a two-tier complaints handling system** to handle all complaints against **private hospitals**.

5.18 At present, the Hospital Authority (HA) adopts a two-level complaints management system for all public hospitals. Specifically, a first-level complaints handling system aims to deal with first-time complaints lodged directly with the hospitals,

and each public hospital has designated a Patient Relations Officer who will serve as a convenient focal point to receive complaints from the public. As the second-level complaints system, the Public Complaints Committee is established under the HA Board to independently consider and decide on all appeal cases.

5.19 With reference to HA's practice, we propose that the first-tier complaints management for private hospitals should be at the service delivery level at which hospitals are required to manage complaints at source according to a standardized complaints handling mechanism prescribed by the regulatory authority. Unresolved cases in the first-tier would be escalated to the second-tier through a centralized and independent mechanism. We recommend that an Independent Committee on Complaints against Private Hospitals should be established to handle all complaints at the second-tier. The Independent Committee on Complaints against Private Hospitals should be empowered to investigate and review all appeal cases and make recommendations to the regulatory authority for consideration and follow-up actions.

Applicability to Non-hospital PHFs

5.20 The two-tier complaints handling would incur considerable amount of administrative workload and compliance costs for non-hospital PHFs which have a much smaller scale of operation and lower complexity in the organizational structure. The burden of complying with a comprehensive mechanism designed for full-fledged hospitals would unavoidably drive up cost of service which would eventually be borne by consumers. To strike a balance, we **propose** that a **simplified mechanism** should be adopted for non-hospitals PHFs, such that a designated complaints handling channel should be established. The complaints handling channel should include basic features such as a designated complaints method (say a fixed telephone number or email address), a designated staff of the PHFs concerned as the complaints manager and standard arrangements on how complainants should be informed of the investigation result.

(A4) Establishment of an Information System Connectable with eHRSS

Existing Requirements

5.21 Cap. 165 CoP requires hospitals to maintain comprehensive medical records for each patient (all medical records are required to be accurate, sufficiently detailed, legible, current, complete and organized). Cap. 165 CoP further requires private hospitals to draw up policies for handling, storage and destruction of records in order to ensure security and confidentiality of personal information.

5.22 Cap. 343 CoP stipulates that patients' health information should be stored in a dedicated patient medical record. It further sets out requirement on information to be included in the medical record, such as patient's name, gender, date of birth, residential address and contact telephone number, etc.

Observations

5.23 We observe that at present, hospitals and medical clinics have no difficulties in complying with the requirement of Cap. 165 CoP and Cap. 343 CoP to create and maintain medical records for each patient. To facilitate the best use of resources and provide the framework necessary for smooth transition of patients between different levels of care and between the public and private sectors, we foresee that it would be essential to develop a system which enables better access and sharing of patients' health records with patients' consent, to improve quality of care.

5.24 To this end, the Government is developing a territory-wide and patient-oriented eHRSS with a view to strengthening collaboration and sharing of information among different sectors of healthcare providers. The eHRSS provides an information infrastructure for healthcare providers in both the public and private healthcare sectors. With informed and express consent of the patient and proper authorisation for access to the system, PHFs could share electronic health records they keep on the patient with other healthcare providers and vice versa.

5.25 Benefits of the eHRSS to patients include maintaining comprehensive online record for health providers, providing timely and accurate information for care and reducing duplication of tests and treatment. As for medical practitioners/PHFs, eHRSS enables efficient and quality assured clinical practice and reduces errors associated with paper records. The eHRSS is expected to be launched in 2015, subject to the passage of an eHR-specific legislation in 2014/15.

Proposal

5.26 We propose that **hospitals** should, in time, **develop an electronic medical/patient record system** that can meet the technical requirements **to be connectable with the eHRSS**.

5.27 Whilst healthcare providers' and patients' participation in eHRSS will be voluntary, we consider that patients, healthcare service providers and the regulatory authority would all benefit from an connectable medical record system since both patients and hospitals would be able to share the benefits brought by the eHRSS as mentioned in paragraph 5.25 above. Moreover, hospitals would be able to better detect

health problems, define priorities, identify innovative solutions and allocate resources to improve services provided.

Applicability to Non-hospital PHFs

5.28 Development of an electronic health information system would incur significant amount of administrative and compliance costs which might become a burden to non-hospitals PHFs that operate in limited scales, such as clinics and ambulatory medical centres, which might in turn be transferred to patients through escalated medical fees. Non-hospital PHFs might require substantial capital investment to procure the necessary hardware (such as computers and other equipment) and software (those compatible to and can be integrated with the Government's eHRSS) for compliance with this regulatory requirement. Therefore, we consider that it practical to confine, for the time being, the applicability of this regulatory requirement to hospitals only.

(A5) Maintenance of Hospital Accreditation Status

Existing Requirements

5.29 Both Cap. 165 and Cap. 343 have no requirements regarding hospital accreditation. In Cap. 165 CoP, hospital accreditation is suggested as one of the quality assurance activities.

Observations

5.30 Private hospitals in Hong Kong currently participate in hospital accreditation programmes on a voluntary and self-initiated basis. All existing 11 private hospitals were accredited by the Trent Accreditation Scheme of the United Kingdom (which, however, ceased to operate in 2010) and, as at July 2014, ten of them have also been awarded full accreditation by the Australian Council on Healthcare Standards (ACHS).

5.31 Hospital accreditation is a recognition which hospitals may achieve to demonstrate that they have met prescribed standards set by an independent healthcare accreditation body. It is conducted through self-assessment and external peer assessment of hospitals' level of performance in relation to established standards and also continuous implementation of quality improvement measures. Accreditation promotes continuous improvement and strengthens corporate governance and is therefore an important quality assurance activity for the provision of hospital services.

5.32 The Government launched a Pilot Scheme on Hospital Accreditation in 2009 to develop a set of common hospital accreditation standards for measuring the performance of hospitals in Hong Kong and to also engage public and private hospitals in the accreditation programme on a territory-wide scale. The Pilot Scheme, concluded in 2011, has developed a set of locally applicable accreditation standards, namely the Evaluation and Quality Improvement Programme (EQulP) Hong Kong Guide, based on ACHS EQulP standards with minor modifications made to take into account of the local context. Phase II of the Hospital Accreditation Programme was launched in October 2011 which aims to implement hospital accreditation in more public hospitals and to train more local accreditation surveyors. The scheme is envisaged to achieve its target by 2016 to 2018.

5.33 Assessments of hospitals' performance consist of four stages, namely pre-accreditation self-assessment, organization-wide survey, periodic review and post-accreditation self-assessment. The assessment process would take into account evidence including results of on-site survey, hospital records and data (e.g. health records, patient and staff surveys, number of adverse events and near misses, guidelines and procedures etc).

Overseas Practice

According to World Health Organization (WHO), among the 47 countries studied in its 2003 survey on accreditation¹, there were 36 country-wide accreditation programmes in operation. One third of the programmes had various level of legislative backup (e.g. France, Italy, Netherlands, Poland and Scotland of UK etc.); while France and Italy made accreditation mandatory for all health services. In France, the French National Authority for Health, an independent public body mandated by law, manages accreditation programme for all healthcare organizations including hospitals. In Italy, all 20 regional governments are required to put in place accreditation programmes for healthcare institutions including hospitals.

1 World Health Organization, *Quality and Accreditation in Health Care Services: A Global Review* (2003), 113-116.

Proposal

5.34 We propose **making hospital accreditation a mandatory regulation requirement for private hospitals in the long run** when the regulatory authority is convinced that it is appropriate to adopt such programme as part and parcel of the registration/ re-registration conditions. In the interim, accreditation programme should be recognized explicitly as one of the desirable quality control measures, rather than as a suggestion as it is now. Private hospitals should keep the regulatory authority

informed of any change to their accreditation status, in which case the regulatory authority may take follow-up actions as appropriate.

Applicability to Non-hospital PHFs

5.35 The implementation of accreditation at ambulatory medical centres and clinics will not be considered before the completion of the entire Hospital Accreditation Programme in 2018, when the effectiveness and extent of application of hospital accreditation would be more fully evaluated. In the meantime, we will conduct research on overseas experience with a view to identifying appropriate accreditation systems for non-hospital PHFs. We will adopt an incremental approach before applying any quality assurance systems suitable to local circumstances.

Chapter 6

Standard of Facilities

6.1 It is important that the conditions of private healthcare facilities (PHFs) are fit for safe and effective provision of medical services. The facilities should have the essential physical conditions which include safe accommodation and reliable utility systems, etc. that are essential for providing medical services. Operators of PHFs must set out policies/rules in ensuring effective premises management in the facilities. The operators must also take measures to manage the specific risks encountered in healthcare setting, such as emergency preparedness and infection prevention and control.

6.2 We consider that PHFs should comply with the three regulatory aspects on standards of facilities: **(B6) Premises Management, (B7) Physical Conditions and (B8) Infection Control.**

(B6) Premises Management

Existing Requirements

6.3 The Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) stipulates that the Director of Health (Director) may refuse an application for registration of a private hospital if the situation, construction, accommodation, staffing or equipment of the hospital are not fit to be used for a hospital. The Medical Clinics Ordinance (Cap. 343) also stipulates that the Registrar of Clinic may refuse an application for registration of a medical clinic for reasons connected with sanitation, construction, accommodation, staffing or equipment that are not fit to be used for a clinic.

6.4 Both the Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes (Cap. 165 CoP) and the Code of Practice for Clinics Registered under the Medical Clinics Ordinance (Cap. 343 CoP) require the physical setting of a facility, including its design, layout and condition, should be appropriate for safe delivery of proposed service and meet the needs of patient, and require appropriate equipment in the establishment for intended services. Equipment should be kept in good working order and properly maintained.

Observations

6.5 Proper premises management, which covers coordination of space, infrastructure, people and organization of a PHF, reflects the overall quality of the PHF and administration efficiency of its management.

6.6 In Singapore, the Guidelines for Private Hospitals, Medical Clinics and Clinical Laboratories under the Private Hospitals and Medical Clinics Act prescribe standards on premises of a private healthcare institution including clearance of fire safety measures, cleanliness and hygiene, room or ward facilities, lighting, communication system, transport arrangements, linen service, etc. Compliance with the requirements is a condition for the registration and re-registration of private healthcare institutions.

6.7 In Wales of the United Kingdom, the National Minimum Requirement Standards for Independent Health Care Services require that PHFs should comply with legislation and guidance that are designed and maintained with the safety of patients in mind and ensure that patients' privacy and dignity is protected.

Proposal

6.8 We propose that **all classes of PHFs** proposed to be regulated should be **subject to mandatory requirements on premises management**. Key requirements in respect of premises management of PHF may include, but not limited to –

- (a) properly maintained equipment with good state of repair;
- (b) properly maintained infrastructure with good state of repair;
- (c) properly maintained lighting, air-conditioning and ventilation with good state of repair;
- (d) properly maintained water supply and ablutions;
- (e) properly maintained and written safety and fire precaution measures;
- (f) proper display of licenses, directional signs and names of all staff, rooms and facilities; and
- (g) mechanisms to ensure regular maintenance of all buildings and physical facilities to provide a safe and secure physical environment of care.

6.9 As PHFs operate in different scales with varying sophistication in the provision of medical services, further deliberation would be necessary to work out the details of appropriate premises management requirements that meet the needs of PHFs. Consultation with professional bodies, including but not limited to the Hong Kong Academy of Medicine (HKAM), would be required before deciding on the standards to be adopted.

(B7) Physical Conditions

Existing Requirements

6.10 Under Cap. 165 and Cap. 343, the Director is vested with the power to register or de-register private hospitals and medical clinics subject to conditions including, amongst others, **accommodation, equipment and supporting facilities**.

6.11 Both Cap. 165 CoP and Cap. 343 CoP require that the physical conditions of private hospitals and medical clinics, including design, layout and condition, to be appropriate for safe delivery of proposed service and meet the needs of patients, and that appropriate and well-functioning equipment should be available in the establishment for intended services.

Observations

6.12 Proper physical conditions, both in terms of accommodation and equipment, are crucial to the safety of patient and staff.

6.13 In Singapore, the Guidelines for Private Hospitals, Medical Clinics and Clinical Laboratories under the Private Hospitals and Medical Clinics Act prescribe standards on physical conditions of a private healthcare institution including size, layout, lighting, ventilation, and facilities for protecting privacy, etc. Compliance with the requirements is a condition for the registration and re-registration of private healthcare institutions.

6.14 In Wales of the United Kingdom, the National Minimum Requirement Standards for Independent Health Care Services require that PHFs should comply with legislation and guidance to provide environments that are accessible, well maintained, fit for purpose, safe and secure, protect privacy, and sustainable.

Proposal

6.15 We propose that **all classes of PHFs** proposed to be regulated should be **subject to mandatory requirements on physical conditions**. Key requirements in respect of the physical condition of PHF may include, but not limited to –

- (a) safe environment with adequate and appropriate physical setup (e.g. ventilation and lighting);
- (b) properly maintained premises with good state of repair;
- (c) facilities to provide for privacy of patients where necessary;

- (d) aids to facilitate the movement of the disabled where appropriate; and
- (e) mechanisms to ensure that all buildings and physical facilities are regularly maintained to provide a safe physical environment of care.

6.16 As PHFs operate in different scales with varying sophistication in the provision of medical services, further deliberation would be necessary to work out the details of appropriate physical design and equipment that meet the needs of PHFs. Consultation with professional bodies, including but not limited to HKAM, would be required before deciding on the standards to be adopted.

(B8) Infection Control

Existing Requirements

6.17 There is no provision in Cap. 165 and Cap. 343 governing the infection control of private hospitals and medical clinics. Such requirements may be indirectly inferred from both Ordinances since the Director is vested with the power to register or de-register private hospitals and medical clinics subject to conditions including, amongst others, accommodation and facilities.

6.18 Cap. 165 CoP requires a private hospital to set up an infection control team with trained members and have written policy, procedures and guidance for the prevention and control of infection. The infection control team should involve in training of staff on all aspects of infection prevention. Private hospital should notify the Department of Health (DH) in case of the outbreak of infectious disease, and any suspected or diagnosed statutorily notifiable disease in accordance with the Prevention and Control of Disease Ordinance (Cap. 599).

6.19 Cap. 343 CoP requires the medical-in-charge to implement infection control measures in the clinic with reference to guidelines published by international or local health authorities or agencies. The medical-in-charge should notify DH of any suspected or diagnosed statutorily notifiable disease under Cap. 599.

Observations

6.20 Infection is one of the key risks in the provision of medical services, especially for high-risk procedures such as surgery and haemodialysis. It is essential for PHFs to have in place effective infection prevention, control policy and procedures.

6.21 In Singapore, the Guidelines for Private Hospitals, Medical Clinics and Clinical Laboratories under the Private Hospitals and Medical Clinics Act stipulate requirements for the prevention of transmission of infectious diseases. The guidelines also require private healthcare institutions to ensure that all infectious and waste materials shall be properly disinfected and disposed of in accordance with the existing legislation.

6.22 In Wales of the United Kingdom, the National Minimum Requirement Standards for Independent Health Care Services require that PHFs should have in place infection prevention and control policy (IPC) and are required to ensure that the health, safety and wellbeing of people who use the services will not be adversely affected by inadequate IPC facilities and arrangements.

