CHAPTER 3

Food and Health Bureau
Department of Health

Regulatory control of private hospitals

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REGULATORY CONTROL OF PRIVATE HOSPITALS

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REGULATORY CONTROL OF PRIVATE HOSPITALS

Executive Summary

1. Private hospitals are regulated by the Department of Health (DH) under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165 — the Ordinance) on matters of accommodation, staffing and equipment. The DH has issued a Code of Practice (COP), which does not form part of the Ordinance, but sets out standards of good practices for private hospitals. The Office for Registration of Healthcare Institutions (ORHI) of the DH is responsible for enforcing the Ordinance and the COP. The ORHI regulates private hospitals through conducting inspections, and monitoring sentinel events (i.e. unexpected occurrence involving death or serious injury) and complaints. The Audit Commission (Audit) has recently conducted a review of the DH's regulatory control of private hospitals.

Inspection of private hospitals

2. ***Documenting inspections.*** In the ORHI inspections conducted in 2011 and 2012, Audit noted that a checklist was not used for documenting the inspection results. There were also no records readily available showing the extent of checking performed. The absence of proper documentation may limit the reviewing officers' ability to ensure that the front-line staff have properly identified all cases of non-compliance with the COP. There is room for improvement in the ORHI's system of documentation.

3. ***Advisory/warning letters not issued for some serious irregularities.*** In 2011, the DH issued 6 advisory/warning letters to 6 private hospitals. Audit however found that for some inspections in which serious irregularities were noted, the DH only provided summary reports of inspection to the hospitals concerned for follow-up, but did not issue any advisory or warning letters to them. An example of such serious irregularities included a specialty centre in operation before the registration of its premises. The centre would provide various specialty services including surgical procedures.

Monitoring of sentinel events and complaints

4. ***Reporting of sentinel events.*** Since 2007, the DH has set up a sentinel event reporting system, under which all private hospitals are required to report a sentinel event to the DH within 24 hours upon occurrence of the event and submit a full investigation report within 4 weeks upon occurrence of the event. Given the lack of statutory backing and the voluntary nature of the reporting system, Audit considers that there is a risk of under-reporting. Audit analysis of DH records revealed that in many cases, the private hospitals concerned had taken a long time to report sentinel events or to submit full investigation reports to the DH. Notwithstanding this, the DH had only issued three regulatory letters in respect of 55 cases of delays in reporting of sentinel events from 2008 to 2011.

5. ***Public disclosure and follow-up action of sentinel events.*** Upon receipt of the notification of a sentinel event, the DH will assess whether there is a need to disclose details of the event to the public. From 2007 to 2011, the DH issued only three press releases relating to sentinel events in private hospitals. Besides, the DH also uploads an aggregated figure of sentinel events onto its website on a quarterly basis. However, identities of the private hospitals concerned and details of the sentinel events are not disclosed.

6. In a review in 2010, the Independent Commission Against Corruption (ICAC) stated that the DH adopted a strategy of "partnership approach" towards private hospitals in enforcing the regulatory provisions of the Ordinance. The ICAC also stated that when investigating reports on sentinel events, the DH only issued advisory or warning letters to the private hospitals concerned and did not refer cases involving the professionalism of doctors and nurses to the Medical Council of Hong Kong (MCHK) or the Nursing Council of Hong Kong (NCHK) for follow-up action.

7. ***Handling of complaints.*** Under the COP, private hospitals are required to set up a mechanism for handling complaints, and provide monthly to the ORHI a complaint digest on the complaints received, results of investigation and actions taken. From 2009 to June 2011, private hospitals received a total of 2,063 complaints. From 2009 to 2011, the DH also received 246 complaints directly from the public concerning private hospitals' services. Audit noted that some private hospitals had not always submitted the complaint digests monthly as required. Besides, although the DH noted irregularities in the course of its investigation of a number of complaint cases, it did not issue advisory or warning letters to the private hospitals concerned.

Price transparency in hospital charges

8. ***Promoting price transparency.*** In recent years, there had been growing public concerns about the level and increase of hospital charges and the lack of price transparency in private hospitals. Besides, charges have always been a common source of complaints against private hospitals. Audit reviewed the websites of private hospitals and found that the price information available varied considerably. Apart from services which were offered at packaged charges, most hospitals could not provide comprehensive price information for their services. In this connection, Audit noted that the Hospital Authority made available comprehensive price information on its website regarding private services provided by its hospitals. Audit considers that there is scope for further promoting price transparency of private hospitals.

