Report of the Working Group on Regulation of Private Hospitals

for submission to the Steering Committee on Review of Regulation of Private Healthcare Facilities

Food and Health Bureau
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Executive Summary

Our healthcare system runs on a dual-track basis encompassing both the public and private sectors. Private healthcare, as an essential component of our healthcare system, is a major provider of outpatient services and also provides more personalised inpatient services for those who are financially capable. Private healthcare facilities, including private hospitals, ambulatory medical centres and clinics, are accommodated in a wide range of privately-owned premises providing medical diagnosis and treatment.

2. At present, private healthcare facilities in Hong Kong are subject to different levels of regulation that may not be necessarily commensurate with their intensity of services and level of risk involved. Private hospitals, nursing homes, maternity homes and non-profit-sharing clinics are required to register with the Department of Health (DH) under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) and the Medical Clinics Ordinance (Cap. 343).

3. Cap. 165 and Cap. 343, enacted in 1930s and 1960s respectively, have remained unchanged for decades and are in need of updating to keep abreast with changes in medical technologies and the healthcare market. In order to improve the regulatory regime for private healthcare facilities, the Food and Health Bureau (FHB) established a Steering Committee on Review of the Regulation of Private Healthcare Facilities (Steering Committee) in October 2012 to undertake a review with an objective of better safeguarding public health and consumer rights by enhancing the quality, transparency and accountability of private healthcare facilities.

4. The Steering Committee set up four working groups to conduct in-depth study into four priority areas –

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

(b) Working Group on Defining High-Risk Medical Procedures/ Practices performed in an Ambulatory Setting

(c) Working Group on Regulation of Premises processing Health Products for Advanced Therapies

(d) Working Group on Regulation of Private Hospitals

5. This report sets out the recommendations of the Working Group on Regulation of Private Hospitals (the Working Group). A summary of the Working Group's review and recommendations is presented below.

Strengthening Regulation of Private Hospitals

6. Private hospitals in Hong Kong are regulated under Cap. 165 with respect to accommodation, staffing and equipment. The scope of regulation under Cap. 165 is limited with no provision for essential regulatory standards in the areas of corporate and clinical governance, price transparency and public accountability. This is not in keeping with the fact that private hospitals nowadays provide more comprehensive, complicated and advanced medical service. There are also calls from the community for greater assurance over private hospitals' clinical quality as a result of occasional occurrence of medical incidents as well as enhancing price transparency amidst increasing hospital charges and lack of upfront cost certainty.

7. The Working Group considers that there is a need to enhance the regulatory control of private hospitals. The Working Group's deliberation regarding different aspects of private hospitals regulation and related healthcare facilities registered under the same ordinance (i.e. nursing homes and maternity homes) are elaborated in Chapters 2 to 7 of the Working Group's report. A full account of the Working Group's recommendations is at **Appendix A**.

(a) Scope of Regulation

8. Currently, nursing homes and maternity homes, alongside private hospitals, fall under the scope of regulation of Cap. 165. "Nursing home" is not clearly defined in the law and covers a wide range of healthcare/ quasi-healthcare facilities with heterogeneous nature, such

as residential care of elders, renal dialysis centres, centres for minor operations, residential centres for cancer patients and disabled children and residential centres for treatment of drug dependents. Although some of them provide minimal medical treatment (e.g. residential homes for elders), they are subject to similar level of control as private hospitals. In the case of maternity homes, their role has substantially diminished nowadays as child births at hospitals has become the norm.

9. The Working Group recommends **(Recommendations 1-4)** –

(i) revising the definition of 'hospital' to mean any healthcare facility primarily for the provision of medical care with continuous medical support and lodging ('medical' refers to professional care and practice of registered medical practitioners or registered dentists);

(ii) defining '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 hours";

(iii) removing separate licensing for maternity home, and instead subsuming it under private hospital as a type of medical service; and

(iv) removing 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 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.

(b) Corporate Governance

10. Corporate governance refers to the system of rules, practices and processes by which a company/ organization is directed and controlled. Corporate governance requirements, which are set out in the Code of Practice but not in the existing legislation, are essential to the provision of quality services. In this chapter, three aspects relevant to corporate governance are studied –

I. Organisation of Private Hospitals (Recommendations 5-6)

11. The Working Group recommends that the role of governing bodies of private hospitals should be strengthened by stipulating the requirement in respect of the establishment of board of governors, medical advisory committee (MAC) (also known as quality assurance committee (QAC)) and the appointment of Person-in-charge (PIC) in the statute.

II. Complaints Management (Recommendations 7-10)

12. Management of complaints is a valuable tool for private hospitals in managing and evaluating their performance. The Working Group recommends introducing a two-tier complaints handling system to manage complaints at source and also at appeal stage. The regulatory authority should also be empowered to obtain relevant information from private hospitals and to establish an electronic information system to facilitate exchange of information among hospitals.

III. Hospital Accreditation (Recommendations 11-12)

13. Hospital accreditation is a recognition obtainable by hospitals to demonstrate that they have met prescribed standards set by an independent healthcare accreditation body. The Working Group noted that although most private hospitals in Hong Kong have been accredited, participation in hospital accreditation is voluntary at present. To promote continuous quality improvement of private hospitals, the Working Group recommends that hospital accreditation should become a mandatory requirement in the long run. In the short and medium term, accreditation programme should be recognized as one of the desirable quality control measures by the regulatory authority.

(c) Clinical Governance

14. Clinical governance is a system through which healthcare facilities are accountable for continuous improvement in quality and standard of care. Clinical governance includes seven components: (I) clinical risk management; (II) clinical audit; (III) clinical indicators; (IV) sentinel events reporting, (V) human resources management, (VI) clinical effectiveness and (VII) information management. It would be essential to have these requirements, currently not provided in the law, institutionalized in the revamped regime. The Working Group's recommendations addressing each component are set out below.

I. Clinical Risk Management (Recommendations 13-14)

15 Clinical risk management involves systematic identification, assessment, prioritization and reduction of risk to patients, staff and the public with a view to improving service quality. The Working Group recommends that private hospitals should submit reports on clinical risk management to the regulatory authority and to develop an electronic information system to facilitate communication among private hospitals.

II. Clinical Audit (Recommendations 15-19)

16. Clinical audit is an important professional accountability mechanism to ensure performance and standard of healthcare services provided in private hospitals. The Working Group recommends that the establishment of a clinical audit committee should be made a statutory requirement for private hospitals and private hospitals should develop a comprehensive clinical audit system which comprises development of policies, submission of reports to the regulatory authority, development of database to facilitate data collection.

III. Clinical Indicators (Recommendations 20-22)

17. Clinical indicators are objective measures of the management process/ outcome of care. In order to fully reap the benefit of clinical indicators, the Working Group recommends the regulatory authority be empowered to require private hospitals to submit and manage clinical indicators in prescribed format.

IV. Sentinel Events Reporting (Recommendations 23-30)

18. A sentinel event is 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, private hospitals could identify possible weakness in course of treatment and make relevant improvements. Cap. 165 has no provision on reporting of sentinel events and follow-up action required on the part of private hospitals. There is also no legal or standard rule to govern the access to or disclosure of data of sentinel events, which are often sensitive to hospitals and patients.

19. To address the above concerns, the Working Group recommends establishing a comprehensive sentinel events management system, which requires private hospitals to strengthen internal quality assurance and to empower the regulatory authority to gain access to relevant information, taking into account the confidentiality of information.

V. Human Resources Management (Recommendations 31-32)

20. Effective management of human resources in private hospitals plays an important role in ensuring the quality of healthcare services provided. With a view to improving human resources management of private hospitals, the Working Group recommends that private hospitals should make sure that medical practitioners would attend to patients in need of urgent treatment in the hospital within a reasonable timeframe and should develop policies to ensure the credential of staff.

VI. Clinical Effectiveness (Recommendations 33-34)

21. With a view to ensuring that clinical practice is based on the best available data and evidence, the Working Group recommends that private hospitals should develop relevant written policies and guidance and, in the longer term, draw up standardised guidelines and adopt guidelines promulgated by professional bodies , such as the Hong Kong Academy of Medicine and its Colleges, to enhance clinical effectiveness.

VII. Information Management (Recommendation 35)

22. Proper information management enables private hospitals to detect health problems, define priorities, identify innovative solutions and allocate resources to improve health outcomes. To create the framework necessary for smooth transition of patients between different levels of care and between the public and private sectors, the Government is developing a territory-wide patient-oriented electronic health record sharing system (eHRSS). Whilst participation in eHRSS will be voluntary, the Working Group recommends 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 eHRSS.

(d) Price Transparency

23. There is no statutory requirement under Cap. 165 on the disclosure of price information by private hospitals. The lack of transparency and certainty of hospital charges has often been cited as a significant barrier for many people, even if they are financially capable, in utilising private healthcare services. It is therefore important to enhance price transparency of private hospitals in order to allow the public to have a better estimation of medical fees and make necessary financial arrangement beforehand. The Working Group's recommendations in enhancing price transparency are grouped into four categories as outlined in the following paragraphs.

I. Disclosure of Price Information (Recommendations 36-41)

24. 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 may be levied. The full fee schedule should be readily available at hospitals, and linked to a common electronic platform provided by the regulatory authority for public inspection. The fee schedule should be updated promptly and communicated to patients when there is any change in chargeable items and/ or price levels.

II. Uniform Quotation System (Recommendations 42-49)

25. Patients having investigative procedures or elective, non-emergency therapeutic operations/ procedures for known diseases should be informed of the estimated total charges having regard to individual patient's unique circumstances on or before admission to private hospitals. An estimate should be documented in a prescribed financial estimation form, which is to be completed by a patient's admitting/ attending doctor and/ or hospital administration and signed by the patient, doctor and hospital concerned.

III. Introduction of Recognized Service Packages for Common Operations/ Procedures (Recommendations 50-52)

26. 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 Package" 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.

IV. Disclosure of Historical Statistics (Recommendations 53-54)

27. 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 at least include annual number of discharges, average length of stay, 50^{th} percentile and 90^{th} percentile bill sizes for each reportable treatment/ procedure. The statistics should be made available through the common electronic platform for public consumption.

(e) Regulatory Framework

28. Cap. 165, given its limited scope, has not vested DH with adequate power and flexibility to enforce regulatory requirements and impose sanctions proportionate to the intensity of non-compliance.

29. Specifically, the Working Group considers that there is a need to enhance the power of the regulatory authority to make regulations, promulgate code of practice, conduct inspections, suspend medical services upon breaches, and appoint advisory committees for regulatory purpose. The Working Group also considers that the penalties for non-compliance should be commensurate with the seriousness of offence and in keeping with today's standards for operating unregistered private hospitals and substantiated cases of non-compliance of registered private hospitals. **(Recommendations 55-60)**

(f) Way Forward

30. In view of the public's growing aspiration to institute a more comprehensive and up-to-date regulatory regime for private hospitals, the Working Group has conducted a root-and-branch review on the current regulatory regime and made recommendations to revamp it having regard to international best practices, legitimate public aspirations, sustainability of our healthcare system and circumstances unique to Hong Kong.

31. While some of these recommendations could be implemented via administrative means, a new legislation is required to put into effect and provide the necessary legal backing to ensure effective implementation of the recommendations. The Working Group considers that the above findings and recommendations should be put up for public consultation to gauge the views of the public before implementation. Views from professional organisations, patient groups, consumer groups and the general public should be sought before introduction of the legislative proposal as the next step to revamp the regulatory regime for private hospitals.