Proposal

6.23 We propose that all **classes of PHFs** proposed to be regulated should be **subject to mandatory requirements on infection control**. In particular, hospitals and ambulatory medical centres should develop and regularly update their policy and guidance on the control and prevention of infectious diseases based on latest international and local guidelines. There should also be a designated person to oversee infection control measures. Besides, statutorily notifiable infectious diseases and outbreak of infectious diseases in PHFs should be reported to DH.

Chapter 7

Clinical Quality

7.1 Clinical quality refers to the quality of medical services provided by private healthcare facilities (PHFs) and how well they are delivered. Improving quality is about making healthcare more safe, effective, patient-centred, timely and efficient. Failure in quality and safety management could result in poor patient outcome or even serious harm to patients.

7.2 The revamped regulatory regime seeks to enhance clinical quality through six areas – **(C9) Service Delivery and Care Process, (C10) Resuscitation and Contingency, (C11) Standards Specific to Procedures Performed, (C12) Credentialing of Visiting Doctors, (C13) Establishment of Clinical Audit System and (C14) Sentinel Events Management.** The rationale and significance of each of these six areas are elaborated in the following sections.

(C9) Service Delivery and Care Process

Existing Requirements

7.3 Service delivery and care process covers many aspects including appropriate staffing, protection of patients' rights, proper medical record management, and provision of relevant support services.

7.4 Under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165), the Director of Health (Director) may refuse an application for registration of a private hospital if the staffing of the hospital is not fit to be used for a hospital. Similarly, under the Medical Clinics Ordinance (Cap. 343), the Director may refuse an application for registration of a medical clinic for reasons connected with staffing that are not fit to be used for a clinic.

7.5 The Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes (Cap. 165 CoP) requires private hospitals to ensure that the staff or personnel who provide treatment and care in their establishment are appropriately skilled, qualified and competent. Moreover, private hospitals should at all times have an appropriate number of suitably qualified and experienced medical professionals in the premises, taking into account the number and needs of patients and types of services provided. Private hospitals should also have a policy to protect patients' right, manage medical records and provide access to relevant support services such as radiology and laboratory service.

7.6 The Code of Practice for Clinics Registered under the Medical Clinics Ordinance (Cap. 343 CoP) stipulates that registered clinics should have in place a policy to protect patients' right and manage medical records.

Observations

7.7 Effective service delivery and appropriate care process are the prerequisites for the proper operation of PHFs.

7.8 In Singapore, the Guidelines for Private Hospitals, Medical Clinics and Clinical Laboratories under the Private Hospitals and Medical Clinics Act set out standards related to the service delivery and care process for the PHFs including but not limited to personnel of the facility, workforce planning and organizational development, care planning and provision, records management, etc. The National Minimum Standards for Independent Health Care Services in Wales of the United Kingdom have similar requirements.

Proposal

7.9 We propose that **all classes of PHFs** proposed to be regulated should be **subject to mandatory requirements on service delivery and care process**. The regulatory standards for service delivery and care process should include but not limited to the following:

- (a) sufficient number of qualified staff on duty at all times;
- (b) patients are duly informed of the recommended interventions for treatment and/ or care;
- (c) a properly managed medical record system to ensure all medical records are accurate and up-to-date and are kept in a secure and confidential manner;
- (d) policy to protect patients' rights such as privacy, confidentiality of their medical records, informed consent before medical intervention, and a safe care environment; and
- (e) suitable support services, such as laboratory services, sterilization facility and waste management, available whenever necessary.

(C10) Resuscitation and Contingency

Existing Requirements

7.10 Cap. 165 and Cap. 343 have no provisions regarding resuscitation and contingency in PHFs.

7.11 Cap. 165 CoP requires each private hospital to have written policies and procedures in relation to resuscitation of patients and the handling, use, and administration of blood and blood products for critical patients in place. A member of staff trained in advanced life support resuscitation techniques should be on duty at all times. Resuscitation drills should be carried out regularly. Resuscitation equipment and medication, appropriate for the age of patients, should also be properly maintained and accessible.

7.12 Private hospitals are also required to establish a comprehensive written risk management policy and supporting procedures, covering the assessment of risks throughout the establishment, the identification, analysing and learning from adverse events or near misses, and the arrangement for responding to emergencies, e.g. fire evacuation, cessation of water and electricity supply. There should be a person appointed to coordinate risk identification, management and communication.

7.13 Cap. 343 CoP advises that at least one staff in the clinic shall be familiar with cardio-pulmonary resuscitation (CPR). Cap. 343 CoP also requires all staff in a registered clinic to be familiar with evacuation procedures.

Observations

7.14 In Singapore, the Guidelines for Private Hospitals, Medical Clinics and Clinical Laboratories under the Private Hospitals and Medical Clinics Act prescribe that operation theatres in hospitals shall be provided with emergency lighting and power supply, and medical clinics shall have resuscitation facilities for emergencies and adverse reactions to any form of treatment provided. Compliance with the requirement is a condition for the registration and re-registration of private healthcare institutions.

7.15 The National Minimum Standards and Regulations for Independent Health Care published by the Department of Health of the United Kingdom (UK) states that patients' rights are central to the resuscitation policy, which forms part of the risk management procedures. A written resuscitation policy must be in place and is developed in discussion with senior health care professionals; in line with Resuscitation Council (UK) guidelines and includes ethical/legal consideration. Emergency contingency plans for major plant failure, or loss of utilities, etc. must also be in place for each healthcare facility.

Proposal

7.16 We propose that **all classes of PHFs** proposed to be regulated should be **subject to mandatory requirements on resuscitation and contingency**. Key

requirements may include, but not limited to, the formulation and distribution of resuscitation protocol and contingency plans, proper training of staff in these two aspects, designation of officers-in-charge of resuscitation procedures and contingency plans respectively; and putting in place a mechanism to periodically review the resuscitation procedures and contingency plans to ensure that they meet the prevailing standards and requirements.

7.17 As PHFs operate in different scales with varying sophistication in the provision of medical services, further deliberation would be necessary to work out the standards on resuscitation and contingency that meet the needs of PHFs. Consultation with professional bodies, including but not limited to the Hong Kong Academy of Medicine (HKAM), would be required before deciding on the standards to be adopted.

(C11) Standards Specific to Procedures Performed

Existing Requirements

7.18 There is no explicit provision in Cap. 165 and Cap. 343 governing the standards specific to services provided in private hospitals and medical clinics. There is also no such requirement in Cap. 343 CoP.

7.19 Cap. 165 CoP requires private hospitals to establish policies and procedures which apply on an establishment-wide basis covering items such as patients' rights, ethics, health and safety with a view to ensuring the quality of service provision. It also stipulates regulatory standards specific to facilities conducting high-risk medical procedures such as the administration of cytotoxic drugs for chemotherapy, cardiac catheterisation, renal dialysis, endoscopy, diagnostic or interventional radiology, and so forth. The regulatory standards for these specific procedures mainly cover four areas including: (i) adequate and properly trained personnel to the facility, (ii) management of emergencies, (iii) appropriate and properly maintained equipment in particular for resuscitation, and (iv) specific requirements on accommodation (e.g. ventilation system and back-up power supply).

Observations

7.20 It is observed that many overseas jurisdictions (e.g. Singapore, Australia, Canada, United Kingdom, and United States of America) have adopted a risk-based approach in regulating healthcare facilities providing specialized or high-risk medical procedures/ practices. It is most common for procedures such as endoscopy,

chemotherapy and renal dialysis to be subject to additional regulation specific to the nature of their practices and associated risks apart from the general requirements that are universally applied to all regulated healthcare facilities. Compliance with the requirements is a condition for the registration and re-registration of the healthcare facilities.

In Singapore, the Private Hospitals and Medical Clinics Act and Regulations require that, among others, private hospitals and medical clinics providing haemodialysis for treating patients suffering from chronic renal failure should comply with the Guidelines for Private Healthcare Institutions Providing Renal Dialysis (Guidelines) which stipulate a comprehensive list of regulatory standards, such as –

Physical facilities

- The space occupied by each dialysis station shall be at least 5.8 square meters, large enough to accommodate the dialysis chair or couch, dialysis machine as well as working room for two dialysis personnel. The dialysis station shall be easily accessible in times of emergency and have adequate space for resuscitation to be carried out.

Water quality

- The dialysis centre shall ensure that there is proper treatment of water, which is necessary to rid the water of impurities or to lower the concentration of impurities to within acceptable limits (e.g. the maximum allowable level of fluoride and copper are 0.2mg/l and 0.1 mg/l respectively).
- The water used for dialysis shall be treated by reverse osmosis and/ or deionisers to provide a quality of water which meets with the standards listed in the Guidelines. For example, the water used to prepare the dialysate shall have a bacteriological colony count of less than 200 per ml after 48 hours of incubation.
- At a minimum of six monthly intervals, regular tests of the quality of the water must be carried out and recorded to ensure that standards are met.

Dialysate quality

- The water used to prepare the dialysate must have an electrolyte composition near that of normal extracellular fluid (e.g. the sodium and potassium ion should be within the range of 135 to 145mmol/l and 0 to 3mmol/l respectively), and a bacteriological colony count of less than 200 per ml after 48 hours of incubation.

- The final diluted dialysate shall be analysed every six months. It shall also be analysed with every new batch of dialysate and after each major servicing/ repair of dialysis machine.

Equipment

- The resuscitation equipment shall include, but not limited to, cardiac monitoring device with defibrillator, bag-valve-mask resuscitator, intubation equipment and oxygen supply, etc. The resuscitation equipment must be available at the dialysis centre at all times.
- The physician-in-charge of the dialysis centre is ultimately responsible for ensuring that the monitoring and safety devices and resuscitation equipment are in proper working condition at all times.

Infection control practices

- Standard Precautions, issued by the Ministry of Health of Singapore, shall be used on all patients regardless of whether the Hepatitis B, Hepatitis C and HIV status is known. During dialysis, it is vital for staff to be adequately protected using impervious gowns/ aprons, gloves and eye protection.
- For patients with Hepatitis B, Hepatitis C, or HIV infection, dedicated dialysis equipment shall be used. After each dialysis, non-disposable equipment shall be appropriately cleaned and disinfected. Dialysers and arteriovenous bloodlines must not be shared among patients. Bloodlines shall be used once and discarded.
- Disposable gloves shall be worn by staff for personal protection when performing procedures which are potentially biohazardous. Staff shall wash their hands and use a fresh pair of gloves with each patient to prevent cross-transmission.
- Draining, disinfection and rinsing procedures of the dialysis equipment shall be performed after each dialysis. If blood leak occurs in a circulating system, the usual rinsing and disinfection procedures shall be performed twice before the system is used on a different patient.

Safety

- Emergency electric power supply must be available at all times.

Proposal

7.21 We propose that private hospitals and facilities conducting high-risk medical procedures should be subject to a basic set of core requirements that are pre-requisite to the proper operation of healthcare facilities, and should also be required to comply with additional standards for each of the selected procedures intended to be performed in the facilities. Specific regulatory standards to be imposed will depend on the nature and associated risks of these procedures. The specific standards may include physical standards (e.g. ventilation system, back-up power supply, and sterilization facility) or standards related to the care process (e.g. emergency transfer arrangements, minimum staffing requirement for certain procedures such as surgery under anaesthesia). Compliance with the regulatory standards should be made a condition for the registration and re-registration of the healthcare facilities concerned.

(C12) Credentialing of Visiting Doctors

Existing Requirements

7.22 Under Cap. 165 and Cap. 343, Department of Health (DH) is vested with the power to register or de-register private hospitals and medical clinics subject to conditions including, amongst others, staffing. There is, however, no explicit provision in Cap. 165 and Cap. 343 governing the credential of registered healthcare professionals working in private hospitals and medical clinics.

7.23 Cap. 165 CoP sets out elaborate requirements on staffing, including at all times there should be an appropriate number of suitably qualified and experienced persons in private hospitals; training and supervision should be given to each person working in private hospitals; and the performance of staff working in hospitals should be regularly appraised. The Medical Advisory Committee should make recommendation on eligibility criteria and review, renew, restrict and withdraw practising privileges of medical practitioners according to the criteria. Cap. 343 CoP also stipulates that all medical practitioners and nursing staff working in medical clinics shall possess appropriate qualifications and skills in performing their duties.

Observations

7.24 There is growing awareness of the importance to ensure appropriate credentialing of hospital staff. Private hospitals, on their own initiatives and devised mechanisms, ensure the credential of staff in particular visiting doctors through the grant of admission privileges. At professional level, the Credentials Working Group of the Education Committee of HKAM is working on the level of credentialing required of several key medical procedures.

Overseas Practices

The standard of staffing is usually prescribed in relevant medical regulations of Singapore, England of the United Kingdom and New South Wales of Australia. In the United Kingdom and Australia, the regulations further require private hospitals to recruit sufficient number of qualified and experienced staff on duty at all time, and the staff should be appropriately trained and competent for the work they undertake.

Proposal

7.25 To ensure that the staff of private hospitals are professionally competent, we propose that **private hospitals should have a robust human resource policy** so that staff members serving in hospitals could meet the benchmark desired and adopted by the hospitals concerned. In particular, private hospitals should **implement policies or mechanism for credentialing of staff especially visiting doctors**.

Applicability to Non-hospital PHFs

7.26 We need to carefully weigh the pros and cons of extending the same credentialing requirement to non-hospital PHFs such as ambulatory medical centres and clinics. Non-hospital PHFs are very often small organizations where management and service provision are carried out by a sole or limited number of registered medical practitioners, and hence, issues concerning activities of visiting doctor do not exist under most circumstances. Furthermore, given the nature of the services provided by medical practitioners working in non-hospital PHFs, these medical practitioners should readily be held accountable and easily identifiable for their own practice. The existing professional code of conduct and professional guidance promulgated by HKAM may be sufficient in ensuring the quality of medical service under such circumstances. We consider that it would be appropriate to apply this regulatory aspect to private hospitals only.

(C13) Establishment of Clinical Audit System

Existing Requirements

7.27 There is no provision in Cap. 165 and Cap. 343 requiring private hospitals and medical clinics to conduct clinical audit. There is also no such requirement in Cap. 343 CoP.

7.28 Cap. 165 CoP stipulates that private hospitals should implement a system for reviewing the quality of services, in the form of internal audit at appropriate intervals. Private hospitals should also develop and implement quality improvement plans based

on the findings identified through audit activities. Furthermore, reports on reviews or quality assurance activities should be made available for the inspection of DH.

Observations

7.29 There is only a broadly-framed requirement under Cap. 165 CoP for clinical audit. There is no requirement on frequency and scope of audits activities, nor is there requirement for the appointment of a clinical audit team or clinical audit coordinator to take charge of the hospital's audit activities. As a result, while all private hospitals have reported to have complied with the requirements by conducting clinical audit activities on a regular basis, there are significant variations among private hospitals in terms of arrangement and procedures of clinical audit activities.

Overseas Practices

Singapore, Malaysia, New South Wales of Australia and England of the United Kingdom require private hospitals to conduct regular quality assurance activities, e.g. clinical audits, by law to monitor and evaluate the quality and appropriateness of the services provided. Private hospitals are also required to have clear communication procedures for sharing the audit results with all persons who work in the service and monitor the implementation of improvement measures.

Proposal

7.30 We consider that the introduction of a set of basic requirements, as prescribed by the regulatory authority, for establishing a well-structured clinical audit system should be made mandatory for private hospitals. Private hospitals should submit reports on audit findings and implementation progress to the regulatory authority for inspection as and when required. Specifically, private hospitals should be required to develop policies to review and record clinical audits performed and improve services performance based on audit findings.