Way forward

9. ***Review of the existing regulatory framework.*** The existing Ordinance was enacted in 1936 with major amendments last made in 1966. It has become outdated and failed to meet the rising public expectation for a mechanism that could effectively monitor the performance of private hospitals. A review of the Ordinance was conducted in 2000 (2000 review), but was subsequently held in abeyance. On 11 October 2012, the Government set up a steering committee to conduct a review on the regulatory regime for private healthcare facilities.

Audit recommendations

10. **Audit recommendations are made in the respective sections of this Audit Report. Only the key ones are highlighted in this Executive Summary. Audit 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 MCHK or the NCHK 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.**

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

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

(b) **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.**

Response from the Administration

12. The Administration agrees with the audit recommendations. The Secretary for Food and Health has said that the Administration has commenced a review of the Ordinance which will be completed within a year. The Director of Health has also said that the DH will take proactive measures to enhance the regulatory control of private hospitals.

PART 1: INTRODUCTION

1.1 This PART describes the background to the audit and outlines the audit objectives and scope.

Background

1.2 Private hospitals are an integral part of the healthcare system in Hong Kong. They provide primary healthcare services and a range of specialist and hospital services for members of the public who are willing to choose private services.

1.3 As at January 2012, there were 39 public hospitals (Note 1) and 12 private hospitals in Hong Kong, providing 27,041 (87%) and 4,098 (13%) hospital beds respectively. According to the Administration:

(a) the Hong Kong healthcare system is heavily reliant on public hospitals, which provide over 90% of the in-patient services (in terms of bed-days) and their services are heavily subsidised (95%) by the Government;

(b) over the years, the situation in (a) above has resulted in an imbalance between the public and private sectors in hospital services, and has limited the competition and collaboration between the two sectors; and

(c) to meet the challenges posed by the ageing population and increasing demand for healthcare services, the Government needs to increase the overall capacity of the healthcare system in Hong Kong.

1.4 Various healthcare reform initiatives are under policy consideration, including the proposed Health Protection Scheme under which participating insurers will be required to offer standardised health insurance plans providing the insured

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Note 1: *All public hospitals are managed by the Hospital Authority with government subvention in accordance with the Hospital Authority Ordinance (Cap. 113).*

individuals with benefit coverage and reimbursement levels that will enable them to access general ward class of private healthcare services when needed.

1.5 With a view to increasing the overall capacity of the healthcare system in Hong Kong to cope with the increasing service demand and to address the imbalance between the public and private sectors in hospital services, it is the Government's policy to facilitate and promote private hospital development. The Government is also aiming to rationalise the utilisation of private healthcare services and improve their efficiency, transparency and quality, with a view to enhancing the long-term sustainability of the healthcare system as a whole.

1.6 Apart from supporting the expansion and redevelopment plans of existing private hospitals, the Government has also reserved four Government sites (reserved sites) for private hospital development. In April 2012, the Government put out the first two sites at Wong Chuk Hang and Tai Po for open tender. The tender closed by the end of July 2012. It was expected that the result of the tender exercises will be announced in early 2013.

1.7 Private hospitals (including their maternity homes and satellite clinics) are regulated by the Department of Health (DH) under the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165 — the Ordinance) on matters of accommodation, staffing and equipment. The Ordinance was enacted in 1936 with major amendments last made in 1966. The DH has issued a Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes (COP — Note 2), which sets out standards of good practices for private hospitals and other healthcare institutions to adopt, with a view to enhancing patient safety and quality of service. As the registration authority, the DH conducts inspections, and monitors/investigates sentinel events (Note 3) and complaints, with a view to monitoring compliance of private hospitals with the Ordinance and the COP.

Note 2: *The COP, not forming part of the Ordinance, was first issued in August 2003 and the last update was made in April 2010.*

Note 3: *A sentinel event refers to an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Such events are called "sentinel" because they signal the need for immediate investigation and response.*

1.8 On 11 October 2012, the Government announced the setting up of a steering committee to conduct a review on the regulatory regime for private healthcare facilities in Hong Kong. It will cover, among others, a review of the Ordinance, and is expected to be completed within a year, followed by public consultation (see para. 6.10 for details).

1.9 As at 1 January 2012, there were 12 private hospitals registered in accordance with the Ordinance (Note 4). Ten of them were charitable institutions which were exempt from tax under section 88 of the Inland Revenue Ordinance (Cap. 112 — Note 5). Appendix A shows a list of the 12 registered private hospitals.