Chapter 1
Introduction

This report sets out the findings and recommendations of the Working Group on Regulation of Private Hospitals (the Working Group) under the Steering Committee on Review of Regulation of Private Healthcare Facilities (Steering Committee).

Background

2. Private healthcare facilities embrace a wide range of privately-owned premises which provide medical diagnosis and treatment, including private hospitals, ambulatory medical centres and clinics. At present, private healthcare facilities in Hong Kong are subject to different levels of regulation that may not necessarily commensurate with their intensity of services and level of risk. Private hospitals, nursing homes, maternity homes and non-profit-sharing clinics are required to register with the Department of Health (DH) under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) and the Medical Clinics Ordinance (Cap. 343). Ambulatory medical centres and profit-making clinics are not subject to any form of statutory regulation except for professional regulation over doctors practising there.

3. Private hospitals are an integral part of the healthcare system in Hong Kong. In 2013, there are 11 private hospitals (**Appendix B**) providing a total of around 4 000 hospital beds, mostly catering for the medical needs of the affluent and those with private health insurance. Private hospital services account for around 10% of our total hospital services in terms of bed days, and 20% in terms of admission.

Existing Regulatory Framework for Private Hospitals

4. DH is vested with power under Cap. 165 to register or de-register private hospitals subject to conditions relating to accommodation, staffing or equipment. DH could impose conditions with the registration and is empowered to cancel the registration at any time if the conditions imposed have been contravened. Details of the regulatory arrangements are set out at **Appendix C**.

5. In 2003, DH issued a "Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes" (CoP) with a view to further enhancing patient safety and quality of hospital services. The CoP is promulgated administratively and does not form part of Cap. 165. It sets out the standards of good practice for private hospitals to adopt, including requirements on the management of staff, management of hospital 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. The CoP also includes requirements on various types of clinical and support services, including laboratory services, outpatient services, pharmacy services, imaging services, catering services and maintenance services.

The Need for Change

6. Cap. 165, enacted in 1936, has undergone no substantive amendments since 1960s. The regulatory standards prescribed in Cap. 165 are confined to limited aspects of healthcare services, namely accommodation, staffing and equipment. The regulatory role defined in Cap. 165 is narrow, with no provision for regulating other essential aspects of healthcare services, such as charging policy, patients' rights and clinical standards.

7. Over the past decades, there have been significant changes to the mode of operation and range of services of private hospitals. In view of the advancement in medical technology and changing landscape of the healthcare market, the current regulatory regime has outlived its usefulness. Some of the major areas identified as inadequate under the current regime are listed below –

(a) Cap. 165 provides for the regulation in respect of physical set-up and staffing level only; the quality of clinical services is not one of the parameters being addressed;

(b) Cap. 165 does not provide effective sanctions commensurable with the level of non-compliance warranted to be penalized. For example, the maximum penalty for offences against Cap. 165 is $2,000 and only a narrow scope of specific offences might be subjected to sanctions;

(c) the regulatory authority has no clear statutory power to impose penalty, other than removal of license, on private hospitals for non-compliance with CoP and other registration conditions for private hospitals;

(d) a mechanism to ensure transparency in service provision, especially price transparency, is lacking; and

(e) the scope of Cap. 165 is limited to private hospitals and a few types of private healthcare facilities, leaving out many premises where high-risk medical procedures/ practices are carried out.

8. In so far as the community is concerned, there are demands for greater assurance over the clinical quality of private hospitals, and improved transparency of private hospital charges. A number of medical incidents involving private hospitals have attracted public attention to the latter's clinical quality. Increasing hospital charges and the lack of upfront cost certainty also discourage people from using private hospital services even if they might afford so. There are calls for revamping the regulation of private hospitals and strengthening the regulatory role of DH to better ensure patient safety, service quality and consumer rights.

9. In 2000, DH conducted a review of the legislative intent of Cap. 165, with limitations identified and recommendations made on the regulatory framework of private healthcare facilities (see **Appendix D**). In November 2012, the Audit Commission reviewed DH's regulatory control of private hospitals[1] and pointed to the need for tightening controls (see **Appendix E**).

10. In view of the foregoing, there is a genuine and pressing need to review the existing regulatory framework of private hospitals, having regard to public aspirations to revamp the regulatory regime in keeping with the modern-day requirements, international best practices applicable to local circumstances, as well as responding to the 2000 review and 2012 audit reports on the regulation of private hospitals.

[1] The Audit Commission's report is at: http://www.aud.gov.hk/pdf_e/e59ch03.pdf

The Steering Committee on Review of Regulation of Private Healthcare Facilities

11. Against the above backdrop, the Food and Health Bureau (FHB) established the Steering Committee in October 2012 to review the regulatory approach to private healthcare facilities. The Working Group, chaired by the Permanent Secretary for Food and Health (Health), was set up under the Steering Committee to study how to strengthen the regulatory control over private hospitals with a view to enhancing their quality, transparency and accountability (see **Appendix F** for the Terms of Reference and Membership of the Working Group).

Objective of the Review

12. Taking into account the latest development in the regulatory models of private hospitals in overseas countries (a summary on the overall regulatory regime adopted by Singapore, Malaysia, the United Kingdom, Canada, Australia and the United States is at **Appendix G**), the review aimed to –

(a) make recommendations on the way forward in strengthening the regulatory regime for private hospitals with a focus on the regulatory standards and mechanism to ensure quality of patient care and safety, service accountability, and the role of the regulatory authority in monitoring hospital services; and

(b) identify limitations of the current legislation in fulfilling the present-day purpose of safeguarding public interest and consumer rights.

Review Approach

13. The Working Group adopted the following approaches when conducting the review –

(a) to make reference to the latest developments in the regulatory framework of private hospitals in overseas countries which suit local needs and environment and that for the private hospitals;

(b) to engage the industry and relevant stakeholders in formulating practicable solutions with a view to better safeguarding patient safety, quality of hospital services and consumer protection; and

(c) to strike a balance between regulation and development of healthcare sector, with the primary aim of encouraging compliance through facilitation rather than sanction as far as possible.

14. The Working Group convened five meetings between February 2013 and March 2014. Members deliberated on several major aspects of private hospital governance, namely corporate and clinical governance, price transparency, management of complaints, the powers of the regulatory authority over private hospitals and the scope of regulation which currently also covers nursing homes and maternity homes for historical reasons.

15. The Working Group supports enhancing the regulation of private hospitals. Specifically, the Working Group stresses the need for enhancing the clinical quality and price transparency of private hospital services to meet public aspirations. It is acknowledged that private hospitals are, on their own volition, already steering toward the Government's objectives of bringing their performance up to a higher standard. All private hospitals have been accredited by independent accreditation bodies for their clinical quality and performance in quality improvement. Many are also offering services packages and quotation to provide customers with greater price certainty; some have even provided visiting doctors with the latest charging records for reference to facilitate the latter's provision of quotation to patients.

16. The Working Group's detailed discussions and recommendations regarding different aspects of private hospital regulation are set out in the ensuing chapters.

Chapter 2

Scope of Regulation

Existing Requirements

Three classes of private healthcare facilities, namely private hospitals, nursing homes and maternity homes, are regulated under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165). In Cap. 165, hospital is defined as "any establishment for the care of the sick, injured or infirm or those require medical treatment, including a nursing home". Maternity home is defined as "any premises used or intended to be used for the reception of pregnant women or of women immediately after childbirth".

2. In the Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes (CoP) issued by the Department of Health (DH), the definition of hospitals is elaborated as "hospitals are usually taken to mean premises that provide a comprehensive range of medical services with overnight beds for the treatment of persons requiring acute or rehabilitative treatment and for persons undergoing diagnostic procedures"; and nursing homes as "premises that provide a relatively narrow scope of services". In contrast to the "comprehensive range of medical services" provided by hospitals, nursing homes often have narrow scope of services such as elderly homes, drug treatment centres and renal dialysis centres.

3. As at 30 April 2014, there were 11 and 53 institutions registered as private hospitals and nursing homes respectively under Cap. 165. No stand-alone maternity home exists in Hong Kong nowadays; the existing 10 institutions registered under Cap. 165 as maternity homes are concurrently registered as private hospitals. As the scope of nursing home is not specified in law, the institutions registered as nursing homes are rather diverse in the nature of services they provide which can be categorised as below –

- 33 nursing homes for residential care of elders;
- 10 renal dialysis centres;
- 2 centres for minor operations (one for day surgery of the eye and one for termination of pregnancy);
- 3 residential centres for care of cancer patients and disabled children; and
- 5 residential centres for treatment of drug dependents.

Matters of Concern

4. As shown above, the category "nursing home" under Cap. 165 embraces a wide range of heterogeneous healthcare or quasi-healthcare services. There is no clear definition of nursing home and criterion for registration with DH under such category in law. DH's review on the regulation of private healthcare facilities back in 2000 made a similar observation and suggested to redefine nursing homes.

5. The ambiguity in the definition and scope of nursing home raises some issues that need to be addressed under the revamped regulatory regime. Currently all nursing homes registered with DH are subject to similar level of control as private hospitals regardless of their nature of service. Yet for nursing homes that provide no or low level of medical treatment such as those delivering daily care to elders at community setting, thoughts should be given as to whether the standards catered for full-fledged medical facilities should apply to this kind of nursing facility which is more of a welfare nature. Similar concerns exist in the case of residential centres for treatment of drug dependents which normally provide limited medical treatment. Applying too stringent regulatory standards with substantial medical contents to quasi-healthcare facilities would create unwarranted and unnecessary regulatory burden for both the service providers and the regulatory authority. The escalated costs would eventually be transferred to the users and society as a whole and could undermine the delivery of affordable, efficient social and health services.

6. In the case of maternity homes, child births at maternity homes gradually declined from 1970s onwards and hospital confinement becomes the norm as it is considered safer to give birth at hospitals,

which are better equipped with a full range of supportive facilities to handle complications and contingencies. Given the rising health standard nowadays and that hospitals are easily accessible in Hong Kong, the role of standalone maternity homes has diminished substantially. The 2000 review echoed this view, which recommended that maternity homes should be regarded as a service provided within the hospital and need not be registered separately as stand-alone units.

7. The primary aim of the Working Group on Regulation of Private Hospitals (the Working Group) is to review the scope of the existing legislation especially Cap. 165 to ensure that the enhanced control of healthcare services provided by private hospitals could meet public expectation and keep abreast of time. Members discussed how nursing homes currently registered under Cap. 165 providing a variety of medical and nursing services should be licensed under a new regime. Some Members opined that they should be licensed separately from hospitals. Specifically, some suggested that nursing homes for elderly care would be more appropriately regulated as welfare facilities, rather than medical ones.

Recommendations

8. On the understanding that the level of regulation for healthcare facilities should be commensurate with the extent and level of sophistication associated with the medical treatment and care provided, and taking into account the overseas practices and Department of Health's previous review recommendations, the Working Group recommends adopting a risk-based approach to –

(a) revise the definition of 'hospital' to mean any healthcare facility primarily for the provision of medical care with continuous medical support and lodging ('medical' refers to professional care and practice of registered medical practitioners or registered dentists) **(Recommendation 1)**;

(b) 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 hours" **(Recommendation 2)**;

(c) remove separate licensing for maternity home, and instead subsume it under private hospital as a type of medical service **(Recommendation 3)**; and

(d) 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 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 **(Recommendation 4)**.