Applicability to Non-hospital PHFs

7.31 Currently, medical practitioners working in non-hospital PHFs are only bound by relevant professional codes of practice, in which standards of good practice are set out to ensure service quality and patient safety. While the establishment of a clinical audit system may be conducive to enhancing service quality and transparency of private healthcare services, there is a need to consider the effectiveness in applying such requirement to non-hospitals PHFs that operate in limited scales. As opposed to the case of hospitals where clinical audit activities have proven track records in both local

and overseas context, the worthiness of establishing a full-fledged clinical audit system in other classes of PHFs remains to be justified given the cost of compliance and resource implications. Therefore, it is suggested that the implementation of clinical audit system should be confined to hospital for the time being.

(C14) Sentinel Events Management

Existing Requirements

7.32 There is no provision in Cap. 165, Cap. 343 and Cap. 343 CoP governing the management/reporting of sentinel events or the standard on follow-up actions by PHFs.

7.33 Currently, Cap. 165 CoP requires private hospitals to develop policies and mechanisms, such as engaging independent clinical and quality assurance experts in identifying, reporting and managing sentinel events. In practice, DH requires private hospitals to report sentinel events within 24 hours upon occurrence of the events. Upon receipt of such notification, DH will gather preliminary information from the hospital concerned and may conduct its own investigation into the event as required. In addition to timely notification to DH, the hospital concerned is required to submit to DH a full investigation report within four weeks of occurrence of the event. The full investigation report should indicate the result of the root cause analysis and whether remedial measures are required and implemented.

Observations

7.34 ‘Sentinel event’ refers to an unexpected occurrence involving death or serious physical or psychosocial injury, or the risk thereof. The root cause of a sentinel event could be due to the natural course of disease, inherent risk of procedure, human errors and system faults. Upon the occurrence of a sentinel event, if properly investigated and followed up, hospitals could identify possible systemic weakness and make relevant improvements.

Overseas Practices

Mandatory sentinel/ adverse event reporting systems are in place in Singapore, Malaysia and England of the United Kingdom. The systems often hold private hospitals accountable for their service and guard against unsafe care through penalties and sanctions.

7.35 Currently, the access to or disclosure of data in connection with a sentinel event that is reported to a hospital by its staff, or to the regulatory authority by a hospital,

is not being regulated. There are also concerns about data confidentiality of sentinel events reported, i.e. whether the regulatory authority should disclose information relating to sentinel events reported by hospitals and the hospitals involved.

Overseas Practices

Singapore, Malaysia and New South Wales of Australia and Ontario of Canada impose statutory restrictions on the use of information or documents obtained or produced by private hospitals in the course of root cause analysis of a sentinel/ adverse event in legal discovery or as evidence in litigation or disciplinary proceedings. The privilege aims to enable open and candid discussion between investigators and the personnel involved in the event, hence ensuring thorough investigation into the root cause.

Proposal

7.36 We **propose hospitals** should **establish** a comprehensive **sentinel events management system**.

7.37 The proposal could help strengthen internal quality assurance by having in place a full-fledged mechanism for hospitals to review and learn from sentinel events. For example, a hospital may appoint its internal medical advisory committees (MAC) (please refer to section (A2) under Chapter 5 for more details of MAC) to be responsible for the identification, reporting, investigation and management of sentinel events and other medical incidents. Hospitals should be mandated to report to the regulatory authority the activities, findings and recommendations as and when required.

7.38 The regulatory authority should be empowered to prescribe reporting requirements, and to gain access to records and documents kept by hospitals in connection with sentinel events, including information and reports on the investigation and findings and recommendations of the MAC. Overseas experience has shown that learning systems are more likely to be successful when reporters do not feel at risk in reporting errors. Most health authorities of overseas jurisdiction that implement mandatory systems do not disclose information about the organizations concerned as a strategy to encourage reporting. Furthermore, many jurisdictions provide statutory protection, from legal discovery and from use as evidence in litigation or disciplinary proceedings, for information or documents obtained or produced by MACs in the course of root cause analysis. The privilege aims to enable open and candid discussion between investigators and the personnel involved in the incident, and hence thorough investigation into the root cause. Such privilege does not apply to the underlying medical records or primary documentation relating to the incident under investigation,

which exist irrespective of the activities of MACs. In the light of the foregoing, we propose to **protect the confidentiality of information and documents produced in the course of root cause analysis** by hospitals, except for cases involving criminal behaviours and reckless or purposeful unsafe acts.

Applicability to Non-Hospital PHFs

7.39 Implementing a sentinel event reporting system similar to that for private hospitals in the non-hospital setting is easier said than done. A balance has to be struck between what is ideally desirable and the constraints of resources and practicability. The cost of compliance and resource implications would be significant to non-hospital PHFs that operate in a much smaller scale and thus the requirement of establishing a system to investigate and report sentinel events might outweigh the benefits brought. Therefore, further deliberation would be necessary before deciding whether this aspect should be extended to other PHFs.

Chapter 8

Price Transparency

8.1 Private medical service, by its very nature, should be no different from other business transactions between consenting parties where prices are determined by market force. Under a free economy, market differentiation would naturally result in pricing differential, reflecting differences in quality, efficiency and popularity, etc. Allowing the market to determine prices on its own encourages competition in terms of service quality and efficiency among healthcare services providers.

8.2 Under our dual-track healthcare system where private medical services play a complementary role, we consider it unnecessary and unjustified for the Government to interfere with the pricing for private medical services. While pricing should be left to the market, medical service has the unique nature of being highly asymmetrical in terms of knowledge and information. There is significant room for improvement in terms of the information flow in the medical service market because users (i.e. patients), who generally do not have adequate medical knowledge in the medical services they received, have to, in most cases, rely on word-of-mouth when choosing from hundreds of private healthcare facilities (PHFs) and thousands of independently practising medical practitioners. It is difficult for members of the public to understand and relate the price and service as provided by different combinations of PHFs and doctors. There is a role for the Government to step in and address the gap of information asymmetry through institutional arrangement. Under the new regulatory regime, the promotion of price transparency should be a major area requiring dedicated measures with a view to better safeguarding patients' and consumers' rights.

8.3 By ensuring the communication of comprehensive and complete pricing information to patients/consumers, the public could be better informed of price information before making decisions in meeting their medical needs and making necessary financial arrangements in advance. To achieve this goal, four regulatory aspects should be adopted –

(D15) Provision of Fee Schedule

(D16) Provision of Quotation

(D17) Provision of Recognized Service Packages

(D18) Disclosure of Historical Bill Sizes Statistics

(D15) Provision of Fee Schedule

Existing Requirements

8.4 The Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) has no regulatory requirement on the provision of fee schedule by PHFs.

8.5 The Code of Practice for Private Hospitals, Nursing Homes and Maternity Home (Cap. 165 CoP) stipulates that there should be written policies and procedures to protect the right of patients to know the fees and charges prior to consultation and any procedure. In particular, a schedule of charges should be prepared with respect to room charges, investigative and treatment procedures, medical supplies, etc. and any charges that will be levied. Furthermore, the schedule of charges should be available for patients' reference at the admission office, cashier and wherever appropriate and should be updated when there are changes in fees.

8.6 The Medical Clinics Ordinance (Cap. 343) has no regulatory requirement on the provision of fee schedule by PHFs.

8.7 The Code of Practice for Clinics Registered under the Medical Clinics Ordinance (Cap. 343 CoP) stipulates that patients have the right to know the fees and charges prior to consultation and their undertaking of any procedure. In particular, a notice of charges, written in both Chinese and English, should be posted in conspicuous places and easily available to patients, with the scale of charges being updated in a timely manner when there is any change.

Observations

8.8 At present, hospitals, nursing homes, maternity homes and non-profit-sharing clinics are already required to display fee schedules at its premises. There is no apparent reason why similar requirements cannot be extended to other classes of regulated PHFs. In Singapore, the Ministry of Health makes disclosure of pricing information one of the licensing terms and conditions for private hospitals. In Malaysia, the Minister of Health is empowered to make regulations regarding the provision of fee schedules for PHFs or health related facilities. In the United States, with the enactment of the Patient Protection and Affordable Care Act in 2010, hospitals are required to establish and make public annually a list of their standard charges for items and services provided.

Proposal

8.9 We **propose** that **fee schedules**, covering **all** chargeable items, should be **publicly available at all regulated PHFs**.

8.10 The fee schedule should set out charges on wards, investigative and treatment procedures, medical supplies, medicines, medical reports, photocopy of medical records and any charges that will be levied (except for those indicated and justified that price information is not available for practical reasons).

8.11 A chargeable item may be shown in a price range in the fee schedule if the PHF considers it necessary, but the PHF concerned should justify, upon request, why such arrangement is adopted. In case it is not practicable to quote a price range, the item should still be indicated in the fee schedule and the hospital should justify why such arrangement is adopted in the fee schedule. No fee could be levied for any item of hospital services unless the item is already featured in the fee schedule (either in the form of (i) fixed price, (ii) price range or (iii) marked to indicate that price information is not available).

8.12 Any change in chargeable items and/or price levels could only take effect after the fee schedule has been updated to reflect the changes. PHFs should publish notices and make announcements to inform patients of the release of any update of the fee schedule at least 14 calendar days before the new fee schedule takes effect.

8.13 The fee schedule should also be readily available at the PHFs concerned and accessible through a common electronic platform provided by the regulatory authority for public inspection. It should also be provided upon request.

(D16) Provision of Quotation

Existing Requirements

8.14 Cap. 165 and Cap. 343 have no requirement on the provision of quotation by regulated PHFs.

8.15 Cap. 165 CoP requires that patient should be informed of the charges of service where practicable; however, it has no specific requirement on the provision of quotation to patients/consumers.

8.16 While Cap. 343 CoP stipulates that patients have the right to know the fees and charges prior to consultation and their undertaking of any procedure, there is no provisions or requirements on the provision of quotation.

Observations

8.17 The provision of quotation is important in helping patients/consumers better understand the charging information provided by PHFs in addition to the provision of fee schedule. Fee schedule sets out the price of each chargeable item (such as fees for using operation theatre, consultation fee and charges on the use of equipment of other materials, etc.), nevertheless, it provides little help when it comes to individual bill as the total charge depends on what items are included having regard to the specific conditions of a patient. Under no circumstances could patients, who mostly do not possess professional knowledge of medical practice, deduce on their own the overall charge applicable merely based on the fee schedule because the actual cost is highly dependent on the practice of doctors which may vary greatly. As such, the provision of quotation would facilitate prospective patients to have a good grasp of the quantum of the overall charge beforehand. Besides, the provision of quotation could also facilitate insurance companies to provide an estimate to the claimable amount of insured patients so that a patient with health insurance coverage would have an estimate of the eventual out-of-pocket amount well before receiving the treatment.

8.18 In Singapore, the Ministry of Health makes, among others, provision of quotation (known as 'financial counselling') a licensing condition for private hospitals. Under the requirement, patients should be provided with an estimate of total charges, which is documented in a financial counseling form, and informed of any changes in a timely manner.

8.19 In Malaysia, private hospitals are required to, upon request prior to the initiation of care or treatment, inform the patient of the estimated charges for services based upon an average patient with a diagnosis similar to the tentative or preliminary diagnosis of the patient and of other unanticipated charges for services that is routine, usual and customary. A patient also has the right to be informed of the hospital's billing procedures.

8.20 In the United Kingdom, while there is no specific reference to the provision of quotation under its regulatory regime, the registered person (i.e. service provider or registered manager) of a private hospital is required by law to provide a written statement to the service user specifying the terms and conditions of the services, including the amount and method of payment of fees, prior to the commencement of the services as far as reasonably practicable.

Proposal

8.21 We **propose** that hospitals should **ensure that quotations are provided to patients for the whole course** of investigative procedures or elective, non-emergency therapeutic operations/ procedures for known diseases **on or before admission**.

8.22 The provision of quotation is required for **non-emergency** therapeutic operations/ procedures for **known diseases only** since it would not be practical for hospitals/ doctors to provide a quotation under emergency situation or to provide quotations for diseases that are not yet diagnosed by the hospitals/ doctors. In particular when a doctor considers that a **patient undergoing operation/ procedure experiences emergency situations that require further treatment**, price quotation for these further treatments would be **exempt**.

8.23 Doctors should provide patients, in a prescribed Informed Financial Consent (an illustrative sample is at **Annex D**), with an estimation of total charges for treatment when referring/ admitting patients to private hospitals. Hospitals should request patients to present completed Informed Financial Consent when they are admitted and should inform patients of the potential variation of the estimates when appropriate. In case it is not practicable to provide an estimate, doctors are required to indicate in the Informed Financial Consent to justify why this is the case. An Informed Financial Consent should be completed with the signatures or stamps of the patient, doctor and hospital concerned to make sure that the quotation has been communicated to patients and there are consensus among parties involved. For patients who, with justification provided in the Informed Financial Consent, have not been given a definitive quotation of their hospital bills on or before admission, whenever they receive a definite diagnosis where elective therapeutic operations/ procedures are required after admission, they should be given an estimate as soon as practicable.

8.24 We propose that each hospital should publish a 'List of Common Operations/ Procedures' for which quotation should normally be provided for prospective patients. The regulatory authority may, from time to time, stipulate operations/ procedures that should be included in the List. Private hospitals may also add other operations/ procedures to the List on a voluntary basis. The List should be available at the admission office, cashier, hospital webpage and where appropriate for public's reference.

8.25 We are aware that there are concerns that patients' conditions might change unexpectedly during treatment, making it necessary to update the initial quotation. Flexibility should therefore be provided for hospitals and doctors to update the quotations under justified circumstances. We propose that patients should be informed of the range of potential variation of the estimates (which should be made, among other things, having regard to the hospitals' historical data (the provision of which is proposed to be regulated under section **D18** "Disclosure of Historical Bill Sizes Statistics" of this Chapter)), and document the range in the Informed Financial Consent to Services to be acknowledged with signature of patients. In case there is any material change in estimates beyond a certain proportion as pre-defined by the regulatory authority,

patients who are conscious and stable (or their next-of-kin or authorized persons if otherwise) should be informed of and consent to the latest estimates before any further operation/ procedure will be conducted. The latest estimate should be documented in the Informed Financial Consent duly signed by doctors/ hospitals and patients/ next-of-kin/ authorized persons. A new form may be used if the changes are considered substantial by the doctor or hospital concerned.

8.26 In order to streamline administrative work without compromising the level of price transparency, we propose that patients subscribing to Recognized Service Packages (see section **D17** “Provision of Recognized Service Packages” below) should be exempt from the proposed provision of quotations.

(D17) Provision of Recognized Service Packages

Existing Requirements

8.27 Cap. 165 and Cap. 165 CoP, as well as Cap. 343 and Cap. 343 CoP have no requirements on the provision of service packages.

Observations

8.28 At present, there is no requirement under the regulatory regime on the provision of packaged charges. However, we understand that some hospitals are already offering service packages¹ for certain procedures on their own volition. However, the items covered by and the charging mechanisms of service packages provided by different hospitals vary greatly, and the general public, in most cases, would not be able to compare service packages across different hospitals.

Proposal

8.29 We **propose** that **all regulated PHFs** should be **encouraged to offer Recognized Service Packages (RSPs) to patients**.