Audit review

1.10 Against the above background, the Audit Commission (Audit) has recently conducted a review of the DH's regulatory control of private hospitals, with a view to identifying areas for improvement. The review focused on the following areas:

(a) inspection of private hospitals (PART 2);

(b) monitoring of sentinel events and complaints (PART 3);

(c) price transparency in hospital charges (PART 4);

Note 4: *Because one private hospital (Hong Kong Central Hospital) ceased operation on 2 September 2012 (see para. 2.31), as at 3 September 2012, there were only 11 registered private hospitals.*

Note 5: *According to section 88 of the Inland Revenue Ordinance, any charitable institution or trust of a public character shall be exempt from tax. Tax-exempt charitable institutions must be established exclusively for charitable purposes according to law. As required by the Inland Revenue Department, charitable institutions applying for tax exemption must have a governing instrument which states their objects precisely and clearly. For charitable institutions granted tax exemption, their incomes and properties may only be used for attainment of their stated objects and any distribution of their incomes and properties amongst their members is strictly prohibited.*

(d) performance measurement and reporting (PART 5); and

(e) way forward (PART 6).

1.11 In conducting this review, Audit mainly examined relevant records (including those pertaining to private hospitals) in the possession of the DH. Audit did not have direct access to the private hospitals' records. Furthermore, because of the DH's need to safeguard patient data privacy, Audit's examination did not cover information (mainly relating to private hospitals' sentinel events and complaints) which, in the DH's view, formed part of the patient or patient-related records. Audit has found areas where improvements can be made in the DH's regulatory control of private hospitals, and has made a number of recommendations to address the issues.

1.12 As a related review, Audit has also examined the Government's efforts in monitoring private hospitals' compliance with conditions relating to land grants by private treaty at nil or nominal premium. The results are reported in Chapter 4 of the Director of Audit's Report No. 59.

Acknowledgement

1.13 Audit would like to acknowledge with gratitude the full cooperation of the staff of the Food and Health Bureau (FHB) and the DH during the course of the audit review.

PART 2: INSPECTION OF PRIVATE HOSPITALS

2.1 This PART examines the DH's inspection of private hospitals, focusing on the following issues:

(a) Department of Health's inspection programme (paras. 2.5 to 2.16);

(b) regulatory actions arising from inspections (paras. 2.17 to 2.30); and

(c) closure arrangements (paras. 2.31 to 2.34).

Regulatory framework

2.2 Under the Ordinance (see para. 1.7), all private hospitals are required to be registered with the DH and apply for re-registration annually, subject to conditions relating to accommodation, staffing and equipment. The DH has promulgated the COP which sets out standards of good practices for private hospitals to adopt (see para. 1.7). The COP covers requirements on areas including accommodation and equipment, staff management, quality management of services, rights of patients, risk management, reporting of sentinel events, and standards on specific types of clinical and support services (see Appendix B). Compliance with the COP requirements is a condition for the registration and re-registration of private hospitals.

2.3 The Office for Registration of Healthcare Institutions (ORHI — Note 6) of the DH is responsible for enforcing the Ordinance and the COP. The ORHI is headed by a Principal Medical and Health Officer who is assisted by 11 professional

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Note 6: *Besides enforcing the Ordinance, the ORHI also undertakes the following functions:*

(a) registration of medical clinics under the Medical Clinics Ordinance (Cap. 343) and inspection of the registered clinics; and

(b) inspection of school health under the Education Ordinance (Cap. 279).

staff (Note 7), namely two Senior Medical and Health Officers, three Medical and Health Officers and six other professional staff. An organisation chart (extract) of the DH is at Appendix C.

2.4 The ORHI regulates private hospitals through conducting inspections, and monitoring sentinel events and complaints. The DH has issued guidelines to assist ORHI staff in conducting inspections of private hospitals and monitoring of sentinel events and complaints (DH guidelines).

Department of Health's inspection programme

2.5 The DH conducts inspections on private hospitals for the following purposes:

(a) ***Annual inspection.*** The licence of a private hospital expires on 31 December every year. For the purpose of licence renewal, each private hospital is required to submit to the DH a Report for the Registration of Hospitals and Maternity Homes (Registration Report), in the form of a questionnaire regarding its central administration, policies and procedures, staffing, facilities and equipment, and clinical and supporting services. Based on the information submitted, the DH conducts an annual inspection of the private hospital (Note 8), which normally lasts for one or two days depending on the size of the hospital. An annual inspection mainly comprises the following procedures:

(i) meeting with the hospital management to discuss the Registration Report completed and to exchange views on health issues and other matters;

Note 7: *The Principal Medical and Health Officer also heads the Narcotics and Drug Administration Unit. Prior to 2011, the ORHI had only 6 professional staff supporting the Principal Medical and Health Officer. The number has increased to 11 since 2011.*

Note 8: *Previously, the conduct of annual inspections was announced by the ORHI beforehand for the private hospitals concerned to make necessary arrangements. Since the second half of 2010, the inspection arrangement has been fine-tuned so that all inspections are unannounced (i.e. surprise in nature).*

(ii) inspecting quality assurance reports, adverse incident reports, medication error reports, patients' medical records, facilities management records, staff training records, and other records as required by the COP;