9. The impact of the recommendations on various classes of healthcare/ welfare institutions currently registered under Cap. 165 would be as follows:-

(a) Private hospitals and residential centres for care of cancer patients and disabled children would continue to be regulated under the revised regulatory regime because they provide medical care, treatment and lodging over 12 hours.

(b) Maternity homes would no longer be required to register separately but should be registered as hospitals or become part of registered hospitals.

(c) Registered nursing homes providing residential elderly care services and satisfying the new definition of 'hospital' should be registered as hospitals. For those providing community nursing care and not requiring continuous medical support, thus falling outside the proposed definition for hospital, they will not be licensed under the revised regime. Taking these nursing homes out from Cap. 165 should not give rise to regulatory vacuum as all nursing homes currently licensed under Cap. 165 (except seven) are also regulated as elderly homes under Residential Care Homes (Elderly Persons) Ordinance (Cap. 459). There are comprehensive regulatory requirements under Cap. 459, including physical safety, staffing ratio as well

as an enabling provision for the Director of Social Welfare to request DH to assist in the inspection of these homes. The seven institutions that do not fall under the scope of Cap. 459 will be handled case by case regarding their registration, depending on their nature. The current situation of subjecting nursing homes to two separate and yet largely overlapping regulatory regimes in terms of healthcare requirements will be put to an end under the revised regime for Cap. 165.

(d) Residential centres for treatment of drug dependents currently registered as nursing homes should be registered as hospitals if they satisfy the new definition of 'hospital'. As regards the five existing centres, our view is that since no or very limited medical care is provided there, they do not satisfy the new definition of 'hospital' and should, therefore, not be licensed under the revised regime. Similar to institutions providing residential elderly care services, taking these centres out from Cap. 165 should cause no regulatory concern as they are already regulated under the Drug Dependent Persons Treatment and Rehabilitation Centres (Licensing) Ordinance (Cap. 566).

(e) Renal dialysis centres and centres for minor operations would not be registered as hospitals because they do not provide lodging over 12 hours. These ambulatory facilities, where high-risk medical procedures are performed, should be registered as a separate class of private healthcare facilities and subject to specific regulation due to the risk involved.

Chapter 3

Corporate Governance

Corporate governance refers to the system of rules, practices and processes by which a company/ organization is directed and controlled. In this chapter, three aspects relevant to corporate governance are studied. They are (A) Organisation of Private Hospitals; (B) Complaints Management; and (C) Hospital Accreditation.

A. Organisation of Private Hospitals

2. The organisation of private hospitals concerns the roles and relationships among a company's management, its board, its shareholders and stakeholders. In the case of hospital services, an effective organisation is crucial for good corporate governance to ensure that quality medical services are provided, improves hospital efficiency, and enhances its responsiveness in meeting public aspirations. In particular, the management role and accountability of hospitals' governing bodies need to be defined clearly.

Existing Requirements

3. Under the Hospitals, Nursing Home and Maternity Homes Registration Ordinance (Cap. 165), a private hospital should be under the charge of a qualified resident medical practitioner or a registered nurse. The Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes (CoP) sets out that a private hospital should establish governing bodies, including but not limited to board of governors for overseeing the management of the private hospitals and medical advisory committee (MAC) (also known as quality assurance committee (QAC)) for advising the board of governors on matters relating to clinical practice and medical practitioners in the hospital [2], and to appoint a Person-in-charge. Compliance with the requirement is a condition for the registration and re-registration of private hospitals. Private hospitals

[2] Among other things, the MAC makes recommendations on eligibility criteria for the granting of practising privileges to interested medical practitioners; including review, renewal, restriction or withdrawal of practising privileges. It also monitors the clinical work undertaken at the hospital.

are also required to submit reports and/or records on the work of the private hospitals (including those concerning governing bodies) for inspection by the Department of Health (DH).

4. All registered private hospitals in Hong Kong comply with the requirement of the CoP in establishing board of governors, MAC/ QAC and appointing Person-in-charge. According to the reports submitted to DH for annual re-registration, all Boards of Governors of existing private hospitals consist of six or more members with at least one lay member. Most Boards of Governors have very few or no member who are healthcare professionals, except one private hospital with seven medical practitioners as members (out of 19). However, the extent of information provided on governing bodies varies significantly. Some hospitals provide very detailed account of the membership, terms of reference, items discussed, etc., whereas some merely report the number of committees established and frequency of meetings held for these committees.

Matters of Concern

5. The Working Group on Regulation of Private Hospitals (the Working Group) supports the principle of strengthening the functions of governing bodies in overseeing and monitoring hospital operation and quality of care.

Recommendations

6. The Working Group recommends that the organisation of private hospitals should be strengthened by adopting the following measures –

(a) 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 **(Recommendation 5)**;

(b) 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 **(Recommendation 6)**.

B. Complaints Management

7. Having in place a well-functioning system for complaints management could help private hospitals better manage and monitor their performance. Complaint, if handled properly, could present opportunities for hospital management and regulator to monitor and evaluate the performance of hospital services. While private hospitals should develop a proactive approach to investigate and manage complaints with a view to improving their services and resolving as many complaints as practicable, the regulatory authority would also need to establish an independent and credible review/appeal system to deal with unresolved complaints.

Existing Requirements

8. While there is no express provision in Cap. 165 on complaints management, private hospitals are required under the CoP issued by DH to put in place a mechanism for handling complaints made by patients or their representatives (Section 7.4 of the CoP). The mechanism should consist of procedures for receiving, investigating and responding to complaints. Besides, the CoP also requires private hospitals to provide DH with a complaint digest every month. The complaint digests show a brief description of the complaints received, their nature, the results of investigation, and the action taken by the hospitals. Upon receipt of complaint digests from private hospitals, DH will screen the digests for incidents that have the potential of becoming sentinel events and cases

that require further investigation and action. From 2009 to June 2013, private hospitals received a total of 3566 complaints. In addition, members of the public may also make complaints on private hospitals to DH direct. From 2009 to June 2013, DH received a total of 294 complaints on private hospitals.

Matters of Concern

9. Private hospitals in general comply with the requirements of the CoP to have a mechanism in place for handling complaints made by patients or their representatives. The existing CoP focuses on broad principles on complaints handling rather than specific detail requirements of the mechanism resulting in significant variations among private hospitals in terms of arrangement and procedures. According to the reports submitted to DH for annual re-registration, some hospitals have detailed accounts of the complaints handling procedures, whereas the comprehensiveness of the complaints handling system of some hospitals is not readily proven. The absence of a set of consistent and unified protocol for handling complaints might create unintended confusion to the public who would expect that similar cases should be treated in the same manner no matter which private hospital is involved. When devising a revamped regulatory regime for private hospitals, we consider it necessary to formulate a more consistent and systematic complaint-handling mechanism.

10. The existing complaint handling system allows aggrieved parties to lodge a complaint either with the hospital, DH or both concurrently. There is no appeal channel and no clear distinction as to when a complaint should be made to the hospital and when it should go to DH direct. It lacks clarity and may cause duplication of effort in handling the same matter, resulting in compromised efficiency, lowered effectiveness as it would complicate the ownership of the complaint and confuse the public on the distinct and different roles of the hospitals and regulatory authority in the provision of private healthcare services.

11. Besides, as reported in Chapter three of the Director of Audit Report No. 59 issued in October 2012, while CoP requires private hospitals to provide DH with a complaint digest monthly, nearly half of the private hospitals had not always submitted the complaint digests to

DH on time. Timely submission of complaint digests would better enable DH to screen for any sentinel events unreported and cases that require further investigation. Under the existing regulatory regime, the regulatory authority has no power to take enforcement actions against hospitals failing to submit complaint digests on time.

12. The Working Group considers that an enhanced complaints management system would provide a clear path for lodging and handling complaints, thus boosting the efficiency of both hospitals and the regulatory authority. In this connection, the Working Group studied the two-tier complaints handling systems[3] currently adopted by the Hospital Authority before coming up with its recommendations.

Recommendations

13. The Working Group recommends that, with a view to enhancing the existing complaints management system –

(a) 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 centralized and independent mechanism **(Recommendation 7)**;

(b) A Private Hospital Complaint Committee (PHCC)[4] should be established to handle all complaints at the second-tier. Under the revamped regulatory regime, the PHCC should be

[3] 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 first-level to deal with first-time complaints lodged directly with the hospitals. As the second-level complaint system, the Public Complaints Committee (PCC) is established under the HA Board to independently consider and decide on all appeal cases.

[4] Members of the PHCC are appointed by the Secretary for Food and Health and consist of lay members and medical professionals from community, representatives from private hospitals and the regulatory authority. While secretariat support is provided by the regulatory authority, PHCC will be the independent statutory body established under the Ordinances operating independently to discharge its statutory functions.

empowered to investigate and review all appeal cases and make recommendations to the regulatory authority for consideration and follow-up actions **(Recommendation 8)**;

(c) 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 **(Recommendation 9)**; and

(d) An electronic information system should 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 **(Recommendation 10)**.

C. Hospital Accreditation

14. As another important component of corporate governance for private hospitals, 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.

Existing Requirements

15. While hospital accreditation is not a statutory requirement at present, it is suggested as one of the quality assurance activities in the CoP. Private hospitals in Hong Kong currently participate in hospital accreditation programmes on a voluntary and self-initiated basis. As at April 2014, all existing 11 private hospitals were accredited by the Trent Accreditation Scheme of the United Kingdom (which, however, ceased to operate in 2010) and nine of them have also been awarded full accreditation by the Australian Council on Healthcare Standards (ACHS).

Recommendations

16. 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 **(Recommendation 11)**.

17. 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 **(Recommendation 12).**

Chapter 4

Clinical Governance

Clinical governance is a system through which healthcare facilities are accountable for continuous improvement in quality and safeguarding the standard of care. It aims to enhance clinical practice and ensure effective monitoring of the quality of clinical practice, in particular that practitioners are meeting requisite standards and that health systems are delivering care as intended. Clinical governance includes all activities and information that a healthcare facility deploys to maintain service quality. The Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165) does not address the quality of clinical governance directly, while the Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes (CoP) sets out standards of good practice as elucidated in the ensuring paragraphs.

2. The Working Group on Regulation of Private Hospitals (the Working Group) examined clinical governance from seven aspects namely, (A) clinical risk management, (B) clinical audit (C) clinical indicators, (D) sentinel events reporting, (E) human resources management, (F) clinical effectiveness and (G) information management. Brief accounts for each of the seven aspects are set out below.

A. Clinical Risk Management

3. In a healthcare institution, there are considerable risks to be managed and mitigated to better safeguard its service users including patients and visitors given the complexity of contemporary health treatments and interventions. Clinical risk management involves systematic identification, assessment, prioritization and reduction of risk to patients, staff and members of the public with a view to improving service quality.

Existing Requirements

4. There is no provision in Cap. 165 requiring private hospitals to manage clinical risk. The CoP, however, stipulates that private hospitals should have a comprehensive risk management policy and supporting procedures covering the assessment of risk throughout the institution, the identification, analyzing and learning from sentinel events or near misses, and the arrangement in the case of emergencies, e.g. fire evacuation, cessation of water and/or electricity supply.

Recommendations

5. The Working Group recommends the following measures to further improve the risk management and risk communication in private hospitals –

(a) private hospitals should submit reports and records of clinical risk management work to the regulatory authority for inspection as and when required **(Recommendation 13)**; and

(b) an electronic information system should be developed to communicate and share risk management information and best-practices across private hospitals as soon as practicable **(Recommendation 14)**.