8.30 We consider that service packages should be encouraged to promote transparency and safeguard rights of patients. The proposed RSPs are identically and clearly defined standard services provided at packaged charge for common operations/ procedures based on known diagnosis, e.g. cataract surgery for cataract,

¹ Service packages are defined as a set of service items offered as a whole at a fixed price.

appendicectomy for appendicitis, and laparoscopic cholecystectomy for gallstones. The purpose of RSP is to provide identically and comprehensively structured service packages for common operations/ procedures for easy consumption of the public. It also allows patients and consumers to understand and compare medical services provided by different PHFs more easily.

Operational Arrangement

8.31 To ensure that the services covered by RSPs are identically and clearly defined, we propose that under the new regulatory regime the regulatory authority would provide a platform for regulated PHFs and relevant stakeholders to work out the standards to be uniformly applied to each of the RSPs.

8.32 We suggest that information on RSP should be presented in the form of an “Explanatory Note” drafted in a prescribed format (an illustrative sample form is at **Annex D**) for public’s reference. The ‘Explanatory Note’ should be completed by hospitals and signed by patients subscribing to RSP as authentication. Information on RSP should be readily available at the admission office, cashier, PHFs’ webpages and where appropriate for public’s reference. It will also be linked to the common electronic platform provided by the regulatory authority. Details of RSPs should be actively presented to patients to facilitate their understanding of possible charges ahead before they make a decision on whether to undergo an operation/ procedure.

8.33 The introduction of RSPs would not affect existing service packages provided by healthcare services providers, i.e. PHFs could continue to offer their own service packages to patients. However, these service packages could not be named ‘RSPs’ unless the items and services covered are in compliance to those recognized by the regulatory regime.

8.34 Without prejudice to future deliberation on designing the structure and defining the standards of RSPs, we consider that the following major items could be considered to be included in RSPs –

- (a) **Eligibility** – RSP should specify which customers are eligible (or ineligible).
- (b) **Coverage** – Different healthcare services may mandate different coverage in a RSP. For example, for surgical procedures, items covered may include –
 - Doctors’ fees (including resident and visiting, attending and all other specialist doctors)

- Room charges
 - Diagnostic procedures
 - Treatment procedures
 - Operating theatre charges
 - Anaesthetic fees
 - Nursing care
 - Medications
 - Equipment/ Instrument
 - Consumables/ Materials
 - Implants
 - Registration fees/ Admission fees
- (c) **Exclusions** – All exclusions directly related to the operation/ procedure concerned should be specified and justified.
- (d) **Arrangements for complications** – PHFs should specify how and to what extent treatment for complications directly arising from the operations/ procedures concerned would be covered by RSP, PHFs should also specify an aggregate expenditure for treating complications, below which no additional payment from the patient would be required.
- (e) **Terms and conditions of use** – For instance, in case when patients are diagnosed with disease deviated from the original diagnosis after admission, RSP may no longer apply and patients would be informed as soon as possible and provided with alternative options.

(D18) Disclosure of Historical Bill Sizes Statistics

Existing Requirements

8.35 At present, Cap. 165 does not require hospitals to disclose historical bill sizes statistics for public's reference. Cap. 165 CoP, Cap. 343 and Cap. 343 CoP also do not have such requirement.

Observations

8.36 The provision of historical bill sizes statistics is a regulatory requirement in two overseas jurisdictions studied. The Ministry of Health of Singapore publishes hospital bill sizes (including average bill sizes per day, average total bill sizes, and total bill sizes

at 90th and 95th percentile) of selected medical conditions/ procedures on its website² for public's reference. For the state of Wisconsin of the United States, an electronic platform called "Price Point"³ developed by the Wisconsin Hospital Association Information Center (WHAIC) under a contract with the Wisconsin Department of Administration provides information on billed charges for both inpatient care and outpatient services (data are collected via the website of WHAIC⁴).

8.37 We consider that disclosure of bill sizes statistics could play an important role in enhancing price transparency of private medical service. Patients could have a basic concept in advance on how much they could be charged based on actual bill sizes statistics of similar procedures/ operation. Moreover, the disclosure of historical bill sizes statistics could work in conjunction with the quotation and service packages intended for patients' reference. Patients would be able to contextualize prices given to them having regard to historical bill sizes. They might, if necessary, seek clarification or second opinion in circumstances such as when the quotation provided is way off the perceived market norm suggested by historical statistics. The proposed transparency measures, all put together, would better empower patients to make constructive discussion after balancing all factors based on quality information and statistics.

Proposal

8.38 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.

8.39 The statistics should include annual number of discharges⁵, average length of stay, 50th percentile and 90th percentile bill sizes for each reportable treatment/ procedure. Each hospital should publish its own statistics at the admission office, cashier, hospital webpage and where appropriate for public's reference. Hospitals should also make statistics available through the common electronic platform provided by the regulatory authority for public consumption.

2 http://www.moh.gov.sg/content/moh_web/home/statistics.html

3 <http://www.wipricepoint.org/>

4 <http://www.whainfocenter.com/submitters/data-submission-manual/>

5 Exemption to report for a particular treatment may be provided if less than a prescribed number (say, 30) of cases in the reporting period (usually a year).

Applicability to Non-Hospital PHFs

8.40 While disclosure of historical bill sizes statistics is desirable in enhancing price transparency of PHFs, further consideration may be necessary in applying such requirement to non-hospital PHFs. Keeping and analysing all bill sizes statistics might incur a significant amount of administrative and compliance costs to non-hospital PHFs that operates in a limited scale. We consider that the extension of this regulatory requirement beyond hospitals should not form part of the regulatory regime for non-hospital PHFs for the time being.

Chapter 9

Sanctions

9.1 Sanctions that are commensurate with the seriousness of offences are important in ensuring compliance and deterring non-compliance/violation. Sanctions could take the form of fines and/or imprisonment. For the regulatory regime for private healthcare facilities (PHFs), we consider that sanctions should carry an important role in ensuring compliance of the other eighteen regulatory requirements proposed.

(E19) Sanctions

Existing Requirements

9.2 Under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165), **penalties for unregistered operation** of hospitals is set at a fine of **\$2,000** and, in the case of a second or subsequent offence, a fine at **\$2,000** and imprisonment for **three months**. For **non-compliance** of other provisions¹ of Cap. 165, the penalties are set at a fine of **\$2,000** and, in the case of a continuing offence, to a further fine of **\$50** in respect of each day on which the offence continues after conviction.

9.3 Being an administratively promulgated document, the Code of Practice for Private Hospitals, Nursing Homes and Maternity Home (Cap. 165 CoP) has no provision for sanctions against non-compliance.

9.4 The Medical Clinics Ordinance (Cap. 343) stipulates that, any person who (a) manages, does any medical diagnosis or prescribes/takes part in any medical treatment in a **clinic which is not registered** or (b) carries on or takes part in the management of a registered medical clinic in which no registered medical practitioner is appointed, that person commits an offence and is liable (a) on **summary conviction** to a fine of **\$50,000** and to imprisonment for **two years** or (b) on **conviction upon indictment** to imprisonment for **three years** upon conviction. As for the penalties for any person who performs medical diagnosis/treatments in an unregistered clinic or in a registered clinic without an appointed registered medical practitioner, which **result in personal injury** to another person, the maximum fine is set at **\$100,000** and the maximum imprisonment ranges from **six months to seven years**.

1 Circumstances subject to sanctions under the existing Cap. 165 other than unregistered operation are:

- (i) certificate not affixed in a conspicuous place (section 5);
- (ii) failure to keep patient records (section 6(1)(a));
- (iii) failure to notify deaths (section 6(1)(b)); and
- (iv) refusal or obstruction of entry for inspection (section 7(2)).

9.5 Similar to the Cap. 165 CoP, the Code of Practice for Clinics Registered under the Medical Clinics Ordinance (Cap. 343 CoP), also administratively promulgated, has no provisions for sanctions against non-compliance. In practice, the Department of Health would issue advisory letters and/or warning letters to PHFs that do not comply with requirements under the two Codes of Practice.

Observations

9.6 The severity of the existing sanctions stipulated in Cap. 165 is not commensurate with the scale of operation and the risks involved in the operation of hospitals. There have been calls from the public, including legislative councillors, patient groups and doctors, to increase the sanctions for hospitals. We agree that increasing the sanctions for private hospitals are necessary and justified. As for non-hospital PHFs, there is no standardized sanction for breaches/non-compliance of other provisions of Cap. 343 other than unregistered operation and it might be more desirable to impose a set of standardized sanctions for non-compliance for non-hospitals PHFs.

Proposal

9.7 We **propose** the following **maximum penalties for hospitals and non-hospitals PHFs (and the Person-in-charge in respect of imprisonment)** respectively –

(1) ***Unregistered operation***

- Hospitals: a fine of **\$5,000,000** and imprisonment for **two years**; and
- Other regulated PHFs: a fine of **\$100,000** and imprisonment for **three months**

(2) ***Non-compliance of other provisions in the legislation***

- Hospital: a fine of **\$1,000,000** and a daily fine of **\$10,000** for continuous contravention
- Other regulated PHFs: a fine of **\$25,000** and a daily fine of **\$2,000** for continuous contravention

Chapter 10

Powers of the Regulatory Authority

Background

10.1 The forerunner of the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) was the Nursing and Maternity Homes Registration Ordinance enacted in 1936 providing for the regulation of nursing homes and maternity homes. The Ordinance did not embrace the regulation of hospitals until it was amended in 1966. By then, the regulatory authority was empowered to register or de-register hospitals.

10.2 Cap. 165 was primarily designed for regulating elementary private healthcare facilities (PHFs) like nursing and maternity homes. It has not introduced any specific regulatory standards commensurate with the increased complexity of medical treatment, intensity of care and volume of administration going on at hospitals. In its present form, Cap. 165 is ineffective in reacting to the changes of healthcare environment, advancement of medical technologies and the expansion of the scope and sophistication of medical treatment. This undermines the role of the regulatory authority and weakens its ability to take timely and effective actions. Looking forward, private entities and non-profit making organisations will play an increasingly significant role in the provision of healthcare services. Healthcare services are also evolving towards specialisation, demanding higher professional standard than before and better services for meeting public aspirations. The changes and challenges call for a regulatory authority with sufficient enforcement power to function effectively and to be highly dynamic in reacting to prevailing issues.

Overseas Practices

10.3 It is generally observed that laws regulating private hospitals in overseas jurisdictions are written in greater details when compared with that of Hong Kong. The following are some of the observations –

- (a) In Singapore, Malaysia, England of the United Kingdom and New South Wales of Australia, standards for various services are prescribed by law in the form of statute, regulations or code of practice issued by the regulatory authority. Standards in respect of design and construction, facilities and equipment, staffing, infection control, clinical standards, patients' rights and clinical records etc. are clearly defined and prescribed.

- (b) In Singapore, Malaysia, England of the United Kingdom and New South Wales of Australia, apart from requiring registered private hospitals to meet basic standards for physical facilities and staffing level, their respective legislation also requires private hospitals to conduct regular quality assurance programmes to be overseen by the regulatory authority.
- (c) In Malaysia, there are provisions in legislation that empower the regulatory authorities to close a facility or suspend all/ part of the service if there is an immediate and critical risk to safety of patients. Such provisions would provide the flexibility for the regulatory authority to discharge its duties more effectively.
- (d) Mandatory sentinel/ adverse event reporting systems are in place in Singapore, Malaysia and England of the United Kingdom. The systems often hold private hospitals accountable for their service and guard against unsafe care through penalties and sanctions.
- (e) Singapore, Malaysia and New South Wales of Australia and Ontario of Canada provide statutory restrictions for the use of information or documents obtained or produced by private hospitals in the course of root cause analysis of a sentinel/ adverse event in legal discovery or as evidence in litigations or disciplinary proceedings. The privilege aims to enable open and candid discussion between investigators and the personnel involved in the event, hence ensuring thorough investigation into the root cause.

10.4 The following table provides a summary of the main legislation governing, regulatory frameworks adopted in Singapore, Malaysia, England of the United Kingdom, New South Wales of Australia and Ontario of Canada.

Jurisdiction	Scope of Regulation																	Statutory Power of Regulatory Authority	Protection of Confidentiality of Information							
	Administration and management	Accommodation	Facilities and equipment	Staffing	Clinical standards	Clinical governance	Risk management	Complaints policy	Price transparency	Medical records	Dispensaries	Incident reporting	Performance management	Patient care	Waste and hazardous substances	Issuance of guidelines	Imposition of regulations	Investigation	Variation of terms/ conditions of registration	Issuance of warning/ penalty notices	Prosecution	Suspension of licence/ service	Refusal of licence renewal	Taking control of operation	Applicable	
Singapore	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓					✓		✓					✓			✓	
Malaysia	✓	✓	✓	✓		✓	✓		✓		✓						✓	✓	✓				✓	✓		✓
United Kingdom (England)	✓	✓	✓	✓			✓		✓	✓			✓			✓	✓	✓	✓	✓	✓	✓				
Canada (Ontario)	✓			✓	✓				✓			✓	✓				✓					✓	✓	✓	✓	✓
Australia (New South Wales)	✓	✓	✓	✓		✓	✓	✓	✓	✓			✓	✓			✓						✓			✓

Proposal

10.5 The powers conferred on the regulatory authority are indispensable tools for enforcing regulatory standards. 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. In this connection, we propose that the regulatory authority/ the Government should be vested with the powers to –

- (A) Issue and amend regulations/ code of practice
- (B) Inspect, collect and publish relevant information
- (C) Suspend a facility/ service/ use of equipment
- (D) Appoint advisory committees, devise, review and update the scope and standards of regulation for facilities providing high-risk medical procedures

(A) Issuance of regulations/ code of practice

10.6 While a new legislation provides for the overall framework of the regulatory regime and sets out the general guiding principles in regulation, it would be more appropriate to specify the detailed requirements governing the operation of regulated PHFs relevant to patient safety and public interest in the form of regulations or in a code of practice. This would better enable the regulatory authority to update the regulatory standards and provide greater flexibility in responding to changing regulatory needs. It is essential to provide the regulatory authority with the power to issue regulations and/ or code of practice which set out principles, procedures, guidelines and standards for the operation and management of regulated PHFs and provide practical guidance in areas such as (but not limited to) (1) administration and management, (2) physical facilities including accommodation, facilities and equipment, (3) staffing, (4) corporate and clinical governance, (5) risk management, (6) patient care, (7) price transparency, and (8) medical records management. The regulatory authority should be given the flexibility to amend the regulations and/ or code of practice as and when necessary to ensure timely responses to the ever changing operating environment for PHFs.

(B) Inspection, collection and publication of information

10.7 With statutory power conferred by the new legislation, the regulatory authority should be able to inspect, collect and publish information in respect of PHFs for the purposes of –

- (a) monitoring and/or investigating whether this Ordinance, any regulations and/or code of practice made under this Ordinance has been or is being contravened;

- (b) assessing the quality and standard of the facilities and services provided and the practices and procedures being carried out at the regulated PHFs; and
- (c) investigating complaints/ sentinel events/ medical incidents relating to the regulated PHFs.

10.8 The regulatory authority should also be empowered to have access to records and documents in the custody of regulated PHFs, including information and reports on the investigation, findings and recommendations of the Medical Advisory Committee (MAC) and other relevant committees. Such powers enable the regulatory authority to access the necessary information to monitor and assess whether the regulated PHFs comply with the standards and requirements.