(iii) inspecting various service areas and departments to examine issues relating to patient care, infection control measures, practices on dispensing and administration of medication, medical and nursing documentation, physical environment, medical and other equipment, safety and security, etc.; and

(iv) discussing with the hospital management on areas that need rectification or improvement. A summary report of inspection (containing overall assessment and DH advice) will, after each inspection, be provided to the hospital management for follow-up;

(b) ***Ad-hoc inspection.*** Apart from annual inspection, the DH also conducts at least one ad-hoc inspection every year for each private hospital. During these inspections, surprise checks on patients' medical records, facilities and equipment management records, selected service areas or departments, etc. are carried out. The DH will verbally advise, on the spot, the hospital management on important issues that warrant immediate attention;

(c) ***Follow-up inspection.*** When required, the DH will conduct follow-up inspections of selected private hospitals to ensure that irregularities detected during annual or ad-hoc inspections are rectified;

(d) ***Inspection for matters relating to registration.*** The DH conducts inspections of private hospitals for the purpose of vetting their applications for new registration, alteration or expansion of services. During the inspection, the DH checks whether the conditions relating to accommodation, staffing and equipment are fit for operation; and

(e) ***Inspection of complaints, sentinel events and other incidents.*** When required, the DH will inspect private hospitals upon the receipt of complaints, sentinel events and other incidents to check their compliance with the Ordinance and the COP.

2.6 Table 1 shows the number of DH inspections conducted on private hospitals in the past three years.

Table 1

DH inspections conducted on private hospitals (2009 to 2011)

Inspection	2009 (Number)	2010 (Number)	2011 (Number)
(a) Annual inspection (Note 1)	32	33	40
(b) Ad-hoc inspection (Note 1)	22	24	31
(c) Follow-up inspection	0	0	23 (Note 2)
(d) Inspection for matters relating to registration	16	15	22
(e) Inspection of complaints, sentinel events and other incidents	5	24	18
Total	75	96	134

Source: DH records

Note 1: These inspections included inspections of private hospitals, as well as those conducted on their maternity homes and satellite clinics.

Note 2: These inspections related to an overall review of electricity supply and distribution systems at individual private hospitals.

Developing and using a checklist for guiding and documenting inspections

2.7 Private hospitals are subject to at least one annual inspection and one ad-hoc inspection by the ORHI inspection team each year. According to DH guidelines, a checklist will be used to guide inspections. Audit noted that the checklist had previously been used for the annual inspections conducted in 2009 and for the ad-hoc inspections in 2010. The checklist showed the focus areas for inspection, the recommended practice, the wards/units inspected, and the extent of compliance.

2.8 However, Audit noted that, in more recent inspections (e.g. the inspections in 2011 and 2012), such a checklist was not used for documenting the inspection results. There were also no records readily available showing details of the private hospital's reports/records that had been inspected, or the procedures/practices examined in each service area or department visited. In the circumstances, Audit or a reviewer could not ascertain the extent of checking performed by the ORHI in its inspections.

2.9 Upon enquiry, the DH informed Audit in September 2012 that, since 2010, inspections (e.g. the inspections in 2011 and 2012) on different services and areas of private hospitals have been conducted according to relevant sections and clauses of the COP, which is a detailed and voluminous document of over 100 pages. Audit considers it questionable as to whether the COP can effectively serve as a reminder checklist for guiding and documenting inspections. The absence of proper documentation may limit the reviewing officers' ability to ensure that the front-line staff have properly identified all cases of non-compliance with the COP. In future, the DH needs to consider using a suitable checklist to guide and document its inspections.

2.10 In Audit's view, a checklist could, among other things, serve to:

(a) standardise all areas that need to be covered in an inspection;

(b) facilitate the documentation of areas not covered in the inspection;

(c) help properly record, for each area covered by the inspection, the extent of checking, the staff responsible for performing the checking, and the inspection results (cross-referencing to relevant parts of the inspection report for details); and

(d) provide a useful means for management review (e.g. by supervising staff, DH management and other reviewers such as internal or external auditors) of the adequacy of inspection work performed by the ORHI.

Inspection reports not always prepared

2.11 After an inspection, the ORHI normally documents the results in an inspection report. According to DH records, in 2011, a total of 116 inspections were conducted on private hospitals for purposes including annual inspections, ad-hoc inspections, follow-up inspections, and inspections for matters relating to registration (see items (a) to (d) of Table 1 in para. 2.6). Audit noted that inspection reports had been prepared for 84 (72%) of these inspections. Of the 32 inspections not covered by any inspection reports, 5 had their key results documented in file minutes of the relevant subject folders. For the remaining 27 inspections, upon Audit's enquiry, the DH provided a variety of documents (extracting from different files and mainly in the form of notes of meetings) showing the work done by the ORHI.