B. Clinical Audit

6. Clinical audit is well recognised to be an important professional accountability mechanism to ensure professional performance and standard in the healthcare setting. Aspects of the structure (e.g. use of resources), processes (e.g. procedures for diagnosis and treatment), and outcomes of care (e.g. clinical outcome and quality of life for the patient) are selected during clinical audit for systematic evaluation against explicit criteria.

Existing Requirements

7. There is no provision in Cap. 165 requiring private hospitals to conduct clinical audit. The CoP, however, requires private hospitals to set up quality assurance committee to oversee and coordinate quality improvement activities of the hospital that –

(a) private hospitals should implement a system for reviewing the quality of services, in the form of internal audit at appropriate intervals;

(b) private hospitals should develop and implement quality improvement plans, based on the findings identified through audit activities and suggestions from front-line staff; and

(c) reports on reviews or quality assurance activities should be made available for the inspection of DH.

8. Nevertheless, the CoP lays down no requirement on the frequency and scope of clinical audits. Nor is there any requirement for the appointment of a clinical audit team or clinical audit coordinator to take charge of the hospital's audit activities.

9. As and when required by DH, e.g. in the annual inspection programmes, private hospitals submit relevant statistics/ information for the renewal of hospitals' licenses. However, the comprehensiveness of information provided varies from very detailed tabulation of frequency, scope and items discussed to merely affirming that quality assurance activities have been conducted.

Recommendations

10. The Working Group considers that there is room for strengthening the comprehensiveness and effectiveness of clinical audit conducted in private hospitals and recommends that -

(a) 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 **(Recommendation 15)**;

(b) private hospitals should submit reports on audit findings and implementation progress to the regulatory authority for inspection as and when required **(Recommendation 16)**;

(c) private hospitals should be encouraged to develop database to support the work of clinical audit to facilitate data collection and quality assurance **(Recommendation 17)**;

(d) 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 **(Recommendation 18)**; and

(e) 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 **(Recommendation 19)**.

C. Clinical Indicators

11. Clinical indicators are objective measures of the management process/ outcome of care, and could act as a tool for identifying possible problems and/or opportunities for improvement. They provide measurable dimension of the quality or appropriateness of patient care. Used appropriately, indicators compare and show variations in how the same services are provided in different hospitals or against international benchmarks. They help highlight problem areas in clinical performance, inform or drive quality improvement activities, prompt reflections on clinical practice and identify important issues for further investigations.

Existing Requirements

12. Private hospitals, under the CoP, are required to submit at regular interval to DH information on utilization of facilities and services; births, deaths and disease classification of in-patients treated; staffing situation; audited financial report and any other information or event as required by DH. It is, however, not a statutory requirement. Some important and valuable indicators on safety and quality of services, such as in-patient mortality, unscheduled re-admission, infection rate, etc.

are not necessarily reported. These indicators provide an important quantitative basis for quality improvement and facilitate the identification of incidents of care that trigger further investigation. Also, the capability of private hospitals to collect and analyse clinical indicators in a systematic manner is largely unknown.

Recommendations

13. The Working Group supports that submission of clinical indicators should be made a legal requirement or regular exercise for private hospitals to ensure their performance is regularly monitored and to enhance the overall clinical governance of private hospitals. In order to fully reap the benefit of clinical indicators, the Working Group recommends that –

(a) private hospitals should, as soon as practicable, be mandated to collect more in-depth and comprehensive clinical indicators and perform review and analysis regularly **(Recommendation 20)**;

(b) 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 **(Recommendation 21)**; and

(c) 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 **(Recommendation 22)**.

D. Sentinel Events Reporting

14. A sentinel event is an unexpected occurrence involving death or serious physical or psychosocial injury, or the risk thereof.[5] Sentinel events signal the need of immediate investigation and response. The term "sentinel event" and "medical error" are not synonymous; not all sentinel events occur because of errors and not all errors result in sentinel events.

Existing Requirements

15. With effect from 1 February 2007, DH has required all private hospitals to report a prescribed list of sentinel events within 24 hours upon occurrence of the event (a list of reportable sentinel events effective from January 2010 is at **Appendix J** for reference). Private hospitals are required to develop their own policies and mechanisms to identify, report and manage sentinel events. Upon receipt of the notification, DH will gather preliminary information from the hospital and may conduct its own investigation into the event when needed.

16. However, since Cap. 165 has no provision on reporting of sentinel events and actions required of private hospitals in respect of sentinel events, the existing administrative arrangement lacks legal backing and does not provide clarity and certainty on the requirements and procedures of reporting and the power of regulatory authority to obtain information concerning the events. There are difficulties in ascertaining patient outcome or diagnosis in DH's investigation of some cases where the patients are transferred to another healthcare institution.

Recommendations

17. In coming up its recommendations, the Working Group examined international experience and noted that confidentiality is a major issue for all reporting systems and experience has shown that learning systems are more likely to be successful when reporters do not

[5] Definition by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The Australian Council for Safety and Quality in Health Care (ACSQHC) defines sentinel events as "events in which death or serious harm to a patient has occurred". It also states such events signal catastrophic system failure and have the potential to seriously undermine public confidence in the health care system.

feel at risk in reporting errors. Most health authorities that implement mandatory systems do not disclose identifying information about the organization as a strategy to encourage reporting. Indeed, many jurisdictions provide statutory protection, from legal discovery and from use as evidence in litigations or disciplinary proceedings, for information or documents obtained or produced by the quality assurance committees 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 the quality assurance committees.

18. Besides, the reporting criteria of sentinel event reporting systems for private hospitals have been aligned with that applicable to public hospitals since 2010. The Working Group proposes the following recommendations on enhancing the existing sentinel event reporting system –

Short term

(a) 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 **(Recommendation 23)**; and

(b) 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 **(Recommendation 24)**.

Medium term

(c) 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 **(Recommendation 25)**; and

(d) 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 **(Recommendation 26)**.

Long term

To provide for the following measures in the new legislative regime:

(e) 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 **(Recommendation 27)**;

(f) to mandate reporting of sentinel events to regulatory authority by private hospitals; to prescribe reporting requirements and impose sanctions for non-compliance **(Recommendation 28)**;

(g) 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 **(Recommendation 29)**; and

(h) 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 **(Recommendation 30)**.

E. Human Resources Management

19. Healthcare service is a labour intensive business. The skills, competence and attitude of care providers are key factors in determining the quality of care. Like many other businesses, human resources management in clinical setting involve –

(a) recruitment and credentialing, and clearly defining the scope of work required for the position;

(b) education, training and professional development; and

(c) performance review, monitoring, conducting performance appraisals, and mentoring.

Existing Requirements

20. Under Cap. 165, DH is vested with power to register or de-register private hospitals subject to conditions including, amongst others, staffing. The CoP also sets out comprehensively requirements on the human resources management that at all times there should be an appropriate number of suitably qualified and experienced persons in private hospitals; that training and supervision should be given to each person and that their performance should be regularly appraised.

21. To further safeguard patient's health and safety, for private hospital where it caters for acute in-patient service, the CoP also stipulates that there should be a resident medical practitioner available on immediate call within the establishment at all times to provide urgent patient care. For obstetric emergencies, the medical practitioners should be available within 30 minutes when required. Nevertheless, there is no similar requirement in other specialties.

Recommendations

22. There has been growing awareness of credentialing of hospital staff and private hospitals have put in efforts to ensuring the credential of staff through the grant of admission privileges. The Working Group understands that the Hong Kong Academy of Medicine (HKAM) stands ready to provide assistance on credentialing to private hospitals, and as a start its Credentials Committee is working on the level of credentialing required of a few key medical procedures. With a view to further improving the availability of medical practitioners for emergencies in other specialties, the Working Group recommends that –

(a) when enacting 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) **(Recommendation 31)**; and

(b) 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 **(Recommendation 32)**.

23. Regarding the definition of "reasonable timeframe" in paragraph 22(a) above, private hospitals providing acute in-patient service should have at least one resident medical practitioner available on immediate call within the hospital at all times to provide urgent patient care. Private hospitals should draw up clear policy and guidelines on summoning on-site and/or off-site doctor(s) during life-threatening emergencies to prevent delay. The Working Group considers that detailed requirements could be set out in the Code of Practice for private hospitals in future.

F. Clinical Effectiveness

24. Clinical effectiveness is about striving to ensure that clinical practice is based on the best available data and evidence. By making clinical practice more evidence-based, it improves the effectiveness of clinical service delivery as well as reduces the risk of inappropriate or unnecessary treatment and care. To achieve clinical effectiveness, care, treatment and decision making process should be based on good, solid and up-to-date evidence, and best practice guide should be refined with time.

Existing Requirements

25. Currently, there is no explicit provision in Cap. 165 and the CoP on clinical effectiveness. A significant portion of the medical service of private hospitals in Hong Kong is provided by visiting medical

practitioners who are not employees of the private hospitals. Private hospitals normally do not have a practice to impose requirements on specific medical practices, and focus mainly on managing the admission privileges of visiting medical practitioners. With the advancement of scientific knowledge, medical best practices will change and evolve over time. This makes prescribing requirements based on the latest information an onerous task with significant resources implication for both the regulatory authority and hospital operators. A fine balance has to be struck between what is desirable as a long-term goal and the substantial resources required for implementation, as well as the readiness of private hospitals for such an overhaul of their relationship with doctors with different background and contractual arrangements.

26. There are not many overseas examples where clinical effectiveness is made a regulatory requirement as far as the Working Group learns, except in the United Kingdom where the Private and Voluntary Healthcare Regulations of England stipulates that treatment and services provided by a healthcare facility should reflect published research evidence and guidance issued by the appropriate professional bodies.

Recommendations

27. A more practical and effective means to implement clinical effectiveness in private hospitals for the time being is to promote its application instead of making it a mandatory requirement. The Working Group recommends that –

(a) private hospitals should have in place and implemented written policies and guidance on clinical effectiveness **(Recommendation 33)**; and

(b) consideration would be given to require private hospitals to 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 by the HKAM and its Colleges **(Recommendation 34)**.

G. Information Management

28. Through proper collection, management and use, information management enables private hospitals to detect health problems, define priorities, identify innovative solutions and allocate resources to improve health outcomes.

Existing Requirements

29. Both Cap. 165 and the CoP require private hospitals to keep comprehensive medical records for each patient. The CoP further requires private hospitals to draw up policies for handling, storage and destruction of records in order to ensure security and confidentially of personal information. However, there is no explicit requirement in requiring/ encouraging the aggregation of data for the purposes of analysis or quality monitoring.

Recommendations

30. 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, it would be essential to develop a system which enables better access and sharing of patients' health records with patients' consent. To this end, the Government is developing a territory-wide patient-oriented electronic health record sharing system (eHRSS) with a view to strengthening collaboration and sharing of information among different sectors of healthcare providers.

31. Whilst participation in eHRSS will be voluntary, to address the situation and enhance the information system, the Working Group recommends that 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 eHRSS **(Recommendation 35)**.

Chapter 5

Price Transparency

Public healthcare services are heavily subsidized by the Government. For hospitalisation care, a nominal flat fee of $100 per day is charged for any eligible person to receive any essential treatment as warranted. On the other hand, private hospitals mostly operate in a free market based on commercial principle and may charge thousands of dollars for a single course of treatment. With the huge gap in medical fees between the public and private healthcare sectors, price is among the most important considerations when deciding whether to seek medical services from the private sector.