10.9 There are concerns about the confidentiality of information related to clinical procedures involved in the care or treatment of patients, and also in the course of exercise of functions of MAC (e.g. information about root cause analysis of sentinel events and medical incidents). Preserving the confidentiality of personal or sensitive information is crucial for reporting and investigation of sentinel events and medical incidents by enabling an open discussion among investigators and the personnel involved, hence facilitating fact-finding and investigation. Overseas jurisdictions such as Singapore, Canada (Ontario), Australia (New South Wales) and Malaysia all have explicit legal provisions for protecting the confidentiality of such information. It is therefore suggested to treat the information or documents provided by PHFs in the course of root cause analysis as confidential, unless the disclosure is made for prosecution of a criminal offence or for making or investigating a complaint against registered health professional for sanctionable behaviour. Private hospitals may appeal to an Independent Review Committee on Regulatory Actions to review the regulatory authority's decision in respect of collection and disclosure of information. However, the restriction is not applicable to non-case-specific statistical information concerning PHFs' operation (e.g. statistics on pricing, complaints/ enquires, sentinel events/ adverse medical incidents, service utilisation etc.), and information that would not amount to identifying any individual.

(C) Suspension of a facility/ service/ equipment

10.10 When serious and immediate risk is detected at a regulated PHF, either arising from the use of certain equipment, performance of certain procedures or provision of certain services, it is essential that the regulatory authority could promptly respond to such risk and directly address the source of the problem. However, the existing regime only allows the regulatory authority to close down the PHF, without intermediate sensible

enforcement actions as viable alternative. Such drastic “option” to shut down the PHF is impractical in reality given the grave impact to the quality and continuity of medical service available to patients of the PHFs. A greater variety of enforcement options are necessary to better enable the regulatory authority to make a reasonable and proportionate response to public health risk. In the light of this, the regulatory authority should be given the power to suspend registration of a regulated PHF for a specified period or prevent the use of all or part of the facility/ equipment/ service concerned.

10.11 There should be check-and-balance in the exercise of regulatory powers of a punitive nature. We propose that an Independent Review Committee on Regulatory Actions should be established for PHF aggrieved by the decision of the regulatory authority to lodge an appeal.

(D) Appointment of committees

10.12 To strengthen the regulatory authority’s credentials and public confidence in regulating the highly expertised and specialised medical field and PHFs, we propose establishing committees, comprising, among others, experts of relevant medical fields to provide timely, updated, specific and professional advice on regulatory issues to the regulatory authority. These committees can serve various functions that keep the regulatory authority abreast of the latest development in medical technologies and market landscape, react to social needs dynamically and address public concerns or grievances promptly. Their functions include making suggestions on regulating private hospitals in pace with time; opening up appeal channel for regulated PHFs to settle disputes with the authority; handling complaints as an impartial third party over PHFs and the regulatory authority; and devising, reviewing and updating the scope and standards of regulation for facilities providing high-risk medical procedures. Committees that may be set up include –

- (a) Advisory Committee(s) on Regulation of Private Hospitals – The regulatory authority should be empowered to appoint advisory committee(s) which it considers appropriate to advise on issues in respect of registration, compliance and other matters of concern that relate to its regulation over private hospitals.
- (b) Independent Review Committee on Regulatory Actions – An independent review committee, appointed by the Secretary for Food and Health, should be set up to handle any appeal lodged by registered PHFs or any person who is aggrieved by registration decision (e.g. refusal of registration) or enforcement action (e.g. order of service suspension) made by the regulatory authority. The decision made by the committee shall be final.

- (c) Independent Committee on Complaints against Private Hospitals – An independent committee, appointed by the Secretary for Food and Health, should be set up to handle complaints lodged by the public against the service of private hospitals and against how complaints are handled by private hospitals. The decision made by the committee shall be final.

- (d) Advisory Committee on Defining High-risk Medical Procedures/Practices Performed in Ambulatory Setting – an advisory committee, appointed by the regulatory authority, should be set up to devise, review and update the scope and standards of regulation for facilities providing high-risk medical procedures given that new developments in technology and service delivery may change the risk profiles of individual procedures. Composition of membership shall include representatives from the Hong Kong Academy of Medicine and its member Colleges, academics and professional organisations. The advisory committee shall provide advice, based on modern-day requirements and the best practices identified upon comprehensively examining the latest medical developments and evidence, to the regulatory authority on (1) range of high-risk procedures for which ambulatory facilities should be regulated; and (2) facility standards specific to procedures including but not limited to physical standards (e.g. ventilation system, sterilisation facility) and standards related to the care process (e.g. emergency transfer arrangements, minimum staffing requirement for certain procedures such as surgery under anaesthesia).

Chapter 11

Introducing a New Regulatory Regime

11.1 To implement the aforesaid proposals, we need to introduce a robust and comprehensive regulatory regime for private healthcare facilities (PHFs) by replacing the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) and Medical Clinics Ordinance (Cap. 343) with a new legislation. The new regulatory regime will strengthen oversight of the operation and management of the three classes of PHFs proposed to be regulated, introduce measures to enhance the protection of patients' right and institute a modernized framework for effective regulatory control.

The New Legislation

11.2 Under the new legislation, PHFs to be regulated will be clearly defined by categories, as discussed in Chapter 3. Application for, issue, renewal, cancellation, suspension, amendment, variation of condition and transfer of licenses will also be set out clearly and appeal clauses will be incorporated to establish an appeal channel in respect of decisions made by the regulatory authority. Public officers and the regulatory authority will be vested with appropriate power to administer the new legislation (key aspects are discussed in Chapter 10). For example, new regulations can be made for better carrying out the purposes of the legislation, advisory committees may be appointed to advise on matter related to the regulation of PHFs, authorized public officers will be protected from civil liability for enforcing the new legislation, and certain information collected from PHFs will be kept confidential. The requirements for governing bodies, quality assurance activities, complaints management, price transparency will be incorporated as legal requirements with exemption clauses provided, as appropriate. Sanctions against non-compliance and breaches will be set at levels commensurate with the severity of the offense.

11.3 Upon the enactment of the new legislation, Cap. 165 and Cap. 343 will be repealed.

Regulatory Authority

11.4 The new legislation will confer to the regulatory authority the powers, including suspending a facility/ equipment/ service, appointing committees, etc. necessary for the effective operation of the regulatory regime.

11.5 The Department of Health, or its predecessors, has all along been the executive arm of public health policy in Hong Kong where the Director of Health (Director) has been the regulatory authority under Cap. 165 and Cap. 343. We propose that the Director should be empowered to enforce the regulatory requirements under the new regime.

Chapter 12

Interim Measures

12.1 Before a new legislation is in place to provide for the revamped regulatory regime, we have been collaborating with concerned stakeholders including the Hospital Authority (HA) and statutory bodies including the Hong Kong Academy of Medicine (HKAM) and the Medical Council of Hong Kong (MCHK), to look into the possibility of introducing interim measures that could be implemented administratively to better safeguard public interest as soon as practicable in view of the finding of the reviews conducted over the past few years. Some interim measures to enhance the existing administrative regulatory regime for private healthcare facilities (PHFs) have already been introduced while some are adopted as on-going initiatives. A succinct summary of these measures is set out in the following paragraphs.

A. Implemented/ On-going Interim Measures

(i) Alignment of Reporting Criteria of Sentinel Events between Public and Private Sectors

12.2 As a step to unify the sentinel reporting mechanism of public and private hospitals, the **list of reportable sentinel events for private hospitals** will be **aligned with** that applicable to **public hospitals** starting from January 2015.

(ii) Standard on Credentialing of Doctors

12.3 The quality of medical services and care mainly hinges on the skills, competence and attitude of care providers, i.e. medical practitioners practising in hospitals and other classes of PHFs. We have been maintaining close and continuous liaison with professional bodies, i.e. HKAM and MCHK, to keep track of the progress of their work on defining the scope of clinical practice and to develop a framework and guidelines applicable to all doctors providing medical services in hospitals and other classes of PHFs.

12.4 For instance, HKAM is in the process of establishing a territory-wide credentialing system. Guidelines would be developed and published by HKAM so that HKAM's colleges could set standards specific to respective specialties. Once HKAM has established a set of universally applicable guidelines/standards on credentialing, we would consider how the Government could make the best use of it under the new regulatory regime.

B. Interim Measures to be Adopted

12.5 Before the enactment of the proposed new legislation, we propose to review the Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes (Cap. 165 CoP) and the Code of Practice for Clinics Registered under the Medical Clinics Ordinance (Cap. 343 CoP) to bring the standards up-to-date. In particular, consideration will also be given to enhance requirements in Cap. 165 CoP on price transparency of hospitals.

12.6 As regards facilities providing high-risk medical procedures, we are considering, as the first step, conducting a territory-wide survey to assess the number and types of PHFs that might be affected by the new regulatory regime, as well as range of their services. We will then, introduce an administrative listing system for facilities providing high-risk medical procedures in ambulatory setting before the statutory registration comes into effect.

Chapter 13

Invitation of Views

13.1 Your support and constructive views to the proposals for revamping the existing regulatory regime for private healthcare facilities (PHFs) is much needed. We welcome your views on the proposals set out in this Consultation Document, in particular, the followings –

- (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 **19 regulatory aspects and their applicability** under the revamped regulatory regime; and
- (3) the proposed **powers to be conferred on the regulatory authority.**

13.2 We will consolidate and analyse 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 the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) and the Medical Clinics Ordinance (Cap. 343) by a new legislation regulating PHFs. We aim to introduce the legislative proposal to the Legislative Council in 2015/16.

13.3 Please send us your views on the Consultation Document **on or before 16 March 2015** through the contacts below.

Address

Healthcare Planning and Development Office,
Food and Health Bureau,
19/F, East Wing,
Central Government Offices,
2 Tim Mei Avenue, Tamar,
Hong Kong

Contacts

Fax: 2102 2493

E-mail: hpdo@fhb.gov.hk

Website: www.fhb.gov.hk

13.4 It is optional for you to supply your personal data in providing views on this Consultation Document. Any personal data provided with a submission may be transferred to the relevant Government bureaux and departments for purposes directly related to this consultation exercise. The Government bureaux and departments receiving the data are bound by such purposes in their subsequent use of such data.

13.5 The names and views of individuals and organisations which put forth submissions in response to this Consultation Document may be published for public viewing after conclusion of the public consultation exercise. This Bureau may, either in discussion with others (whether privately or publicly), or in any subsequent report, attribute comments submitted in response to this Consultation Document.

13.6 To safeguard your data privacy, we will remove your relevant data (if provided), such as residential/return address, e-mail address, identity card number, telephone number, facsimile number and signature, where provided, when publishing your views.

13.7 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 publicized in the future.

13.8 Any persons providing personal data to this Bureau in the submission will have rights of access and correction with respect to such personal data. Requests for data access and correction of personal data should be made in writing to:

Address: Senior Executive Officer
(Healthcare Planning and Development Office)³
Food and Health Bureau,
19/F, East Wing,
Central Government Offices,
2 Tim Mei Avenue, Tamar,
Hong Kong.

Fax: 2905 1165

E-mail: hpdo@fhb.gov.hk

Steering Committee on Review of Regulation of Private Healthcare Facilities

Terms of Reference and Membership

Terms of Reference

- To –
 - (i) identify the areas of the current legislations, including Cap. 165 and Cap. 343, requiring enhancement and improvement;
 - (ii) examine the scope of regulation (whether to extend to other healthcare facilities) and to formulate options and examine the pros and cons of each approach; andhaving regard to –
 - (a) the latest developments in the regulatory framework and standards of private healthcare facilities in overseas countries and making reference with local needs and environment; and
 - (b) the views from stakeholders and general public on the regulation of private healthcare facilities,
- To advise on the strategies on public consultation for the way forward.

Membership

Chairman

Secretary for Food and Health

Members

Professor Francis CHAN Ka-leung (*from 17 September 2013*)

Ms CHEUNG Jasminia Kristine

Professor FOK Tai-fai (*until 16 September 2013*)

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

Ex-officio Members

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

Secretary

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

Working Group on Differentiation between Medical Procedures and Beauty Services

Terms of Reference and Membership

Terms of Reference

- To differentiate between medical treatments and ordinary beauty services currently available in the market
- To make recommendations on procedures which should be performed by registered medical practitioners

Membership

Chairperson

Director of Health

Members

Steering Committee members

Ms Connie LAU Yin-hing (*until 14 March 2014*)

Dr Sigmund LEUNG Sai-man

Dr Susie LUM Shun-sui

Dr TSE Hung-hing

Ms Sandy WONG Hang-yee

Dr YEUNG Chiu-fat

Head of Healthcare Planning and Development Office, Food and Health Bureau (or representative)

Co-opted members

Professor Henry CHAN Hin-lee

Ms Rinbo CHAN

Dr HO Chiu-ming

Dr HO King-man

Dr Michael HO Ming-tai

Ms Amy HUI

Mr Nelson IP Sai-hung

Dr Walter KING Wing-keung

Ms Cecilia KUK

Ms Maggie LEUNG

Dr NG Yin-kwok

Ms Quby TANG Mei-yee

Ms Sandra TSOI Lai-ha

Dr David WONG Sau-yan

Dr Hunter YUEN Kwok-lai

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

Terms of Reference and Membership

Terms of Reference

- To define the range of high-risk procedures/practices that should be performed in regulated ambulatory facilities only; and
- To recommend appropriate regulatory approaches to the Steering Committee.

Membership

Chairperson

Professor Raymond LIANG

Members

Steering Committee members

Dr Samuel KWOK

Professor Joseph LAU

Dr Anthony LEE

Dr Sigmund LEUNG

Professor Samantha PANG

Dr TSE Hung-hing

Ms Sandy WONG

Director of Health (or representative)

Chief Executive, Hospital Authority (or representative)

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

Co-opted members

Dr Jane CHAN

Dr Billy CHIU

Dr CHOW Yu-fat

Professor LAU Chak-sing

Dr LAW Chun-key
Dr Roch LEE
Dr NG Fook-hong
Mr Peter POON
Dr Gordon SOO
Professor Frances WONG
Dr Andrew YIP
Dr Hunter YUEN

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

Terms of Reference and Membership

Terms of Reference

- To define and come up with the range of health products for advanced therapies that could be conducted in laboratory/ambulatory setting; and
- To examine whether and how to impose regulatory control on premises where health products for advanced therapies are stored and/or processed having regard to the latest development in medical practice and technology, as well as overseas regulations and international best practices applicable to local circumstances.

Membership

Chairperson

Dr Homer TSO

Members

Steering Committee members

Ms Jasminia Kristine CHEUNG

Mr Andy LAU

Director of Health (or representative)

Chief Executive, Hospital Authority (or representative)

Head of Healthcare Planning and Development Office, Food and Health Bureau (or representative)

Co-opted members

Mr CHAN Wing-kwong

Mr CHANG Hsiu-kang

Dr Celine CHENG

Ms Bella HO Shiu-wun

Dr LAM Tak-sum

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

Working Group on Regulation of Private Hospitals

Terms of Reference and Membership

Terms of Reference

- To review the scope of the existing legislation and the regulatory regime for private hospitals; and
- To formulate recommendations for enhanced control of different aspects related to the provision of healthcare services by private hospitals.

Membership

Chairman

Permanent Secretary for Food and Health (Health)

Members

Steering Committee members

Professor Francis CHAN Ka-leung (*from 17 September 2013*)

Ms CHEUNG Jasminia Kristine

Professor FOK Tai-fai (*until 16 September 2013*)

Dr Samuel KWOK Po-yin

Mr Andy LAU Kwok-fai

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Dr Susie LUM Shun-sui

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Head, Healthcare Planning and Development Office, Food and Health Bureau

Co-opted Members

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Dr William HO Shiu-wei

Ms Vera TAM Sau-ngor

Dr Raymond YUNG Wai-hung

Recommendations proposed by Working Group 2 and endorsed by the Steering Committee

The following recommendations were proposed by Working Group 2 and endorsed by the Steering Committee.