2.12 Audit considers that there is room for improvement in the ORHI's system of documentation of the various types of inspections conducted on private hospitals. As a good management practice to facilitate monitoring of inspection work and future work planning, the DH needs to ensure that the ORHI properly documents each and every inspection conducted, preferably in the form of an inspection report. For a simple ad-hoc inspection or follow-up visit, a brief inspection report may suffice.

Service areas covered in inspection programme

2.13 According to DH guidelines, during annual inspection of a private hospital, the ORHI inspection team has to inspect various service areas to examine issues relating to patient care, infection control measures, practices on dispensing and administration of medication, medical and nursing documentation, physical environment, medical and other equipment, safety and security, etc. (see para. 2.5(a)(iii)). A scrutiny of the inspection reports of two selected hospitals revealed that some of their service areas had not been inspected by the ORHI inspection team for three years. Upon Audit's enquiry in September 2012, the DH explained that the service areas had in fact been covered in its inspections in 2011 as indicated in the relevant inspection plans, though this was not documented in the inspection reports. Audit considers that there is room for improvement in the DH's system in ensuring that all service areas of private hospitals are covered in its inspection programme within a reasonable timeframe.

Monitoring compliance with land grant conditions

2.14 The DH's inspection programme (see para. 2.5) mainly focuses on checking private hospitals' compliance with the Ordinance and the COP. As mentioned in Chapter 4 of the Director of Audit's Report No. 59 (see para 1.12), some of the existing private hospitals are operating wholly or partly on sites granted by the Government through private treaty at nil or nominal premium, and are subject to certain land grant conditions. Audit has noted that the DH's inspection programme does not adequately cover the checking of private hospitals' compliance with the land grant conditions (see PART 3 of the separate report). The DH needs to develop relevant compliance checklists and incorporate appropriate ones into its inspection programme and conduct regular compliance checking.

Audit recommendations

2.15 **Audit has *recommended* that the Director of Health should:**

Developing and using a checklist for guiding and documenting inspections

(a) **consider developing and using a suitable checklist for guiding and documenting ORHI inspections of private hospitals;**

Inspection reports not always prepared

(b) **ensure that the ORHI properly documents all inspections conducted and, as a good management practice, an inspection report should, as far as possible, be prepared for each inspection;**

Service areas covered in inspection programme

(c) **ensure that all service areas of private hospitals are covered in DH inspection programme within a reasonable timeframe; and**

Monitoring compliance with land grant conditions

(d) **develop compliance checklists for checking private hospitals' compliance with relevant land grant conditions, and incorporate appropriate ones into the DH's inspection programme and conduct regular compliance checking.**

Response from the Administration

2.16 The Director of Health welcomes the audit recommendations and will take steps to introduce improvement measures. She has said that:

(a) the DH will introduce a suitable checklist and standardised inspection report to ensure comprehensiveness of the inspections. Records of inspections will be properly maintained and managed; and

(b) since September 2012, the DH has started to use a checklist for monitoring compliance of land grant conditions relating to the provision of healthcare services and has already incorporated these procedures into the inspection programme.

Regulatory actions arising from inspections

2.17 After an annual inspection or an ad-hoc inspection of a private hospital, the DH will verbally advise the hospital management on areas that need rectification or improvement. For annual inspection, the DH will also issue a summary report of inspection, which contains its advice and overall assessment, to the private hospital for follow-up (see para. 2.5(a)(iv)). Where necessary, the DH may also issue an advisory or warning letter to the hospital concerned. According to DH guidelines, the DH will issue an advisory letter if one or more of the following irregularities are noted in the inspection:

(a) non-compliance with established policies and procedural guidelines;

(b) lack of guidelines/protocols on essential procedures that link to patient safety; or

(c) inadequacies that require prompt rectification or improvements.

If the above irregularities concern accommodation, staffing or equipment, a warning letter will be issued.

2.18 Apart from issuing summary reports of inspection and advisory/warning letters, the DH may also impose such conditions relating to accommodation, staffing and equipment as it thinks fit on the certificates of registration issued to private hospitals. Furthermore, under the Ordinance:

(a) any person operating an unregistered healthcare institution is liable on summary conviction to a fine of $2,000 (with effect from August 2012), or in the case of a second or subsequent offence, to a fine of $2,000 and imprisonment for three months. Other offences may incur a fine of $2,000, and a further fine of $50 for each day while the offences continue. Examples of these offences include "certificate not kept affixed in a conspicuous place" and "refusal or obstruction of entry for inspection"; and

(b) the DH may at any time cancel the registration or refuse the re-registration of a private hospital if any condition relating to accommodation, staffing or equipment is unfit.