2. Under a dual-track healthcare system, government does not have a role in the determination of prices for private medical care. While pricing itself should be left to market forces, we consider that government does have a key role to play in ensuring pricing transparency to facilitate the public to be better informed before making decisions in meeting their medical needs and make necessary financial arrangements in advance. Consumer rights would also be better protected under a more transparent disclosure regime.

3. A patient seeking care in a private hospital is at the same time a consumer of the latter's service and price transparency is important. Most complaints against private hospitals received by the Consumer Council over the years were related to price transparency. Despite the introduction of package pricing by some private hospitals for selected services in recent years, there is still room for further improvement.

Existing Requirements

4. The Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165), under which private hospitals are regulated, has no provision on the disclosure of price information. Section 7.3 of the Code of Practice for Private Hospitals, Nursing Homes

and Maternity Homes (CoP)[6] issued by the Department of Health (DH) stipulates that patients visiting private hospitals have the right to be informed of hospital charges prior to consultation and any procedures. The CoP requires private hospitals to prepare a schedule of charges in respect of room charges, investigative and treatment procedures, medical supplies, medicines, medical reports, photocopy of medical records, and any charges that will be levied (para. 7.3.1). The schedule should be available for patients' reference at the admission office, cashier and wherever appropriate and should be updated when there is a change in the charges (paras. 7.3.1-7.3.2). Besides, patients should be informed of service charges where practicable (para. 7.3.3). On the regulatory front, DH, as the regulatory authority under Cap. 165, monitors the compliance with the above requirements during inspections.

Matters of Concern

5. While DH detects no non-compliance with the requirements on price information by private hospitals, it is noted that around 17% of the complaints received by private hospitals (614 cases from 2009 to June 2013) and DH (52 cases from 2009 to June 2013) were related to charges (mainly on unexpected price increase, unreasonable charges and price information, such as doctor's fee, not communicated in advance to patients). Furthermore, the Audit Commission considered in its 2012 review that "the price information available on the websites of the private hospitals listed varied considerably". Audit Commission's staff's visits to all private hospitals in May 2012 revealed that while five hospitals could provide complete price information on laparoscopic and/or open procedures, the other hospitals could not advise on doctor and anaesthetist fees or could only provide price information after specialist consultation. Audit Commission pointed out that it was possible for private hospitals to provide comprehensive information regarding some common operations (para. 4.10 of Audit Report No. 59)[7].

[6] The CoP is at : http://www.dh.gov.hk/english/main/main_orhi/files/code_english.pdf

[7] The Audit Commission's report is at: http://www.aud.gov.hk/pdf_e/e59ch03.pdf

6. Having said that, it is worth noting that the Hong Kong Private Hospitals Association has recently undertaken initiatives to introduce a quotation system for patients. Several private hospitals are also offering service packages[8] for certain procedures on their own volition, with varying scope and coverage.

7. The Working Group on Regulation of Private Hospitals (the Working Group) supports enhancing price transparency of private hospital services. Members agreed that a uniform quotation system is an effective approach to give customers greater price certainty and greater clarity. However, flexibility should be allowed to amend the quotation when more information becomes available in the course of investigation and/or treatment of the disease. Under some circumstances, estimates should be presented in a price range instead of a fixed sum, because the choice of medicines, consumables and the occupancy period of operation theatres and so forth are highly unpredictable and could vary considerably.

8. The Working Group also suggests that doctors should be encouraged to discuss possible risks or complications that might give rise to price changes with their patients as far as practicable. There are readily available information sheets on risk disclosure, which have been widely used in many healthcare institutions where doctors and patients would go through the chargeable items and possible complications together. Hospitals may also provide price information of past similar cases to doctors for reference to facilitate doctors in making accurate estimates.

Recommendations

9. The Working Group's recommendations in enhancing price transparency are divided into four areas –

I. Disclosure of Price Information

Private hospitals should prepare a fee schedule setting out charges on various items of medical services and any charges that may be levied. The full fee schedule should be readily available at

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

hospitals, linked to a common electronic platform provided by the regulatory authority for public inspection and updated promptly and communicated to patients when there is any change.

Information contained in fee schedule

(a) 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 **(Recommendation 36)**.

(b) 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 **(Recommendation 37).**

(c) 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) **(Recommendation 38)**.

Availability of fee schedule

(d) 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 **(Recommendation 39)**.

(e) The hospital webpages showing fee schedules should be linked to a common electronic platform provided by the regulatory authority **(Recommendation 40)**.

Change in fee schedule

(f) 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 three calendar days ahead **(Recommendation 41)**.

II. Uniform Quotation System

The Working Group recommends introducing a quotation system which allows patients to be informed of the estimated total charges given individual patient's unique circumstances on or before admission to private hospitals.

Provision of estimated total charges

(g) 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 **(Recommendation 42)**.

(h) 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 **(Recommendation 43)**.

(i) 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 **(Recommendation 44)**.

Quotation procedure

(j) Doctors should provide patients, in a prescribed financial estimation form (a draft template is at **Appendix H**), 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 form **(Recommendation 45)**.

(k) 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 **(Recommendation 46)**.

(l) A financial estimation form should be completed with the signatures or stamps of the patient, doctor and hospital concerned. Hospitals should request patients to present completed financial estimation forms when they are admitted. They should inform patients of the potential variation of the estimates when appropriate **(Recommendation 47)**.

Change in estimate

(m) 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 financial estimation form 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 financial estimation form 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 **(Recommendation 48)**.

Exemption

(n) Patients subscribing to Recognized Service Packages (see section (III) 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 **(Recommendation 49)**.

III. Introduction of Recognized Service Packages for Common Operations/ Procedures

(o) 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 **(Recommendation 50)** –

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.

(p) Information on RSP should be presented in a prescribed format (a draft Explanatory Note for indicative purpose is at **Appendix I**). 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 **(Recommendation 51)**.

(q) 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 **(Recommendation 52)**.

IV. Disclosure of Historical Statistics

(r) 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 90^{th} percentile bill sizes for each reportable treatment/ procedure **(Recommendation 53)**.

(s) 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 **(Recommendation 54)**.

Chapter 6
Regulatory Framework

In the previous chapters, various key regulatory aspects of private hospitals have been examined with recommendations put forward. Previous reviews by the Department of Health (DH) in 2000 (see **Appendix D**) and Audit Commission in 2012 (see **Appendix E**) both suggested that it is essential to revamp the regulatory framework to have an effective monitor of the performance of private hospitals. To achieve this goal, the Working Group on Regulation of Private Hospitals (the Working Group) has examined legislation regulating private hospitals in overseas jurisdictions (see **Appendix G**) and found that they are written in greater details when compared with that of Hong Kong. In particular,

(a) standards in respect of design and construction, facilities and equipment, staffing, infection control, clinical standards, patients' rights, clinical records, etc are generally and clearly defined and prescribed in legally binding literature such as the statue, regulations or code of practice issued by the regulatory authority;

(b) regulatory authorities are empowered to inspect, collect information and close a facility or suspend all/part of the service if there is an immediate and critical risk to safety of patients; and

(c) sanctions involving fine and/or imprisonment proportionate to the level of offence would be imposed for contravention of regulations.

Recommendations

2. Having regard to the findings of previous reviews and the best practices identified upon comprehensively examining the system adopted in overseas jurisdictions, the Working Group considers that there is a need to enhance the statutory power of the regulatory authority and

impose penalties commensurate with the severity of offence in order to strengthen the regulatory framework for private hospitals. The Working Group recommends that –

(a) Enhancing the statutory powers of the regulatory authority

I. Issuance of regulations/ code of practice **(Recommendation 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.

II. Inspection, collection and publication of information **(Recommendation 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.

III. Suspension of a facility/ equipment/ service **(Recommendation 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 advisory committee and appeal channel) to ensure the regulatory authority would invoke such power only on a fully justified basis.

IV. Appointment of committees **(Recommendation 58)**

(i) *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.

(ii) *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.

(iii) *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

V. Penalty for unregistered operation **(Recommendation 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 2 years, and a fine of $10,000 for each day during which the offence continues.

VI. Penalty for non-compliance **(Recommendation 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.

Chapter 7

Way Forward

A vibrant and well-functioning private healthcare sector is in keeping with the policy direction of the Government in promoting the sustainability of our healthcare system. This report sets out the Working Group on Regulation of Private Hospitals (the Working Group)'s regulatory proposals in modernising and revamping the existing regulatory regime for private hospitals. By implementing the recommended regulatory measures and thus enhancing the quality of private healthcare services, the Working Group envisages that the public, particularly those who can afford to, would have greater confidence in making use of private healthcare services provided by private hospitals.

2. The recommendations of the Working Group, when implemented, would overhaul and modernise the regulatory regime for private hospitals. They would help ensure the healthy and sustainable development of the dual-track healthcare system with long-lasting impact on the private healthcare sector. It is, thus, essential to seek the views from professional organisations, patient groups, consumer groups and the general public so that their views and concerns will be considered when taking the matter forward through preparing legislative proposals.

3. With community support for the recommendations in this report, the Government should undertake to proceed to legislative amendments to implement the recommendations to institute a new regulatory regime for private hospitals.

Appendix A

Recommendations
of the Working Group on Regulation of Private Hospitals

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 ('medical' refers to professional care and practice of registered medical practitioners or registered dentists).

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 hours".

3. Remove separate licensing for maternity home, and instead subsume it under private hospital as a type of medical service.

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

Organisation 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 centralized 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

<u>Short term</u>

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 three 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 financial estimation form (a draft template is at **Appendix H**), 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 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. A financial estimation form should be completed with the signatures or stamps of the patient, doctor and hospital concerned. Hospitals should request patients to present completed financial estimation forms 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 financial estimation form 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 financial estimation form 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.

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 (a draft Explanatory Note for indicative purpose is at **Appendix I**). 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 90^{th} 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 2 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.

Appendix B

List of Registered Private Hospital

1 Canossa Hospital (Caritas)

2 Evangel Hospital

3 Hong Kong Adventist Hospital

4 Hong Kong Baptist Hospital

5 Hong Kong Sanatorium & Hospital

6 Matilda & War Memorial Hospital

7 Precious Blood Hospital (Caritas)

8 Union Hospital

9 St. Paul's Hospital

10 St. Teresa's Hospital

11 Tsuen Wan Adventist Hospital

Current regulatory arrangements under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165)

Section 2(1) of Cap. 165

- Healthcare institutions required to be registered under Cap 165 are –
  - Hospital – "Any establishment for the care of the sick, injured or infirm or those who require medical treatment, including a nursing home"; and
  - Maternity home – "any premises used or intended to be used for the reception of pregnant women or of women immediately after childbirth"

- The following premises are exempted from registration –
  - Public hospital that is within the meaning of the Hospital Authority Ordinance (Cap. 113);
  - Maternity home maintained by government or run as part of the public hospital within the meaning of the Hospital Authority Ordinance

Section 3(4) of Cap. 165

- The Director of Health has the power to lay down conditions relating to accommodation, staffing or equipment as she thinks fit when she issues a certificate of registration to an applicant.

- The Director of Health has the power to refuse registration or cancel the registration if the applicant or any person employed by him at the hospital or maternity home is not a fit person to carry on or to be employed at a hospital or maternity home; if the situation or construction is not appropriate, accommodation or equipment is not fit to be used, or the staffing levels are inadequate.