Recommendation (1)

High-risk procedures/practices should be performed only in regulated ambulatory facilities or hospitals by qualified health professionals.

Recommendation (2)

Any procedure defined by ANY one of the following three factors will be regarded as high-risk medical procedure -

- (a) risk of procedures
- (b) risk of anaesthesia involved
- (c) patient's condition

Medical practitioners and dentists should take into account, in addition to the criteria for defining high-risk and hospital-only medical procedures, the age, body size and other physical conditions of the patient when deciding whether a medical procedure is high-risk and should be performed in ambulatory facility or hospital.

Recommendation (3)

Certain high-risk procedures should only be performed in hospital in view of its risk. Overall, high-risk medical procedures may be performed in ambulatory setting only if -

- (a) the patient is discharged in the same calendar day of admission;
- (b) the expected total duration of procedure and recovery requiring continuous confinement within the facility does not exceed 12 hours; and
- (c) patient's condition is not Class 4 or worse (i.e. Class 4 or 5) by American Society of Anaesthesiologists (ASA) Physical Status Classification System¹.

¹ ASA Physical Status Classification System :

Class 1 – normal healthy patient

Class 2 – mild systemic disease

Class 3 – severe systemic disease – stable

Class 3 – severe systemic disease – unstable (acute exacerbation)

Class 4 – severe systemic disease that is a constant threat to life

Class 5 – moribund patient who is not expected to survive without the operation

Recommendation (4)

It is recommended to adopt the scope of high-risk and hospital-only medical procedures as set out in Annex B(1).

Recommendation (5)

A statutory registration system should be introduced for ambulatory facilities where high-risk medical procedures are performed. An administrative listing system may be implemented before the mandatory registration system comes into effect.

Recommendation (6)

Regulated ambulatory facilities should be subject to a set of core facility standards and requirements that cover –

- (a) Management of the facility;
- (b) Physical conditions;
- (c) Service delivery and care process;
- (d) Infection control; and
- (e) Resuscitation and contingency.

Regulated facilities will also be imposed further facility standards that are specific to the procedures being performed in the facilities, e.g. haemodialysis (Annex B(2)), cytotoxic chemotherapy (Annex B(3)) and anaesthesia².

Recommendation (7)

It is recommended that the regulatory authority will have a mechanism to devise, review and update as required, the scope of regulation and standards with regards to the expert advice of the Hong Kong Academy of Medicine on -

- (a) the range of high-risk procedures; and
- (b) the relevant procedure-specific facility standards.

Recommendation (8)

Regulated ambulatory facilities should be subject to general requirements that are applicable to other comparable regulated healthcare facilities.

² The “Guidelines on Procedural Sedation” promulgated by the Hong Kong Academy of Medicine is recommended to be the regulatory standards on anaesthetic safety. Class 5 – moribund patient who is not expected to survive without the operation

Recommended Scope of High-risk and Hospital-only Procedures

General Principles

1. Any procedure defined by ANY one of the following three factors will be regarded as high-risk medical procedure -
 - (a) risk of procedures
 - (b) risk of anaesthesia involved
 - (c) patient's conditions

2. Medical practitioners and dentists should take into account, in addition to the criteria for defining high-risk and hospital-only medical procedures, the age, body size and other physical conditions of the patient when deciding whether a medical procedure is high-risk and should be performed in ambulatory facility or in hospital.

A) Risk of Procedures

3. High-risk surgical procedures include the following procedures –
 - (a) Creation of surgical wound to allow access to major body cavity or viscus³ (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]

³ Not including needle injection into joint cavity, intraocular injection with fine needle by ophthalmologists and injection of Botox

- (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 products⁴) 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

4. 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 cystoscopy⁵] 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

5. 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
- (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

⁴ Include platelet-rich plasma (PRP)

⁵ 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.

6. 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

B) Scope of High-risk Anaesthetic Procedures⁶

7. A procedure is considered to be high-risk if it involves any of the following modes of anaesthesia or sedation:
- (a) General anaesthesia
 - (b) Neuroaxial blocks (spinal, epidural, caudal)
 - (c) Major plexus block (brachial, lumbar, sacral)
 - (d) Intravenous regional anaesthesia
 - (e) Intercostal nerve block
 - (f) Major nerve block:
 - Glossopharyngeal nerve, vagus nerve or their terminal branches, including superior, inferior and recurrent laryngeal nerves;
 - Sciatic and femoral nerves; or
 - Posterior tibial nerve, pudendal nerve or para-cervical block
 - (g) Use of sedative or analgesic drugs with reasonable expectation that it will, in the manner used, result in deep sedation⁷ for a significant percentage of a group of patients
 - (h) Tumescant anaesthesia

C) Patient's condition

8. A procedure is considered high-risk if it is performed on a patient whose physical status is Class 3-unstable or worse (i.e. Class 3-unstable, Class 4 or Class 5) as classified by the American Society of Anaesthesiologists (ASA) Physical Status Classification System.

6 The risks of anaesthesia considered by the Working Group include risk of gross, vital physiological derangement, risk of inadvertent systemic injection (such as neurovascular bundle and intra-dural injection), loss of protective reflexes, prolonged disturbance of mobility or body balance, disturbance/loss of major functions of vital organs.

7 Definition of "deep sedation" should refer to the "Guidelines on Procedural Sedation" promulgated by the Hong Kong Academy of Medicine.

D) Hospital-only procedures

9. The following high-risk procedures should only be performed in hospitals:
- (a) Administration of chemotherapy (cytotoxic) into body cavity or deep-seated organ
 - (b) Image-guided core biopsy of deep-seated organ
 - (c) Transarterial catheterisation or deep venous catheterisation
 - (d) Continuous venous-venous haemofiltration /haemodiafiltration
 - (e) Organ transplant [except corneal transplant] or complicated transplant procedures
 - (f) Bronchoscopy or pleuroscopy
 - (g) Therapeutic gastrointestinal endoscopy on children aged under 12 years old
 - (h) Injection of sclerosing/embolisation agents into vascular/lymphatic compartment of deep-seated head and neck region

Regulatory Standards for Facilities Providing Haemodialysis

Requirements/Standards	References		
	Infection Control Guidelines ^a	Code of Practice ^b	Accreditation Guide ^c
1 Staffing 1.1 Requirements on advisor and medical in-charge for the facility 1.2 Requirements on nurse in-charge for the facility 1.3 Requirements on other staff and operator of the facility		Section 21.1	Section III
2 Accommodation and equipment 2.1 Minimum requirements on design and space 2.2 Resuscitation equipment 2.3 Back-up electricity 2.4 Maintenance of haemodialysis machines and back-up machines 2.5 Provision of service during maintenance work Section	Section 7.1, 7.3, 7.4	Section 21.2	Section II, IV
3 Infection control 3.1 Infection control policies 3.2 Water treatment system 3.2.1 Disinfection 3.2.2 Test for residue 3.2.3 Microbiological testing 3.3 Haemodialysis machines 3.3.1 Disinfection 3.3.2 Test for residue/contaminant 3.3.3 Microbiological testing 3.4 Serology screening 3.5 Immunisation	Section 3, 4, 5, 6, 7	Section 9.6	Section V, VI, VII, VIII, IX
4 Occupational safety 4.1 Blood and body fluid exposure 4.2 Chemical disinfectants	Section 9	Section 9.4	
5 Other requirements 5.1 Emergency transfer 5.2 Regular assessment by nephrologists 5.3 Medication management 5.4 Chemical and waste management	Section 7.5, 7.7	Section 21.1, 21.3, 34.5	

a Infection Control Guidelines on Nephrology Services in Hong Kong (Second Edition) issued jointly by Infection Control Branch, Centre for Health Protection and Central Renal Committee, Hospital Authority http://www.chp.gov.hk/files/pdf/ic_gu_nephrology_services_in_hk_2nd_ed_final.pdf

b Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes (April 2010) promulgated by the Department of Health http://www.dh.gov.hk/english/main/main_orhi/files/code_english.pdf

c Accreditation of Renal Dialysis Unit issued by the Hong Kong College of Physicians and Central Renal Committee, Hospital Authority http://www.hkcp.org/docs/TrainingGuidelines/renal_dialysis_unit.pdf

Regulatory Standards for Facilities Providing Parenteral Chemotherapy (Cytotoxic) Treatment

(1) Introduction

- 1.1 This set of standards serves as facility standards specific for facilities providing parenteral chemotherapy (cytotoxic) treatment.
- 1.2 Chemotherapy (cytotoxic) is defined as cytotoxic drugs used in medical treatments.

(2) General standards

- 2.1 Resuscitation equipment should be available in the facility.
- 2.2 An appropriate and well-functioning biosafety cabinet or isolator should be installed if reconstitution of chemotherapy (cytotoxic) would take place in the facility.
 - (a) The reconstitution of chemotherapy (cytotoxic) should be performed in a Class II biosafety cabinet (Type A2 or B), a Class III biosafety cabinet or isolator to protect both staff safety and product quality.
 - (b) If volatile chemotherapy (cytotoxic), i.e. chemotherapy (cytotoxic) that may evaporate under room temperature, is to be reconstituted, an exhaust vent to outdoor should be installed to the biosafety cabinet or isolator, or alternatively, an appropriate activated charcoal filter should be installed to the biosafety cabinet or isolator.
 - (c) The biosafety cabinet or isolator should be regularly serviced and maintained.
 - (d) Closed-system drug transfer device could also be used for the reconstitution of chemotherapy (cytotoxic) inside the biosafety cabinet to further enhance staff safety. The closed-system drug transfer device does not replace the role of biosafety cabinet.
- 2.3 Healthcare professionals responsible for reconstitution of chemotherapy (cytotoxic) should have completed training in the safe and proper use of the biosafety cabinet, infection control and occupational safety.
- 2.4 Proper procedures should be established for the preparation, reconstitutions and administration of chemotherapy (cytotoxic).
- 2.5 Suitable and adequate personal protective clothing should be provided to the operators (disposable gowns and impervious gloves are recommended).

- 2.6 Spill kit should be available to handle any spillage of chemotherapy (cytotoxic).
- 2.7 During the course of intravenous infusion, at least one competent and trained healthcare professional should be present in the facility to oversee the process. Medical practitioner should attend to the patient in case of medical emergencies.

(3) Standards on occupational safety and health

- 3.1 A safe system of work should be put in place to ensure safe handling of chemotherapy (cytotoxic) in an ambulatory setting which includes their storage, preparation, transport and disposal. In particular, the system should cover the following aspects:
 - (a) The person-in-charge of the facility should assess the health and safety risk related to the handling of chemotherapy (cytotoxic) in the workplace and the assessment should be documented. If there are any significant changes, the risk should be re-assessed and remedial measures should be implemented accordingly. The re-assessment and any remedial measures implemented should also be documented.
 - (b) Proper procedures should be established for the preparation, reconstitution and administration of chemotherapy (cytotoxic) to ensure the safety and health of the operators.
 - (c) Isolated areas or separate rooms should be designated for the preparation and administration of chemotherapy (cytotoxic).
 - (d) An isolator or a biological safety cabinet (BSC) of Class II (Type A2 or B) should be used for preparation or reconstitution of injectable chemotherapy (cytotoxic) under aseptic technique. The exhaust of the isolator or BSC shall be fitted with HEPA filter. The isolator or BSC should be regularly serviced and maintained. Use of needleless and closed-system drug transfer device in preparation or reconstitution of chemotherapy (cytotoxic) inside the isolator or BSC is preferable.
 - (e) Suitable and adequate personal protective clothing should be provided to the operators – Disposable gowns and impervious gloves are recommended.
 - (f) Proper arrangements and facilities should be provided for the storage and labelling of chemotherapy (cytotoxic) which shall be kept in locked cabinets with warning signs in both Chinese and English.
 - (g) Proper arrangements and facilities should be provided for the transport of chemotherapy (cytotoxic) - Secure facilities shall be used for transport to prevent breakage and leakage.
 - (h) Spillage handling procedures should be established, with suitable spillage handling kits provided.

- (i) Suitable hazardous waste disposal procedures and facilities (with warning signs in both Chinese and English) should be provided for handling and disposal of spent and unwanted chemotherapy (cytotoxic) and contaminated containers according to the applicable legislation.
- (j) Adequate information, instruction and training should be provided to the operators on the handling of chemotherapy (cytotoxic). The topics covered should include health and safety hazards of chemotherapy (cytotoxic), safe operating procedures, spillage handling techniques, proper care and use of personal protective equipment.

Recommendations proposed by Working Group 4 and endorsed by the Steering Committee

I. Scope of Regulation

1. Revise the definition of 'hospital' to mean any healthcare facility primarily for the provision of medical care with continuous medical support and lodging.
2. Define 'lodging' 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 hour.
3. Remove separate licensing for maternity home, and instead subsume it under private hospital as part of the facility.
4. Remove the category of nursing home in the new legislation on the regulation of private healthcare facilities. Instead, the existing nursing homes registered under Cap. 165 should be registered as private hospitals or ambulatory medical centres for the purpose of performing high-risk medical procedures if they provide primarily medical care. For nursing homes providing mainly residential service with no or limited medical care, they should be regulated as welfare/ rehabilitative institutions by separate pieces of legislation, depending on the nature of service.

II. Corporate Governance

Organization of Private Hospitals

5. Provisions should be added to the new legislation to make the establishment of board of governors, quality assurance committee and the appointment of Person-in-charge mandatory. Minimum requirements on the composition of board of governors and quality assurance committee, the qualification of Person-in-charge, their functions and responsibilities should be stipulated, and the regulatory authority should be empowered to, as and when

necessary, require private hospitals to submit information concerning the set up and operation of the board of governors, quality assurance committee and Persons-in-charge as required under the CoP.

6. Consideration should be made, for the sake of further strengthening the monitoring mechanism, to hold the Person-in-charge accountable (and liable to penalty if the offence is substantiated) for breaches or non-compliance that would seriously affect the safety or integrity of hospital services which he should be reasonably in control when appropriately discharging his responsibilities under the revamped regime.

Complaints Management

7. A two-tier complaints handling system should be established to handle all complaints against private hospitals. The first-tier should be at the service delivery level at which private hospitals should manage complaints at source according to a standardised complaints handling mechanism as prescribed by the regulatory authority. The second-tier should handle unresolved cases according to a centralised and independent mechanism.
8. A Private Hospital Complaint Committee (PHCC), with members appointed by the Secretary for Food and Health, should be established to handle all complaints at the second-tier. Under the revamped regulatory regime, the PHCC should be empowered to investigate and review all appeal cases and make recommendations to the regulatory authority for consideration and follow-up actions.
9. The regulatory authority should be empowered by the new legislation to obtain information and reports, including details of the complaints received, investigation findings and actions taken from private hospitals.
10. An electronic information system be developed to communicate and share information on management of complaints on private hospitals, analysis of causes and actions, lessons learnt and best-practices across private hospitals.

Hospital Accreditation

11. In the light of the usefulness of hospital accreditation in promoting continuous improvement and strengthening corporate governance, the Working Group recommends that hospital accreditation should become a mandatory

requirement for registering private hospitals in the long run as and when the regulatory authority is convinced that it is appropriate to adopt such programme as part and parcel of the registration/ re-registration conditions.