2.19 Table 2 shows the DH's regulatory actions on private hospitals in the past three years.

Table 2

DH regulatory actions on private hospitals
(2009 to 2011)

Regulatory action	2009 (Number)	2010 (Number)	2011 (Number)
(a) Inspections conducted (see Table 1 in para. 2.6)	75	96	134
(b) Advisory or warning letters issued arising from			
• inspections conducted	0	2	6
• monitoring of sentinel events	2	0	3
• monitoring of complaints	3	2	6
• monitoring of other medical incidents	0	2	2
(c) Initiating prosecution actions under the Ordinance	0	0	0

Source: DH records

Format and content of advisory and warning letters

2.20 In 2011, the DH issued 6 advisory/warning letters (regulatory letters) to 6 private hospitals in respect of various irregularities found during inspections. The following are examples of irregularities covered by these regulatory letters in 2011:

(a) no specialist in paediatrics appointed to take charge of or as an advisor to the nursery service;

(b) admission of maternity cases outside the maternity unit;

(c) insufficient nurses to take care of the nursery service;

(d) lack of an effective system to keep track of and ensure timely maintenance of medical equipment;

(e) anaesthetists put on-call for a long period;

(f) undesirable arrangements in discharging patients from recovery areas of the operating theatre to wards;

(g) undesirable arrangements in nursing observation of newborns in the nursery service; and

(h) insufficiencies in electricity supply system that posed risks to patient safety.

2.21 Audit noted that all regulatory letters were issued by the DH under the same letterhead, and there was no caption or subject title to indicate explicitly whether a letter was an advisory or warning letter. In other words, the private hospital concerned might not be able to differentiate whether it was receiving an advisory letter or a warning letter. In fact, the private hospital might well take such a regulatory letter as just normal correspondence for following up irregularities recorded in an inspection report previously issued by the DH. For the avoidance of doubt, in future, the DH should consider indicating explicitly whether a regulatory letter issued to a private hospital is an advisory or warning letter (e.g. using a special letterhead or stating it clearly in the caption or subject title of the letter). A warning letter should make it clear that more stringent regulatory action will be taken if there is recurrence or if the matter is not rectified within a reasonable timeframe.

Advisory/warning letters not issued for some serious irregularities

2.22 Audit found that for some inspections in which serious irregularities were noted, the DH only provided summary reports of inspection to the hospitals

concerned for follow-up, but did not issue any advisory or warning letters to them. Examples of such irregularities included:

(a) ***Specialty centre in operation before registration of the premises.*** In May 2011, a hospital informed the DH of its plan to relocate its specialty centre to a commercial building for operation. The specialty centre would provide various specialty services including a surgical and breast clinic, plastic surgery, urology service, and oncology service. In June 2011, the DH informed the hospital to submit an application for registration of the hospital with the inclusion of the said centre, together with relevant documents, for its consideration. In August 2011, after receiving the application and all relevant documents from the hospital, the ORHI conducted an inspection of the premises for operating the proposed centre. During the inspection, the ORHI found that the specialty centre had already been in operation. Several patients were in the waiting hall and a patient was being seen by a doctor in one of the four consultation rooms. The ORHI verbally informed the hospital management that the premises had not yet been registered under the Ordinance, and advised the hospital management to take step to ensure that the specialty centre would operate only after the premises was registered. Upon the ORHI's onsite instruction, the hospital immediately stopped the service. On 30 August 2011, the DH issued a letter attaching the Certificate of Registration for the specialty centre and generally reminded the hospital of the need to seek DH approval before commencement of any proposed new service. However, no advisory/warning letter was issued;

(b) ***Fridges for storing drugs and vaccines not regularly maintained.*** In an annual inspection of a hospital conducted in October 2011, the ORHI noted that the fridges for storing drugs and vaccines in all clinical services (e.g. pharmacy service, operating theatres, and out-patient department) were not regularly maintained by the hospital. Besides, the highest and lowest temperatures of the fridges for storing vaccines had not been monitored. At the time of visit, the temperature reading of the medication fridge in the operating theatre was 13°C, which was outside the recommended range of 2°C to 8°C. The above irregularity related to non-compliance with the requirements on equipment which might present patient safety risks. Advice was given to the hospital in the form of a summary report of inspection, but no advisory/warning letter was issued;

(c) ***Issues relating to the Chinese Medicine Service.*** In an annual inspection of a hospital conducted in December 2011, the ORHI found that only a listed Chinese medicine practitioner was appointed to take charge of the Chinese Medicine Service, which was not in compliance with the COP requirement that a registered Chinese medicine practitioner should be appointed to play this role (Note 9). The irregularity related to non-compliance with the staffing requirement, which might present patient safety risks. Advice was given to the hospital in the form of a summary report of inspection, but no advisory/warning letter was issued; and

(d) ***Medication management.*** In an annual inspection of a hospital conducted in December 2011, the ORHI noted from the hospital's medication incident reports and its investigation findings that there were repeated occasions on which prescriptions in clinical notes were illegible, thus resulting in medication errors. Advice was given to the hospital in the form of a summary report of inspection, but no advisory/warning letter was issued.