Section 8 of Cap. 165

- If any person is guilty of an offence against the Cap. 165, he shall in respect of each offence be liable on summary conviction to a fine of $1,000, 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. Where a person convicted of an offence against this Ordinance is a company, the chairman and every director of the company and every officer of the company concerned in the management thereof shall be guilty of the like offence, unless he proves that the act constituting the offence took place without his knowledge or consent.

Summary of the 2000 Review by Department of Health

In order to improve the regulatory regime for private healthcare facilities, DH conducted a Review of Legislation for the Regulation of Health Facilities in 2000. The review identified the following inadequacies in the existing regulatory framework.

Limitations Identified

Lack of effective control over the quality of clinical services

2. The Hospitals, Nursing Homes and Maternity Homes Registrations Ordinance (Cap. 165), from the outset, focuses only on conditions of private hospitals relating to physical facilities and staffing level. It has no provision for monitoring the quality of clinical services which begs the question as to whether such a regulatory framework was capable of sufficiently regulating private hospitals and safeguarding public health.

Limited flexibility in enforcement power

3. Though the regulatory authority has the authority to revoke a registration of a private hospital when there is non-compliance with Cap. 165, there is no explicit provision that allows for the immediate closure of a facility or suspension of a healthcare service if there is an immediate and critical risk to patient safety. For example, the regulatory authority at present does not have intermediate measures, other than attempting to shut down the hospital through de-licensing, to stop a private hospital from undertaking services where adequate back-up facilities and support arrangements are not in place.

No sufficient and effective sanctions

4. The circumstances subject to sanctions are limited to a rather narrow scope which is clearly far from sufficient. In addition, the sanctions imposed fall short of commensurating with the level of non-compliance. For example, the maximum penalty for second or

subsequent offence of carrying on a hospital without being duly registered is $1,000 and imprisonment for 3 months. Such sanctions are apparently ineffective in today's standards.

Major Recommendations

i. The existing Cap. 165 be repealed and replaced by a new ordinance for the control of hospitals, nursing homes, healthcare facilities, medical clinics run by doctors with limited registration and procedure centres

ii. Maternity homes should no longer be registered as standalone units

iii. Nursing Homes should be redefined

iv. The Licensing Authority should be given the flexibility to amend the range of healthcare facilities requiring registration to respond to changing needs

v. The regulation should be extended to cover premises providing services with invasive devices on human body for the purpose other than treatment

vi. The private hospitals should put in place a mechanism to ensure that medical technology of proven safety and efficacy is bought into hospital setting by providers who have appropriate training and qualifications

vii. The appropriate standards should be set for core services and individual disciplines

viii. The health institutions should be required to undertake quality assurance activities and participate in accreditation programmes

ix. The regulatory authority should be given the flexibility to add or change licensing conditions expediently in terms of urgency

x. The powers of regulatory authority should be enhanced in the inspection and collection of data from all the registered facilities for monitoring purposes

xi. The regulatory authority should be given the power to suspend immediately treatments or procedures, use of equipment, certain sections or units within a registered healthcare institution that is providing services which are endangering the safety of patients/clients

xii. The regulatory authority should be given the power to close down premises operating without registration

xiii. The fees to be charged for new registration and renewal of private hospitals and nursing homes should be revised in accordance to their size and complexity

xiv. DH remains the Regulatory Authority for the new ordinance and a dedicated unit should be set up to carry out the licensing activities

Appendix E

Summary of Major Recommendations of the 2012 Audit Review

Audit Report on Regulatory Control of Private Hospitals
(Report No. 59 Chapter 3)

With a view to enhance the effective regulation of 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 Commission has recommended that the Director of Health should:

Inspection of private hospitals

(a) consider developing and using a suitable checklist for guiding and documenting ORHI inspections of private hospitals, and ensure that the ORHI properly documents all inspections conducted;

(b) issue advisory/warning letters to private hospitals when serious irregularities are detected during inspections;

Monitoring of sentinel events and complaints

(c) closely monitor the effective implementation of the sentinel event reporting system;

(d) consider directly referring cases of sentinel events involving professional misconduct/substandard performance to the Medical Council of Hong Kong or the Nursing Council of Hong Kong for investigation and follow-up;

(e) consider disclosing in a timely manner the identities of private hospitals and more details of the sentinel events, including the cumulative number of sentinel events for each private hospital; and

(f) ensure that private hospitals submit their complaint digests to the ORHI monthly, and issue advisory or warning letters to private hospitals when serious irregularities are detected during investigation of complaints.

Audit has also recommended that the Secretary for Food and Health should, in collaboration with the Director of Health:

(g) take measures to further enhance the price transparency of private hospitals; and

(h) take into account the audit observations and recommendations, and take on board the findings and recommendations of the 2000 review when conducting the forthcoming review on the regulatory regime for private healthcare facilities.

Appendix F

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, JP (from 17 September 2013)
Ms CHEUNG Jasminia Kristine
Professor FOK Tai-fai, SBS, JP (until 16 September 2013)
Dr Samuel KWOK Po-yin
Mr Andy LAU Kwok-fai
Ms Connie LAU Yin-hing, JP (until 14 March 2014)
Dr Anthony LEE Kai-yiu
Professor LEE Sum-ping (until 16 September 2013)
Professor Gabriel LEUNG, GBS, JP (from 17 September 2013)
Professor Raymond LIANG Hin-suen, JP
Dr Susie LUM Shun-sui
Professor Samantha PANG Mei-che
Dr Homer TSO Wei-kwok, SBS, JP
Dr YEUNG Chiu-fat
Director of Health (or representative)
Chief Executive, Hospital Authority (or representative)
Head, Healthcare Planning and Development Office, Food and Health Bureau

Co-opted Members

Ms Elaine CHAN Sau-ho
Dr William HO Shiu-wei, JP
Ms Vera TAM Sau-ngor
Dr Raymond YUNG Wai-hung, M.H.

Overseas Regulatory Frameworks of Private Hospitals

SINGAPORE

Regulatory Measures

In Singapore, private hospitals are regulated by the Director of Medical Services (the Director) under the Private Hospitals and Medical Clinics Act and the Private Hospitals and Medical Clinics Regulations (the Regulations).

2. Private hospitals are required to be licenced. Apart from the statutory requirements set out in the legislation, every licensee of a private hospital shall comply with the guidelines issued by the Director with respect to the management, operation, maintenance or use of private hospital.

3. The Director or an authorized officer may, at any time and without warrant, enter, inspect and search any private hospital in order to investigate breach of regulations and assess the quality of facilities and services.

Regulatory Standards

Scope

4. The regulatory standards of the Singapore regime cover a various aspects of healthcare services, including administration and management, accommodation, facilities and equipment, staffing, clinical standards, clinical governance, risk management, price transparency, medical records and dispensaries.

Price Transparency

5. One prominent feature of the Singapore regime is that private hospitals are required by law to uphold price transparency with reference to a set of well-developed and comprehensive guidelines. Regulation 11 of the Regulations stipulates that:

> *Every manager of a private hospital shall ensure that every patient be informed, on or before his/her admission to the private hospital,*

of the estimated total charges which are likely to be incurred in respect of his hospitalisation and treatment.

6. The Ministry of Health (MoH) makes disclosure of pricing information one of the licensing terms and conditions for private hospitals. Patients should be provided with information on estimated total charges and any changes in a timely manner, which is to be recorded in a financial counselling form. MoH also publishes hospital bill sizes of 81 medical conditions/procedures to show the variation in costs among public and private hospitals on its website.

Clinical Governance

7. The Singapore government requires private hospitals to carry out their own internal clinical audit. Private hospitals are also required to establish quality assurance committee consisting of its own medical, nursing, administrative and ancillary staff in order to –

i. monitor and evaluate the quality and appropriateness of the services provided and the practices and procedures carried out at the hospital;

ii. identify and resolve problems that may have arisen in connection with any service provided or any practice or procedure carried out at the hospital;

iii. make recommendations to improve the quality of the services provided and the practices and procedures carried out at the hospital; and

iv. monitor the implementation of the recommendations.

Complaints Policy

8. Without establishing an independent medical ombudsman, MoH encourages a complainant to lodge his complaint with the specific healthcare provider at the first stage. If unsatisfied, the complainant can write to MoH in regard to health finance policy queries or public health safety issues. MoH will then order the specific healthcare provider to

investigate the case. For matters involving professional conduct of healthcare providers, the complainant may appeal to the professional boards for investigation.

9. If the complainant does not agree with the institution's explanation or he intends to seek financial compensation or close-door apology, he/she may contact the Singapore Mediation Centre for mediation.

Sanctions

10. If a private hospital establishment is not licensed or is used otherwise than in accordance with the terms and conditions of its licence, every person having the management or control thereof shall be liable on conviction to a fine not exceeding SGD 20,000 or to imprisonment for a term not exceeding 2 years or to both.

11. In the case of a continuing offence, a further fine not exceeding SGD 1,000 would be imposed for every day or part thereof during which the offence continues after conviction.

12. Furthermore, the Director may suspend or revoke a licence if the licensee contravenes the regulations or if it is in the public interest to do so. The Director may also prohibit usage of apparatus or practice that is dangerous or unsuitable for the purpose for which it is used.

MALAYSIA

Regulatory Measures

In Malaysia, private healthcare facilities, including private hospitals, are regulated under the Private Healthcare Facilities and Services Act 1998 (the Act) and the Private Healthcare Facilities and Services (Private Hospitals and Other Private Healthcare Facilities) Regulations 2006 (the Regulations). The regulatory authorities are the Minister of Health (the Minister) and the Director General of Health (the Director General). Private hospitals are required to be registered and obtain a certificate of registration from the Director General.

Regulatory Standards

Scope

2. The Malaysia regulatory regime for private hospitals covers various aspects including management and administration, apparatus and equipment, price transparency, accommodation of patients, medical records, etc.

Price Transparency

3. The Minister may make regulations prescribing a fee schedule for any or all private healthcare facilities or services or health related facilities or services. The Minister may also, from time to time, after consulting the Director General, amend the fee schedule by order published in the Gazette.

4. Private hospitals which fail to comply with any fee schedule prescribed under the Act commit an offence. Private hospitals shall also, 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.

Clinical Governance

5. The Act stipulates that the licensee of private hospitals shall establish a Medical Advisory Committee whose members shall be registered medical practitioners representing all medical practitioners practising in the facilities to advise the Board of Management, the licensee and/or the person-in-charge on all aspects relating to medical practice.

Complaints Policy

6. Complaints handling mechanisms are referred to as "grievance mechanisms" in both the Act and the Regulations. The Act stipulates that the Minister may make such regulations as appears to him necessary or expedient for carrying out the provisions of the Act and the Regulations may be made for, inter alia, prescribing all matters relating to grievance mechanism.

7. The Regulations require all complaints received to be documented and that the licensee or person-in-charge of a private hospital shall provide a patient grievance mechanism plan which shall include:

(a) appointment of a patient relations officer to serve as a liaison between the patient and the private healthcare facility or service;

(b) an outline of the job description of the patient relations officer;

(c) a description of the extent of decision-making authority given to the patient relations officer;

(d) a method by which each patient will be informed of the patient relations officer and how the patient relations officer may be contacted; and

(e) provision for inclusion in new employee orientation programmes of a briefing on the facility or service grievance procedure and at least annually transmission of information to all staff who have direct patient contact covering the grievance mechanism.

8. The regulations also stipulate that the licensee or person-in-charge shall investigate the complaints received and provide the result to the complainant within ten working days after the complaints were received.