12. Before the implementation of the aforesaid longer term initiative, accreditation programme should be recognized explicitly (rather than as a suggestion as it is now) in the CoP as one of the desirable quality control measures. Besides, should there be any change to the accreditation status, the regulatory authority would have to be informed by the private hospital concerned in order for the regulatory authority to conduct regulatory actions as appropriate.

III. Clinical Governance

Clinical Risk Management

13. Private hospitals should submit reports and records of clinical risk management work to the regulatory authority for inspection as and when required.
14. An electronic information system should be developed to communicate and share risk management information and best-practices across private hospitals as soon as practicable.

Clinical Audit

15. Private hospitals should, as soon as practicable, develop policies, meeting a minimum standard as prescribed by the regulatory authority, to review and record clinical audits performed and improve services performance based on audit findings.
16. Private hospitals should submit reports on audit findings and implementation progress to the regulatory authority for inspection as and when required.
17. Private hospitals should be encouraged to develop database to support the work of clinical audit to facilitate data collection and quality assurance.
18. The regulatory authority should devise a standardised reporting system for the compliance of private hospitals on the performance of clinical audits for ease of data management and analysis.

19. Under the revamped regulatory regime, the implementation of clinical audits and establishment of clinical audit committee should be made statutory requirements for the compliance of private hospitals.

Clinical Indicators

20. Private hospitals should, as soon as practicable, be mandated to collect more in-depth and comprehensive clinical indicators and perform review and analysis regularly.
21. Private hospitals should be encouraged, at the earliest convenience, to adopt a systematic approach (e.g. electronic information system) to collect and analyse clinical indicators in an effective and efficient manner.
22. Under the revamped regulatory regime, there should be provision which empowers the regulatory authority to require private hospitals to submit clinical indicators to the regulatory authority as and when necessary. In particular, the regulatory authority should be empowered to specify the clinical indicators required and the format of submission, e.g. by a prescribed electronic template; and the timing and frequency of submission.

Sentinel Events Reporting

Short term

23. To require private hospitals to have clear written policy and procedures for communicating to patients, families, regulatory authority and media, as appropriate, on sentinel events and to provide relevant staff training.
24. To continue the practice of making public announcement about sentinel events if the event carries significant or on-going public health risk as assessed by the regulatory authority, and to improve the risk communication by publication of quarterly newsletter on sentinel events to hospitals, which will also be published for public's information.

Medium term

25. To require private hospitals to review, and enhance as needed, their capability in detecting and handling sentinel events, including but not limited to providing training and engaging of appropriate personnel, to ensure effective management of and learning from sentinel events.

26. To engage independent clinical and quality assurance experts to assist in the assessment of root cause analysis reports submitted by private hospitals and to make recommendations where appropriate.

Long term

27. To mandate private hospitals to establish quality assurance committees which will be responsible for activities related to the identification, reporting, investigation and management of sentinel events and other medical incidents, and report to the regulatory authority the activities, findings and recommendations as and when required.
28. To mandate reporting of sentinel events to regulatory authority by private hospitals; to prescribe reporting requirements and impose sanctions for non-compliance.
29. To empower the regulatory authority to access records and documents in connection with sentinel events, including information and reports on the investigation and findings and recommendations of the quality assurance committee.
30. To protect the confidentiality of information and documents produced in the course of root cause analysis by the quality assurance committee to ensure an effective learning system, except for cases involving criminal or reckless behaviours where a prima facie case warranting sanctions may be established.

Human Resource Management

31. When making the new legislation, consideration should be made, for the sake of further enhancing patient safety, to require private hospitals to make sure that medical practitioners are available within a reasonable timeframe to attend to patients in need of urgent treatment in the hospital (rather than confining to obstetric service only).
32. Private hospitals should be required to draw up and implement policies or mechanism to ensure the credential of staff serving in the hospital concerned, particularly those involved in performing high risk treatments/ procedures.

Clinical Effectiveness

33. Private hospitals should have in place and implemented written policies and guidance on clinical effectiveness.
34. Consideration would be given to require private hospitals draw up standardised guidelines to ensure clinical effectiveness in the longer term if supported by professional bodies such as the Hong Kong Academy of Medicine (HKAM), and to adopt guidelines promulgated by HKAM and its Colleges.

Information Management

35. Under the revamped regulatory regime, consideration should be made to stipulate that private hospitals, in the long run, should have in place an electronic medical/patient record system that can meet the technical requirements for joining the electronic health record sharing system (eHRSS).

IV. Price Transparency

(a) Disclosure of Price Information

Information contained in fee schedule

36. Private hospitals should prepare a fee schedule setting out charges on wards, investigative and treatment procedures, medical supplies, medicines, medical reports, photocopy of medical records and any charges that will be levied.
37. A chargeable item may be shown in a price range in the fee schedule if private hospitals consider it necessary, but the hospital should justify, upon request, why such arrangement is adopted. In case it is not even practicable to quote a price range, the item should still be indicated in the fee schedule and the hospital should justify why such arrangement is adopted in the fee schedule.
38. No fee could be levied for any item of hospital services unless the item is shown in the fee schedule (either in the form of (i) fixed price, (ii) price range or (iii) marked to indicate that price information is not available).

Availability of fee schedule

39. The fee schedule should be readily available at the admission office, cashier, hospital webpage and where appropriate for public's reference. It should also be provided upon request.
40. The hospital webpages showing fee schedules should be linked to a common electronic platform provided by the regulatory authority.

Change in fee schedule

41. Any change in chargeable items and/ or price levels (except for those indicated and justified that price information is not available for practical reasons) could only take effect after the fee schedule has been updated to reflect the changes. When an updated fee schedule is released, private hospitals should publish notices, update hospital webpages and make announcements to inform patients of the release at least fourteen calendar days ahead.

(b) *Uniform Quotation System*

Provision of estimated total charges

42. Patients having investigative procedures or elective, non-emergency therapeutic operations/ procedures for known diseases should be informed of the estimated total charges for the whole treatment course on or before admission to private hospitals.
43. For patients who have not been given an estimation of their hospital bills on or before admission, whenever they receive a definite diagnosis where elective therapeutic operations/ procedures are required after admission, they should be given an estimate in advance as far as practicable.
44. Each private hospital should publish a "List of Common Operations/ Procedures" for which quotation will be provided for prospective patients. The regulatory authority may, from time to time, stipulate operations/ procedures that should be included in the List. Private hospitals may also add other operations/ procedures to the List on a voluntary basis. The List should be available at the admission office, cashier, hospital webpage and where appropriate for public's reference.

Quotation procedure

45. Doctors should provide patients, in a prescribed Informed Financial Consent, with an estimation of total charges for treatment when referring/ admitting patients to private hospitals. In case it is not practicable to provide an estimate, doctors are required to indicate and justify why this is the case in the consent form.
46. While private hospitals may give quotation for hospital charges under their control, for the sake of expediency, doctors may use their best endeavours in providing price quotes for hospital charging items.
47. An Informed Financial Consent should be completed with the signatures or stamps of the patient, doctor and hospital concerned. Hospitals should request patients to present completed Informed Financial Consent when they are admitted. They should inform patients of the potential variation of the estimates when appropriate.

Change in estimate

48. Hospitals should inform patients of the range of potential variation of the estimates (which should be made in accordance with hospitals' historical data), and document the range in the Informed Financial Consent to be signed by patients. In case there is any material change in estimates beyond a range of the original estimates defined by the regulatory authority, patients who are conscious and stable (or their next-of-kin or authorized persons if otherwise) should be informed of and consent to the latest estimates before any further operation/ procedure will be conducted. The latest estimate should be documented in the Informed Financial Consent duly signed by doctors/ hospitals and patients/ next-of-kin/ authorized persons. A new consent form may be used if the changes are considered substantial by the doctor or hospital concerned.

Exemption

49. Patients subscribing to Recognized Service Packages (see section (c) below) are exempt from quotation. In case at doctors' clinical judgment that patients undergoing operations/ procedures, emergency or life threatening situations require further treatment, price quotation for items beyond those the patients concerned have consented to would be exempted.

(c) Introduction of Recognized Service Packages for Common Operations/ Procedures

50. Private hospitals are encouraged to offer Recognized Service Packages (RSP), which are identically and clearly defined standard services provided at packaged charge through standard beds for common operations/ procedures based on known diagnosis. The term “Recognized Service Packages” may only be used for a combination of service items provided that it has satisfied all the requirements and included all the components prescribed by the regulatory authority. The purpose of RSP is to provide identically and comprehensively structured service packages for common operations/ procedures for easy consumption of the public. Subject to further discussion among the regulatory authority and private hospital operators, some of the major items that could be considered to be included are set out below –

- i. *Eligibility* – RSP should specify which customers are eligible (or ineligible).
- ii. *Coverage* – Different healthcare services may mandate different coverage in a RSP. For example, for surgical procedures, items covered may include –
 - Doctors’ fees (including resident and visiting, attending and all other specialist doctors)
 - Room charges
 - Diagnostic procedures
 - Treatment procedures
 - Operating theatre charges
 - Anaesthetic fees
 - Nursing care
 - Medications
 - Equipment/ Instrument
 - Consumables/ Materials
 - Implants
 - Registration fees/ Admission fees
 - Others (e.g. treatment for complications arising from the original operation/ procedure and/or known diagnosis, with the aggregate expenditure capped at a fixed amount)
- iii. *Exclusions* – All exclusions directly related to the operation/ procedure concerned should be specified and justified.

- iv. *Control of complications* – Private hospitals should specify how and to what extent treatment for complications directly arising from the operations/ procedures concerned would be covered by RSP, as well as the cap on the aggregate expenditure. It should state clearly what arrangements would be available for patients if treatment for complications is not completely covered. For example, patients might be transferred to public hospitals when the expenditure for treating their complications arising from the original operation/ procedure and/ or known diagnosis exceeds the cap, after their conditions are stabilized.
- v. *Terms and conditions of use* – For instance, in case when patients are diagnosed with disease deviated from the original diagnosis after admission, RSP may no longer apply and patients would be informed as soon as possible and provided with alternative options.

- 51. Information on RSP should be presented in a prescribed format. The Explanatory Note should be completed by hospitals and signed by patients subscribing to RSP. Each party should keep a copy of the form for record.
- 52. Information on RSP should be readily available at the admission office, cashier, hospital webpage and where appropriate for public's reference. It will also be linked to the common electronic platform provided by the regulatory authority.

(d) *Disclosure of Historical Statistics*

- 53. Private hospitals should develop a database of key historical statistics on their actual bill sizes for common treatments/ procedures that are reportable as prescribed by the regulatory authority. The statistics should include annual number of discharges, average length of stay, 50th percentile and 90th percentile bill sizes for each reportable treatment/ procedure.
- 54. Each hospital should publish its own statistics at the admission office, cashier, hospital webpage and where appropriate for public reference. Statistics of all private hospitals will be made available through the common electronic platform provided by the regulatory authority for public consumption.

V. Enhancing the Regulatory Framework of Private Hospitals

(a) *Enhancing the Statutory Powers of the Regulatory Authority*

Issuance of regulations/ code of practice

55. The regulatory authority should be given the power to issue regulations and/ or code of practice which set out principles, procedures, guidelines and standards for the operation and management of private hospitals and provide practical guidance in areas such as (but not limited to) (1) administration and management, (2) physical facilities including accommodation, facilities and equipment, (3) staffing, (4) corporate and clinical governance, (5) risk management, (6) patient care, (7) price transparency, and (8) medical records handling and management under the revamped regulatory framework. The regulatory authority should also be given the flexibility to amend the regulations and/ or code of practice as and when needed.

Inspection, collection and publication of information

56. The regulatory authority should be given the power to inspect, collect and publish information from private hospitals for regulatory purposes and public scrutiny. The regulatory authority should also be empowered to have access to records and documents, including information and reports on the investigation, findings and recommendations of the Quality Assurance Committee of the private hospital.

Suspension of a facility/ equipment/ service

57. The regulatory authority should be given the power to suspend a registration or prevent the use of all or part of a facility/ equipment/ service to enable a proportionate response to manage an immediate and serious risk to patient safety. Given the grave implications to the operations of private hospitals and well-being of patients, a robust mechanism should be put in place (such as an appeal channel) to ensure the regulatory authority would invoke such power only on a fully justified basis.

Appointment of committees

58. (a) *Advisory Committee on Regulation of Private Hospitals* – The regulatory authority should be empowered to appoint advisory committees which

it considers appropriate to advise on issues in respect of registration, compliance and other matters of concern that relate to its functions.

(b) *Independent Review Committee on Regulatory Actions* – An independent review committee, appointed by the Secretary for Food and Health, should be set up to handle appeal lodged by registered private hospital or any person who is aggrieved by the registration decision (e.g. refuse of registration) or enforcement actions (e.g. order of service suspension) taken by the regulatory authority. The decision made by the committee shall be final.

(c) *Independent Committee on Complaints against Private Hospitals* – An independent committee, appointed by the Secretary for Food and Health, should be set up to handle complaints lodged by the public against the service of private hospitals or the handling of complaints by private hospitals. The decision made by the committee shall be final.

(b) *Imposing Penalties Commensurate with Offences*

Penalty for unregistered operation

59. Under the revamped legislation framework, it is an offence for any person: (1) to operate a private hospital without registration, or (2) to continue to operate a private hospital after the registration has been revoked by the regulatory authority, or (3) to continue to operate the services/ facilities/ equipment after the services/ facilities/ equipment have been suspended by the regulatory authority. Any person committing any of the abovementioned offences is liable to a maximum fine of \$5,000,000 and imprisonment for a term not exceeding two years, and a fine of \$10,000 for each day during which the offence continues.

Penalty for non-compliance

60. A private hospital contravenes any provisions of the legislation, or fails to comply with any regulation/ code of practice and the result of which poses grave threat to patients' safety may be liable to a maximum fine of \$1,000,000, and a fine not exceeding \$10,000 for each day during which the offence/ non-compliance continues.

服務預算同意書 (只供參考) Informed Financial Consent to Services (For Illustration Only)

說明： 本頁由醫生及醫院填寫，並由病人、醫生及獲醫院授權人士簽名及蓋章作實。**預算費用只作參考**，最終收費視病人實際接受的治療、程序及服務而定。
Statement: This page is to be completed by doctor and hospital, and to be signed by patient, doctor and the authorised person of the hospital with hospital stamp. **The estimated charges are for reference only.** Final payments are subject to charges incurred from treatment, procedures and services performed.

病人姓名 (中文) (Chinese): _____ 身份證號碼 / 護照號碼*
Patient Name (英文) (English): _____ Hong Kong Identity Card/ Passport Number*: _____

初步診斷 Provisional Diagnosis: _____

入住的私家醫院 Private Hospital (to be) Admitted: _____

預計住院時間 Estimated Length of Stay: _____ 小時 Hour(s) / 日 Day(s)* 病房級別 Class of Ward: _____

治療 / 手術 Treatment / Surgical Operation: _____

轉介 / 主診醫生 Admitting / Attending Doctor: _____

是否能夠估算費用? 是 Yes (請填寫以下欄目。Please complete the following sections.)
Are estimated charges available? 否 No (請另頁提供理由。Please provide reasons on a separate sheet.)