2.23 As the irregularities mentioned in paragraph 2.22 generally highlighted inadequacies in hospital procedures and practices relating to patient safety, which required prompt rectification or improvements, it would appear that the DH should issue advisory or warning letters to the hospitals concerned in accordance with its guidelines (see para. 2.17).

Disseminating good practices to address common irregularities

2.24 Audit's scrutiny of DH inspection reports completed in recent years for six selected private hospitals (Hospitals A to F) revealed that there were frequent irregularities of similar nature (i.e. common irregularities) found in some of these private hospitals. Table 3 shows examples of common irregularities identified during inspections.

Note 9: *Under the registration system for Chinese medicine practitioners set up in 2000, a registered Chinese medicine practitioner is professionally qualified for practising Chinese medicine in Hong Kong. The system provides transitional arrangements for those who were practising Chinese medicine before 2000 but have not yet obtained the recognised professional qualifications to continue their practice under restricted terms as listed Chinese medicine practitioners.*

Table 3

Common irregularities identified during DH inspections

Irregularity concerning	Hospital	2007	2008	2009	2010	2011
(a) availability and checking of emergency trolleys for resuscitation purpose (Note 1)	A			×		×
	B			×		×
	C	×	×			×
	D		×	×		
	E			×		×
	F					×
(b) monitoring of the temperature of medication fridges to ensure that the temperature is suitable for storing drugs and vaccines (Note 2)	A	×	×	×		
	B	×	×			×
	C	×	×	×		×
	D	×	×			
	E	×	×	×	×	
	F	×	×	×		
(c) dangerous drugs (Note 3)	A		×	×		
	B			×	×	×
	C	×				
	D	×	×			×
	E		×	×		×
	F	×	×		×	

Legend: × The irregularity was found in at least one ward/unit of the hospital concerned.

Source: DH records

Note 1: Examples of irregularities included: (a) no emergency trolley was found in a service unit; (b) only one emergency trolley was placed in an operating theatre room for shared use in operating theatres, recovery room and endoscopy unit; (c) the items in the emergency trolleys were not regularly checked; (d) there were expired items (e.g. endotracheal tubes and a 3-way connector) kept in the emergency trolleys; and (e) access to emergency trolleys was blocked by objects.

Note 2: Examples of irregularities included: (a) use of a defective fridge to store vaccines and drugs; (b) the fridge temperature was not checked twice daily as recommended; and (c) the fridge temperature was found outside the recommended range of 2°C to 8°C.

Note 3: Examples of irregularities included: (a) the records of dangerous drugs had not been properly kept in accordance with the Dangerous Drugs Ordinance (Cap. 134); and (b) dangerous drugs were not checked once in every shift.

2.25 The fact that there were frequent irregularities of similar nature identified during inspections of private hospitals is a cause for concern. The DH needs to strengthen its efforts in disseminating relevant good practices to help private hospitals address such common irregularities. In this connection, Audit notes that the DH has been disseminating good practices and learning points of cases to all private hospitals through an annual newsletter (i.e. Patient Safety Digest) and through letters for important issues. The cases chosen for sharing were mainly selected from complaints, sentinel events and other events reported to the DH. More recently, the Patient Safety Digest issued in September 2012 also covered cases relating to findings of DH inspections. Audit welcomes the DH's initiative and considers it necessary for the DH to sustain its efforts.

Stepping up regulatory actions

2.26 The DH conducts inspections to monitor private hospitals' compliance with the Ordinance and the COP. The regulatory actions that can be taken by the DH include issuing advisory/warning letters, and imposing such conditions relating to accommodation, staffing and equipment as it thinks fit on the certificates of registration issued to private hospitals (see paras. 2.17 and 2.18). Under the provision of the Ordinance, the DH may at any time cancel the registration or refuse the re-registration of a private hospital if any condition relating to accommodation, staffing or equipment is unfit (see para. 2.18(b)). Cancelling the registration or refusing the re-registration of a private hospital is a drastic step, and the DH has not invoked such actions. Neither has it initiated any prosecution action against any party under the Ordinance (see para. 2.18(a)).

2.27 Audit also noted that the regulatory actions taken by the DH were not always effective to ensure prompt remedial actions by the hospitals concerned. Case 1 is an example.