Sanctions

9. The Act stipulates that a licensee or a holder of a certificate of registration shall –

(a) ensure that the licensed or registered private healthcare facility or service is maintained or operated by a person in charge;

(b) inspect the licensed or registered private healthcare facility or service in such manner and at such frequency as may be prescribed;

(c) ensure that persons employed or engaged by the licensed or registered private healthcare facility or service are registered under any law regulating their registration, or in the absence of any such law, hold such qualification and experience as are recognized by the Director General; and

(d) comply with such other duties and responsibilities as may be prescribed.

10. A person contravening the above requirements shall be liable, on conviction to a fine not exceeding RM (ringgit) 100,000 or to imprisonment for a term not exceeding two years or to both.

UNITED KINGDOM

Regulatory Measures

In England of the United Kingdom (U.K.), the Health and Social Care Act 2008, the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009 provide that independent/private hospitals falling within one of the 15 regulated activities: "treatment of disease, disorder or injury" are subject to regulation by the Care Quality Commission (CQC) starting from 2009 (formerly known as the National Care Standards Commission). CQC is an independent regulatory body of all health and social care services in England under the general guidance of the Secretary of State.

2. Private hospitals are required to be registered with CQC. The minister may impose regulations and "essential standards of quality and safety" (formerly known as the "national minimum standards"). Private hospitals, by law, must meet the essential standards in order to be registered.

3. CQC conducts unannounced inspection to private hospitals at least once a year in order to check against hospitals' compliance with the essential standards. CQC may enforce the essential standards by issuing warning notices, prosecution, serving penalty notices, imposing, varying or removing conditions of registration, suspending or cancelling registration etc. Reports of inspection and enforcement action are published on CQC's website.

Regulatory Standards

4. The regulations cover various aspects of hospital services, including administration and management, patient care, dispensaries, accommodation, equipment, complaints policy, medical records and staffing.

Price Transparency

5. The regulations governing private hospitals in the U.K. merely provides a general direction on how private hospitals should ensure price transparency. 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 as to the amount and method of payment of fees, prior to the commencement of the services as far as reasonably practicable.

Clinical Governance

6. The regulations set out general principles to which the registered person should adhere when assessing and monitoring the quality of service provision. Specifically, he/she should regularly assess and monitor the quality of the services provided against the requirements of the regulations. The registered person must send to CQC, when requested to do so, a written report setting out how the requirements are being compiled with. While an official internal clinical governance mechanism seems to be lacking in the English system, CQC is largely responsible for upholding the clinical standards of private hospitals by ensuring that the essential standards have been complied with.

Complaints Policy

7. By law, every private hospital must have a complaints system in place for identifying, receiving, investigating and responding to complaints. A summary of complaints and responses should be sent to CQC when requested.

8. Patients will need to resolve complaints with the hospital involved first. If patients are unsatisfied with hospital's response and if the service concerned is funded by NHS within a private hospital, patients can contact the Parliamentary and Health Service Ombudsman (the Ombudsman). The Ombudsman is a free and independent service set up by Parliament to investigate complaints that individuals have been treated unfairly or have received poor service from government departments and other public organisations and the NHS in England. If the Ombudsman is satisfy that the unresolved complaints has already been dealt with by

the organizations concerned and that they fall under the Ombudsman's purview, the Ombudsman will investigate the complaints by looking at all the facts, gathering additional evidence and information and getting expert advice. If the Ombudsman upholds a complaint, it might requests the organisations concerned to rectify the matter in various ways, including acknowledging their mistake, apologising, paying compensation and/or preventing the same mistake from happening again.

9. For complaints about privately-funded healthcare, patients can seek help from the Independent Healthcare Advisory Service (IHAS), a trade body which represents some independent healthcare providers. IHAS administers the Independent Sector Complaints Adjudication Service (ISCAS), a membership organization which issued a Code of Practice for Handling Patients' Complaints to help member hospitals manage patients' complaints, including conducting investigation, making an apology and putting in place remedial measures. The Code retains a three stage process of handling complaints: Stage 1 – local resolution; Stage 2 – organization review by hospital's senior officer; Stage 3 – independent adjudication. At Stage 3, an independent adjudicator appointed from outside ISCAS membership will consider unsettled complaints and decide on remedial action (e.g. ex gratia award) required. Complains about health professionals can be referred to relevant professional bodies. For private hospitals which are not members of the IHAS, complainants could refer to a list of private health professional associations (i.e. professional bodies with which private healthcare practitioners are registered that regulate that area of practice). These professional bodies may assist with disputes or can provide useful information on practitioners concerned.

Sanctions

10. A person contravening the regulations is liable to a fine ranging from £300 to £50,000, or an imprisonment for a term varying from not exceeding 12 months to not exceeding 2 years. Registration might be suspended or cancelled in circumstances that private hospitals fail to abide by compliance actions taken by the authority or commit an offence with major impact and so on.

ONTARIO, CANADA

Regulatory Measures

In Ontario, private hospitals are regulated by the Minister of Health and Long-Term Care (the Minister) under the Private Hospitals Act, Regulation 937 and the Excellent Care for All Act, 2010.

2. Before commencing operation, private hospitals need to apply for a licence and comply with the regulations. An inspector appointed by the Minister may, at any time, enter and inspect private hospitals.

Regulatory Standards

Scope

3. The legislation governing private hospitals sets out regulatory standards with respect to administration and management, staffing, clinical requirements, performance management, patient care and medical records.

Price Transparency

4. In Ontario, the legislation empowers the Minister to make regulation with respect to the rates and charges for patients. Most basic and emergency healthcare services, including surgery, hospital stays, physician and nursing care, and diagnosis services (except prescriptions) are publicly funded on a prescribed schedule.

Clinical Governance

5. The Ontario government adopts a robust approach to clinical governance: private hospitals are under both internal and external surveillance to uphold clinical standards. Internally, every private hospital is required to establish a quality committee in order to monitor quality of services and make recommendations regarding quality improvement initiatives. It shall develop and make public a quality improvement plan every year. Additionally, payment of compensation for any executive under a compensation plan is linked to the achievement of

the performance improvement targets set out in the annual quality improvement plan. Each private hospital shall also conduct annual/biannual surveys of patients/employees in order to collect information on level of satisfaction with the services.

6. Externally, an independent statutory government agency, Health Quality Ontario, has been set up to measure and make public report on the performance of the health system and support quality improvement activities. It publishes indicators of patient safety and quality of hospital services, such as mortality ratio, infection rate, treatment wait times, chronic disease management, etc.

7. Furthermore, at administrative level the provincial auditor has an oversight role over hospitals in regard to their service quality. It is worth mentioning that although the Ombudsman which is an independent officer of the Legislature who oversees and investigates the provincial government, is not empowered to investigate hospitals in Ontario, whereas it has the power to do so in all other provinces of Canada. At communal level, patients may seek help from patient advocates (self-employed agents who provide advisory and liaison services regarding patients' rights) when encountering problems relating to patients' rights, treatment review, insurance claims and so on.

Complaints Policy

8. A "self-resolving" approach is adopted in the complaints policy front in Ontario. Those who intend to file a complaint about private hospital are advised to contact the hospital directly or seek assistance from patient advocates to resolve their cases with the hospital. Complaints about health professionals should be referred to regulatory colleges for investigation.

Sanctions

9. Responsible persons who contravene the regulations are subject to a maximum fine of CAD 25,000 or imprisonment for a term of not more than 12 months or to both. For a subsequent offence, the penalty would be raised to a maximum fine of CAD 50,000 or to imprisonment for a term of not more than 12 months, or to both.

10. Furthermore, the Minister may revoke a licence if the licensee contravenes the regulations or if it is in the public interest to do so. The Minister may take control of and operate the private hospital for a period not exceeding six months.

NEW SOUTH WALES, AUSTRALIA

Regulatory Measures

Private hospitals in New South Wales, referred as private health facilities, are regulated by the Minister for Health under the Private Health Facilities Act 2007 (the Act) and the Private Health Facilities Regulation 2010.

2. Private hospitals require to be licenced and comply with relevant guidelines and codes.

3. An authorised officer may, at any time, enter and inspect any private hospitals, access any document and make investigations and inquiries in order to determine whether the statutory requirements have been contravened.

Regulatory Standards

Scope

4. The statutory requirements on private hospitals in New South Wales touch on different aspects of healthcare services, for example, administration and management, accommodation, facilities and equipment, staffing, clinical governance, risk management, patient care, complaints policy, medical records, dispensaries and waste and hazardous substances.

Price Transparency

5. The government does not regulate fees charged for healthcare services by private health providers. Some professional associations, such as the Australian Medical Association, however suggest "recommended" fees which are not obligatory. The government also sets a Medicare Benefits Schedule fee, which is used to work out how much Medicare (a publicly-funded health financing scheme) will pay. Doctors, however, can charge their patients more than the schedule fee if they wish, and most do. Besides, private hospitals are, on a voluntary basis, advised to discuss charges with patients before providing the services.

6. If patients have problems with hospital charges, they can either contact the hospital, the Department of Human Services (which administers Medicare), Private Health Insurance Ombudsman (if they are members of health fund) or Office of Fair Trading (for seeking refund).

Clinical Governance

7. Clinical governance in New South Wales demonstrates a comprehensive structure, with both internal and external surveillance in place. Internally, the licensee of a private hospital must appoint a medical advisory committee consisting of medical practitioners and other representatives with a view to advising the licensee on matters concerning accreditation and clinical responsibilities of practitioners to provide services, clinical practice, patient care and safety.

8. When a reportable incident occurs, the licensee is required to appoint a root cause analysis team in order to analyze the nature and significance of the incident.

9. The licensee must conduct regular compliance audits to ensure that the facility is complying with statutory requirements as well as the facility's policies and procedures. He/she should also conduct outcome audits to monitor the effectiveness of the policies and procedures of the facility as well as clinical services and patient outcomes.

10. Externally, the Clinical Excellence Commission, a statutory health corporation with the CEO reporting directly to the Minister for Health of New South Wales, is established to promote and monitor clinical quality and safety of public health organizations, as well as identify, develop and disseminate information about safe practices in healthcare on a statewide basis.

Complaints Policy

11. New South Wales has a vigorous healthcare complaints management policy and mechanism. The government has enacted the Health Care Complaints Act 1993 specifically to provide for the making, resolution, investigation and prosecution of complaints about healthcare services; to constitute a joint committee of members of the Parliament, the Health Care Complaints Commission (the Commission) and the Health Conciliation Registry and to specify their functions.

12. A private hospital must have a written complaints policy outlining the procedure to be followed in managing and responding to complaints, of which patients or their relatives are informed.

13. The establishment of an independent medical ombudsman provides an accountable platform for complaints management. The ombudsman, known as the Health Care Complaints Commission, is an independent body established by law to resolve complaints relating to the professional conduct of (registered or unregistered) individual health practitioners and also clinical care and treatment provided by health service organizations. Upon receipt of complaints, the Commission will have the complaints assessed by its internal medical and nursing advisors, and subsequently resolve, refer (to the Department of Health, relevant councils or healthcare organizations) or investigate the complaints as appropriate. For serious and substantiated cases, it may refer the cases to the Director of Proceedings[9] who has the power to issue a prohibition order against or deregister a registered practitioner. However, the Commission cannot compel health service providers to make compensation, refund or alter their fees.

Sanctions

14. Responsible party who contravenes the regulations is subject to a fine ranging from 5 penalty units (AUD 550) to 5 000 penalty units (AUD 550,000).