預算醫院費用 Estimated Hospital Charges (由醫院填寫 To be completed by hospital)

醫院費用 Hospital Charges:	\$ _____ x _____ 日day(s)	\$ _____ ~ \$ _____
- 住宿及膳食 Room and Board:	\$ _____	\$ _____ ~ \$ _____
- 其他項目及收費 Other Items and Charges:	\$ _____	\$ _____ ~ \$ _____

(醫院須另頁補充醫院費用總額的明細供病人參考。)
(Hospital should provide a breakdown of total hospital charges on a separate sheet for patient's reference.)

預算醫生費用 Estimated Doctor's Fees (由醫院 / 醫生* 填寫 To be completed by hospital/doctor*)

每日醫生巡房費 Daily Doctor's Round Fee:	\$ _____ x _____ 日day(s)	\$ _____ ~ \$ _____
手術費 Surgical Fee:	\$ _____	\$ _____ ~ \$ _____
麻醉科醫生費 Anaesthetist Fee:	\$ _____	\$ _____ ~ \$ _____
住院時專科醫生診療費用 In-hospital Specialist's Fee:	\$ _____	\$ _____ ~ \$ _____
	\$ _____	\$ _____ ~ \$ _____
其他項目及收費 Other Items and Charges:	\$ _____	\$ _____ ~ \$ _____
	\$ _____	\$ _____ ~ \$ _____

(如不敷應用，請另頁補充。Please continue on a separate sheet if required.)

總計 Total \$

病人簽署 Patient's Signature

本人知悉上述預算費用及右列保險賠償額僅為參考，並不包括因併發症所產生的額外費用，並同意最終收費以醫院賬單所列為準。
I understand that the estimated charges above and the claimable amount from insurance on the right are for reference only. Additional charges incurred from complications are not covered. I agree that payment should be made in accordance with hospital invoice.

_____	_____	_____
病人 / 親屬 / 獲授權人士姓名* Name of Patient / Next-of-kin / Authorised Person*	病人 / 親屬 / 獲授權人士簽署* Signature of Patient / Next-of-kin / Authorised Person*	日期 Date

醫生及醫院聲明 Doctor's and Hospital's Declaration

本人已向病人解釋上述預算費用，並徵得其同意。
I have explained to the patient the details of the above estimated charges and have sought his / her agreement.

_____	_____	_____
醫生姓名 Name of Doctor	醫生簽署 Signature of Doctor	日期 Date

本院知悉上述預算費用。此表格正本會存放在本院的病人醫療記錄內，副本供病人和醫生參考。
This hospital has noted the above estimated charges. The original of this form will be filed as hospital's medical records, and copies will be given to patient and doctor for reference.

_____	_____	_____
獲醫院授權人士姓名 Name of Authorised Person of Hospital	獲醫院授權人士簽署及蓋章 Signature of Authorised Person of Hospital and Stamp	日期 Date

* 請刪去不適用者 * Please delete as appropriate

本欄只適用於受自願醫保計劃住院保險保障的人士 Only Applicable to Patients Covered by Hospital Insurance under Voluntary Health Insurance Scheme

說明： 本頁由承保機構填寫，並由獲承保機構授權人士簽名及蓋章作實。**預算賠償額及自付費用只作參考**，最終收費視病人實際接受的治療、程序及服務而定。
Statement: This form is to be completed by the insurer and signed, with stamp, by the authorised person of the insurer. **The estimated claimable amount and out-of-pocket payment are for reference only.** Final payments are subject to charges incurred from treatment, procedures and services performed.

承保機構名稱 (中文) (Chinese) _____

Name of Insurer: (英文) (English) _____

保單編號 Policy Number: _____

承保機構經辦人姓名
Name of Action Officer of Insurer: _____

承保機構經辦人聯絡電話
Telephone Number of Action Officer of Insurer: _____

保障限額 Benefit Limit

賠償額 Claimable Amount

\$ _____ / 日 day	\$ _____ ~ \$ _____
\$ _____	\$ _____ ~ \$ _____
\$ _____	\$ _____ ~ \$ _____

(承保機構須另頁補充賠償額的明細供病人參考。)
(Insurer should provide a breakdown of claimable amount on a separate sheet for patient's reference.)

保障限額 Benefit Limit

賠償額 Claimable Amount

\$ _____ / 日 day	\$ _____ ~ \$ _____
\$ _____	\$ _____ ~ \$ _____
\$ _____	\$ _____ ~ \$ _____
\$ _____	\$ _____ ~ \$ _____
\$ _____	\$ _____ ~ \$ _____
\$ _____	\$ _____ ~ \$ _____
\$ _____	\$ _____ ~ \$ _____

總計 Total \$

\$ _____ ~ \$ _____

減 Less

因等候期 / 其他原因的調整 Adjustment due to Waiting Period/Other Reasons:	-\$ _____
分擔費用 Co-payment:	-\$ _____
淨賠償額 Net Claimable Amount:	\$ _____ ~ \$ _____
預計自付費用 Estimated Out-of-pocket payment:	\$ _____ ~ \$ _____

承保機構聲明 Insurer's Declaration

本公司已根據病人的保單估算預算賠償額及預計自付費用。資料僅供參考，最終賠償額及自付費用須按醫院賬單所列的最終收費及保單條款而定。
Our company has provided the estimated claimable amount and estimated out-of-pocket payment in accordance with the insurance policy of the patient. The estimated amounts are for reference only. The actual claimable amount and actual out-of-pocket payment will be subject to the final payment as stated in the hospital invoice and in accordance with the policy terms and conditions.

_____	_____	_____
承保機構獲授權人士名稱 Name of Authorised Person of Insurer	承保機構獲授權人士簽署及蓋章 Signature of Authorised Person of Insurer and Stamp	日期 Date

備註 Remarks:

1. 病人如因已知的疾病接受醫療檢查程序或選擇性的非緊急治療手術 / 程序，私家醫院應在他們入院時或之前，告知他們整個療程的預算費用總額。如因病情導致病人不能及早獲知預算，醫生須另紙說明詳細情況。
Patients having investigative procedures or elective, non-emergency therapeutic operations/ procedures for known diseases should be informed of the estimated total charges for the whole treatment course on or before admission to private hospitals. Doctors should provide details in separate sheets if patients' conditions do not allow them to be informed of the estimated total charges in advance.
2. 病人如在入院時或之前未獲提供預算住院費用的資料，他們入院後，在每次就確診病症接受選擇性的治療手術/程序時，醫院都應盡可能預先向他們提供預算費用的資料。
For patients who have not been given an estimation of their hospital bills on or before admission, whenever they receive a definite diagnosis where elective therapeutic operations/ procedures are required after admission, they should be given an estimate in advance as far as practicable.
3. 每間私家醫院都應公布一份「常見手術/程序清單」，向病人提供有關手術/程序的報價。該份清單應備存於入院登記處、繳費處、醫院網頁或適當地方，供市民參考。
Private hospitals should publish a "List of Common Operations/ Procedures" for which quotation will be provided for prospective patients. The List should be available at the admission office, cashier and hospital webpage and where appropriate for public's reference.
4. 如手術期間出現併發症，或須專科醫生會診，令預算費用有任何重大變動，超逾原來預算的幅度，而病人神智清醒和病情穩定，則醫院應告知病人最新的預算費用，並取得其同意，方可進行任何手術/程序。如病人神智不清和病情反覆，醫院則應告知其近親或獲授權人士。最新的預算費用應記入本費用預算表格內，並由醫生 / 醫院及病人 / 近親 / 獲授權人士妥為簽署。如有關醫生或醫院認為變動幅度太大，則可採用新的表格記錄。
In case of any material change in estimates beyond the range of the original estimates due to complications during operation or those from necessary specialist visits, patients who are conscious and stable (or their next-of-kin or authorised persons if otherwise) should be informed of and consent to the latest estimate before any further operation/ procedure is conducted. The latest estimate should be documented in this consent form and duly signed by doctors, authorised persons of hospitals and patients/ next-of-kin/ authorised persons of patients. A new form may be used if the changes are considered substantial by the doctor or hospital concerned.
5. 若病人在18歲以下、失去知覺或有認知障礙，其親屬或獲授權人士可代病人簽署文件。
In case the patient is under 18, unconscious or has cognitive impairments, the next-of-kin or authorised person should act on the patient's behalf.
6. 病人如選用認可服務套餐，醫院可獲豁免遵從報價規定。如醫生的臨床判斷認為，正接受手術/程序或病情緊急或危及性命的病人須進行其他緊急治療，則醫院可獲豁免就有關病人已同意的服務以外的收費項目提供報價。
Patients subscribing to Recognised Service Packages are exempt from quotation. In case at doctors' clinical judgment that patients undergoing operations/ procedures, emergency or life threatening situations require further urgent treatment, price quotation for items beyond those the patients concerned have consented to would be exempted.
7. 在自願醫保計劃下個人住院保險須就訂明的非住院程序、訂明的先進診斷成像檢測及非手術癌症治療訂定一筆過套餐式保障限額。這些保障限額因不同程序、檢測或治療而異。醫生及 / 或醫院須就這些項目另行報價。
Under the Voluntary Health Insurance Scheme, individual Hospital Insurance should provide coverage for prescribed ambulatory procedures, prescribed advanced diagnostic imaging tests and non-surgical cancer treatments in the form of packaged benefit limits. These benefit limits vary by procedure, test or treatment. Doctors and/or hospitals should provide separate quotation for these items.

VIII. 套餐收費不包括下列項目：
Exclusions:

IX. 併發症的處理：
Control of Complications:

X. 使用條款：
Terms and Conditions of Use:

例子Example:

- (1) 如病人入院後診斷出的病因與原來不同，並需要另一種治療，醫院可宣告套餐收費無效，而收取治療所需的費用。病人或其親屬或獲授權人士須在接受進一步治療前獲事先告知並同意新的收費。
If patients are diagnosed with disease which deviates from the original judgment and requires a new course of treatment subsequent to admission to hospital, the hospital may void the packaged rates and charge according to the treatment required. In that case, patients (or their next-of-kin/ authorised persons) should be informed of and consent to the new charges before the performance of further treatment in advance.

XI. 購買套餐的顧客資料
Personal Details of Customer subscribing to the Package

姓名(中文)： 姓名(英文)：
Name in Chinese: Name in English:

身份證號碼 / 護照號碼*：
HKID / Passport No.*:

初步病情診斷：
Provisional Diagnosis:

轉介 / 主診醫生姓名：
Name of Admitting / Attending Doctor:

顧客簽署：
Customer's Signature:

本人知悉套餐的使用條款及可能收取的額外費用，並同意最終應繳費用以醫院賬單所列為準。
I understand the terms and conditions of use of the package and possible additional charges that might be incurred. I agree that payments should be made in accordance with hospital invoices.

病人 / 親屬 / 獲授權人士姓名*
Name of Patient / Next-of-kin / Authorised Person*

病人 / 親屬 / 獲授權人士簽署*
Signature of Patient / Next-of-kin / Authorised Person*

日期
Date

醫院聲明：
Hospital's Declaration:

本人已向顧客解釋套餐的使用條款及可能收取的額外費用，並徵得其同意。
I have explained to the customer the terms and conditions of use of the package and possible additional charges that might be incurred and have sought his / her agreement.

醫院職員姓名
Name of Hospital Staff

醫院職員簽署
Signature of Hospital Staff

日期
Date

XII. 額外費用
Additional Charges

收費項目 Chargeable Items : _____ 收費Charges : _____

總計 Total : \$

(如篇幅不敷應用，請另頁補充。Please continue on a separate sheet if required.)

顧客簽署：
Customer's Signature:

本人知悉並同意繳付上述額外費用。
I have been informed of and agree to pay the additional charges indicated above.

病人 / 親屬 / 獲授權人士姓名*
Name of Patient / Next-of-kin / Authorised Person*

病人 / 親屬 / 獲授權人士簽署*
Signature of Patient / Next-of-kin / Authorised Person*

日期
Date

醫院聲明：
Hospital's Declaration:

本人已知會顧客須收取套餐收費以外的額外費用，並徵得其同意。
I have notified the customer of the additional charges incurred on top of the packaged rates and have sought his / her agreement.

醫院職員姓名
Name of Hospital Staff

醫院職員簽署
Signature of Hospital Staff

日期
Date

如未能在治療前知會顧客額外費用，請提供理由：
Please provide reasons if the customer is not informed of any additional charges before treatment:

醫院職員姓名
Name of Hospital Staff

醫院職員簽署
Signature of Hospital Staff

日期
Date

* 請刪去不適用者。Please delete as appropriate.

標準床位：若醫院有多於一個種類或級別而收費不同的病床，標準床位指收費(床位和相關費用)最低的住院病床(特定批地條件要求的低收費病床除外)，如醫院只有一個種類或級別的病床，該種類或級別的病床則為標準床位。

Standard beds: Where more than one category or class of hospital beds with different charges is provided in the hospital, standard beds refer to in-patient beds for which the lowest level of occupancy fees and related fees are charged (except low-charge beds required by specific land grant conditions). If only one category or class of hospital beds is available, such category or class of hospital beds shall be the standard beds.

List of Abbreviations

2000 review	Review of Legislation for the Regulation of Health Facilities
ACHS	Australian Council on Healthcare Standards
ASA	American Society of Anaesthesiologists
Audit	Audit Commission
Audit report	Director of Audit's Report No. 59 Chapter 3 (October 2012) – Regulatory control of private hospitals
Cap. 113	Hospital Authority Ordinance
Cap. 134	Dangerous Drugs Ordinance
Cap. 138	Pharmacy and Poisons Ordinance
Cap. 156	Dentists Registration Ordinance
Cap. 161	Medical Registration Ordinance
Cap. 164	Nurses Registration Ordinance
Cap. 165	Hospital, Nursing Homes and Maternity Homes Registration Ordinance
Cap. 165 CoP	Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes
Cap. 231	Undesirable Medical Advertisements Ordinance
Cap. 303	Radiation Ordinance
Cap. 343	Medical Clinics Ordinance
Cap. 343 CoP	Code of Practice for Clinics Registered under Medical Clinics Ordinance
Cap. 359	Supplementary Medical Professions Ordinance
Cap. 465	Human Organ Transplant Ordinance
Cap. 549	Chinese Medicine Ordinance
Cap. 566	Drug Dependent Persons Treatment and Rehabilitation Centres (Licensing) Ordinance
Cap. 599	Prevention and Control of Disease Ordinance
CoP	Code of Practice
CPR	Cardio-pulmonary resuscitation
DH	Department of Health

Director	Director of Health
eHRSS	Electronic Health Record Sharing System
EQulP	Evaluation and Quality Improvement Programme
HA	Hospital Authority
HKAM	Hong Kong Academy of Medicine
IPC	Infection prevention and control policy
MAC	Medical Advisory Committee
MCHK	Medical Council of Hong Kong
ORHI	Office for Registration of Healthcare Institutions
PAC	Public Account Committee of the Legislative Council
PHFs	Private healthcare facilities
PHMC	Private Hospitals and Medical Clinics
PIC	Person-in-charge
QAC	Quality assurance committees
RSPs	Recognised Service Packages
Steering Committee	Steering Committee on Review of Regulation of Private Healthcare Facilities
UK	United Kingdom
WG1	Working Group on Differentiation between Medical Procedures and Beauty Services
WG2	Working Group on Defining High-risk Medical Procedures/ Practices Performed in Ambulatory Setting
WG3	Working Group on Regulation of Premises Processing Health Products for Advanced Therapies
WG4	Working Group on Regulation of Private Hospitals
WHAIC	Wisconsin Hospital Association Information Center