15. The Minister may suspend a licence if the licensee is in breach of a licencing standard, which is likely to cause a serious and substantial risk to the health or safety of patients at the facility; and if the licensee does not have a medical advisory committee appointed. The Minister may also cancel a licence if the licensee breaches the licencing conditions; the licensee is not a fit person to be a licensee or it is in the public interest to do so.

[9] Section 90A of the Act stipulates that the Commission is to appoint a member of its staff to be Director of Proceedings who shall exercise some functions of the Commission in relation to complaints received.

WISCONSIN, UNITED STATES
(on price transparency only)

In the United States (U.S.), at least 30 states have proposed or enacted some form of price transparency legislation and at least 25 states have price transparency initiatives that provide publicly accessible websites with health care price information. Additionally, with the enactment of the Patient Protection and Affordable Care Act in 2010, hospitals operating in the U.S. are required to establish and make public annually a list of their standard charges for items and services provided. One of the states which have a well-established hospital price information disclosure system is Wisconsin.

2. Wisconsin's state law Chapter 153 "Health Care Information" stipulates that the entity under contract shall collect, analyze and disseminate the health care information required by the Department of Health Services from hospitals and ambulatory surgery centers. Furthermore, the data organization under contract may request health care claims information from insurers and administrators and shall provide that information to the Department of Health Services without charge. The data organization shall analyze and publicly report the health care claims information with respect to the cost, quality, and effectiveness of health care, and shall develop and maintain a centralized data repository.

3. Hospitals are required to report certain price increases to the Wisconsin Hospital Association Information Center (the "Center"). When a price increase causes a hospital's gross patient revenue to increase faster than the rate of inflation, the hospital must report the price increase to the Center and to its community by publishing a notice in a local newspaper.

4. An electronic platform called "Price Point"[10] developed by the Center under a contract with the Wisconsin Department of Administration provides information on billed charges for all types of inpatient care and selected outpatient services. Consumers can search through 100 types of hospitalizations; median charges for 75 most common types of hospitalizations are also listed out.

[10] URL: http://www.wipricepoint.org/ (Retrieved on 19/5/2014)

私家醫院住院及手術費用預算表格

Financial Estimation Form for Hospital Admission and Surgery in Private Hospital

Statement:

說明：本表格共三頁，由醫生或醫院填寫，並由顧客、醫生及醫院簽名作實。
預算費用只能作為參考，顧客最終應繳費用視乎其實際接受的治療、程序及服務而訂。

This form has 3 pages, which is to be completed by doctors or hospitals and signed by customers, doctors and hospitals. **The estimated charges are for reference only**. Final payments are subject to charges incurred from treatment, procedures and services performed.

姓名 (中文) Name in Chinese: _____

姓名 (英文) Name in English: _____

身份證號碼 / 護照號碼* HKID / Passport No.*: _____

初步病情診斷 Provisional Diagnosis: _____

入住的私家醫院 Private Hospital 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？ Are estimated charges available?
是 Yes ☐ (請填寫以下欄目。Please complete the following sections.)
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

醫院費用總額 Total Hospital Charges #:		$	~ $
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顧客參考。
Hospital should provide the breakdown of total hospital charges on a separate sheet for customer's reference.

預算醫生費用 Estimated Doctor's Fees

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

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

總計 Total $

顧客簽署 Customer's Signature

本人知悉上述預算費用僅為參考，並不包括因併發症所產生的額外費用，並同意最終應繳費用以醫院賬單所列為準。

I understand that the above estimated charges 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 / Authorized Person*	病人 / 親屬 / 獲授權人士簽署* Signature of Patient / Next-of-kin / Authorized Person*	日期 Date

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

本人已向顧客解釋上述預算費用，並徵得其同意。

I have explained to the customer 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，此表格的正本會存放在本院的病人醫療記錄內，副本供顧客參考。

This hospital has noted the above estimated charges. The original copy of this form has been kept with the hospital's medical records, and a duplicate copy has been given to the customer for reference.

醫院職員姓名 Name of Hospital Staff	醫院職員簽署 Signature of Hospital Staff	日期 Date

預算費用更改 Change in Estimated Charges

更改項目 Changed Items:	最新收費 Latest 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

本人知悉並同意上述預算費用的更改。

I agree with the above change in estimated charges in the full knowledge of it.

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

醫生或醫院聲明 Doctor's or Hospital's Declaration

本人已知會顧客更改預算費用，並徵得其同意。

I have notified the customer of the above change in estimated charges and sought his / her agreement.

醫生 / 醫院職員姓名 Name of Doctor / Hospital Staff	醫生 / 醫院職員簽署 Signature of Doctor / Hospital Staff	日期 Date

如未能在治療前知會顧客更改預算費用，請提供理由：
Please provide reasons if the customer has not been informed of any change in estimated charges before treatment:

醫生 / 醫院職員姓名 Name of Doctor / Hospital Staff	醫生 / 醫院職員簽署 Signature of Doctor / Hospital Staff	日期 Date

*請刪去不適用者。Please delete as appropriate

使用條款 Terms and Conditions of Use:

1. 顧客接受診斷程序或為治療已知疾病而施行的選擇性、非緊急的手術，均須在入院前或其時獲告知醫療費用總額的預算。如顧客的情況不適合報價，醫生須提供理由。
Customers having investigative procedures or elective, non-emergency therapeutic operations/ procedures for known diseases should be informed of the estimated total charges on or before admission to private hospitals. Doctors should provide reasons if customers are not eligible for quotation.

2. 入院時未獲告知醫療費用總額的預算的顧客，一旦入院後得以確診病因並須接受手術，均應盡量事先獲得報價。
For customers who have not been given an estimation of their hospital bills at the point of admission, whenever they receive a definite diagnosis where elective operations/ procedures are required after admission, they should be given an estimate in advance as far as practicable.

3. 私家醫院應公佈一個可供報價的「常見手術列表」。該列表須張貼於登記處和繳費處，並上載到醫院網頁供公眾參考。
Private hospitals should publish a "List of Common Operations/ Procedures" for which quotation will be provided for prospective customers. The List should be available at the admission office, cashier and hospital webpage for public's reference.

4. 顧客應在入院時將填妥的表格交予醫院。醫院應保留此表格的正本，並將複本交予顧客及醫生，以作紀錄。
Customers should present completed financial estimation forms to hospitals at the point of admission. Hospitals should retain original copies and give a copy to the customers and doctors concerned for retention.

5. 若費用預算有任何重大更改，清醒和病情穩定的顧客應在進一步接受任何手術前獲知會並同意更改的預算，更改的預算應記錄在此表格，並由醫生/醫院和顧客簽名作實。如有重大更改，醫生/醫院可填寫新的表格。
In case there is any material change in an estimate, customers who are conscious and stable 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 form and signed by doctors/ hospitals and customers. A new form may be used if the changes are considered substantial by the doctor or hospital concerned.

6. 若顧客在 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顧客簽署文件。
In case when customers are under 18, unconscious or have cognitive impairments, their next-of-kin or authorized person should act on the customers' behalf.

7. 顧客如購買「認可服務套餐」，可免報價。顧客若在接受手術期間或在危急情況下出現併發症或意外而須支付額外費用，亦可免報價。
Customers subscribing to Recognized Service Packages are exempt from quotation. In case when customers are undergoing operations/ procedures, emergency or life threatening situations, and are identified with complications or incidental conditions that incur additional charges, quotation would be exempt.

Draft Explanatory Note for Recognized Service Packages

[For indicative purpose]

手術認可服務套餐 (根據已知診斷) **Recognized Service Package for Surgical Procedures based on Known Diagnosis**		
I. **醫院名稱：** **Hospital Name:**	*[To be provided by hospitals]*	
II. **手術：** **Surgical Procedure:**	*[To be provided by hospitals]*	
III. **適用病症：** **Disease(s) Applicable:**	*[To be provided by hospitals]*	
IV. **預計住院時間：** **Estimated Length of Stay:**	*[To be provided by hospitals]*	小時 / 日* Hour(s) / Day(s)*
V. **費用 (標準床位)#：** **Price (Standard Bed)#:** $____	*[To be provided by hospitals]*	
VI. **使用資格：** **Eligibility:**	*[To be provided by hospitals]*	

VII. 套餐收費包括監管機構訂明的以下項目(基於手術及/或已知診斷，以及標準床位住宿而訂)：
The provision of the following items, as prescribed by the regulatory authority, are covered by the package (based on the original operation and/or known diagnosis, and the occupancy of standard beds) :

例子 Examples:

- 醫生費(包括所有主診醫生及專科醫生、駐院及非駐院醫生的收費)
  Doctors' fees (including all attending and specialist, resident and visiting doctors' fees)
- 病房收費(包括住宿及膳食)
  Room charges (including accommodation and meals)
- 診斷(包括內窺鏡檢查、病理化驗及診斷造像病理化驗)
  Diagnostic procedures (including endoscopy, pathology testing and diagnostic imaging pathology)
- 治療(包括急救、輸血等)
  Treatment procedures (including emergency procedure, blood transfusion etc.)
- 手術室收費(包括逾時手術的額外手術室收費)
  Operating theatre charges (including extra operation theatre charges for prolonged surgical operations)
- 麻醉
  Anaesthetic fees
- 護理
  Nursing care
- 藥物
  Medications
- 儀器設備

Equipment / Instrument

- 消耗品 / 物料
  Consumables / Materials
- 植入物
  Implants
- 登記費 / 入院費
  Registration fees / Admission fees
- 其它：*(請註明)*
  Others: *(Please specify)*
  例如：套餐包括醫治由原來的手術治療引發的併發症所需的費用，但總額限於(固定金額)。
  e.g. Expenditure for treating complications arising from the original operation and treatment are covered by the package, with the aggregate expenditure capped at (a fixed amount).

VIII. 套餐收費不包括下列項目：
Exclusions:
[To be provided by hospitals]

IX. 併發症的處理：
Control of Complications:
[To be provided by hospitals]

X. 使用條款：
Terms and Conditions of Use: *[To be provided by hospitals]*

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/ authorized 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)： Name in Chinese:	姓名(英文)： 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 / Authorized Person*	病人 / 親屬 / 獲授權人士簽署* Signature of Patient / Next-of-kin / Authorized 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 / Authorized Person*	病人 / 親屬 / 獲授權人士簽署* Signature of Patient / Next-of-kin / Authorized 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.

Appendix J

List of Reportable Sentinel Events (As at 30 April 2014)

No.	Categories of Sentinel Events
Events that leads to death/ serious outcomes	
1.	Surgery or interventional procedure involving wrong patient or body part
2.	Unintended retention of instruments or other materials after surgery or interventional procedures
3.	Transfusion reaction arising from incompatibility of blood/ blood products
4.	Medication error involving death or serious injury
5.	Intravascular gas embolism resulting in death or serious injury
6.	Death of an in-patient from suicide
7.	Unanticipated maternal death or serious maternal injury associated with labour or delivery and occurring within 42 days after delivery
8.	Infant discharged to wrong family or infant abduction
9.	Unanticipated death or serious injury of a full-term infant within 7 days after birth
10.	Unanticipated death or serious injury that occurs during or within 48 hours after operation or interventional procedures
Unanticipated events that possibly lead to death or serious injury / possess significant public health risk	
11.	Medication error that carries a significant public health risk
12.	Patient misidentification which could have led to death or serious injury
Others	
13.	Any other events that have resulted in unanticipated death or serious injury or with significant public health risk