Case 1

Admitting maternity cases to non-maternity wards

1. To ensure adequate care for the maternity patients and their newborns, the COP sets out special requirements on accommodation, staffing and equipment for a registered maternity home. A non-maternity ward generally does not meet such special requirements. On 6 May 2011, the ORHI inspected one private hospital and found that it had a regular practice of admitting maternity cases to non-maternity wards.

2. On 8 June 2011, the ORHI issued a regulatory letter to the hospital requesting it to restrict admission of maternity cases to the registered maternity home (Note).

3. On 30 June 2011, the ORHI conducted a follow-up inspection and noted that the hospital was still regularly admitting maternity cases to non-maternity wards.

4. On 11 July 2011, the ORHI issued another regulatory letter to the hospital requesting it to restrict admission of maternity cases to the registered maternity home. In the letter, the ORHI warned the hospital that the Director of Health might at any time cancel the registration or refuse re-registration of the hospital if any condition relating to accommodation, staffing and equipment was unfit.

5. In October and November 2011, the ORHI conducted further inspections on the hospital. The ORHI found that the hospital was still regularly admitting maternity cases outside the registered maternity home. Over 100 maternity patients a month were admitted to non-maternity wards in the past few months. The overall nursing manpower (particularly midwives) for taking care of all maternity patients and newborns was considered undesirable. The ORHI advised the hospital to rectify the irregularity immediately and to report the actions taken in writing to the DH no later than 15 February 2012. In the Certificate of Registration of a Maternity Home issued to the hospital in December 2011, the DH also imposed a condition that the hospital should restrict admission of maternity cases to the registered home and report action taken to the DH not later than 17 February 2012.

Case 1 (Cont'd)

6. In December 2011, the hospital applied for expansion of its maternity services from 25 to 35 maternity beds. In January 2012, the ORHI conducted an inspection to assess the application, and observed that the staff arrangement of the intended expanded maternity services was insufficient. In early February 2012, the hospital submitted further information to substantiate that measures to address the insufficiencies had been put in place. On 22 February 2012, the DH approved the hospital's expansion of its maternity services, and issued a new Certificate of Registration of a Maternity Home to the hospital, with the condition that the hospital should restrict admission of maternity cases to the registered maternity home.

Source: *DH records*

Note: *As at August 2012, 10 of the 12 private hospitals were providing maternity services in Hong Kong. Apart from being registered as "hospitals" under the Ordinance, these hospitals were also registered as "maternity homes" under the same Ordinance, which states that maternity home is any premises used or intended to be used for the reception of pregnant women or of women immediately after childbirth.*

2.28 Case 1 shows that the hospital concerned had not taken prompt rectification despite the DH's repeated advice or warnings given in its regulatory letters that admission of maternity cases should be restricted to the registered maternity home (see paras. 2, 4 and 5 in Case 1). It is unacceptable that it took over nine months (i.e. May 2011 to February 2012) to rectify the irregularities found. The DH needs to critically review the adequacy of its regulatory actions, including the need to step up its actions (e.g. initiating prosecution actions) if serious irregularities identified are not rectified within a reasonable timeframe. As a good practice, once a serious irregularity is detected, the DH should immediately impose a timeframe within which such irregularity should be rectified and take prompt follow-up actions.

Audit recommendations

2.29 **Audit has *recommended* that the Director of Health should:**

(a) **indicate explicitly a regulatory letter issued to a private hospital as an advisory letter or a warning letter;**

(b) **issue advisory/warning letters to private hospitals when serious irregularities are detected during inspections in accordance with DH guidelines;**

(c) **strengthen DH efforts in disseminating relevant good practices to help private hospitals address frequent irregularities of similar nature identified during inspections;**

(d) **critically review the adequacy of DH regulatory actions, including the need to step up its actions if serious irregularities identified are not rectified within a reasonable timeframe; and**

(e) **once a serious irregularity is identified, impose a timeframe within which the irregularity should be rectified, and take prompt follow-up actions.**

Response from the Administration

2.30 The Director of Health welcomes the audit recommendations. She has said that the DH will take steps to introduce improvement measures.

Closure arrangements

2.31 One of the private hospitals, namely the Hong Kong Central Hospital which is situated in leased premises, decided in June 2012 to cease operation with effect from September 2012, following a decision by the landlord to terminate the tenancy agreement with the hospital. In order to safeguard patients' interests and ensure compliance with relevant legal requirements, the DH instructed the hospital to submit a plan on its closure arrangements. The plan should include, among others, arrangements for existing in-patients, handling of medical records, and disposal of hospital equipment and wastes. The DH also reminded the hospital to ensure that the continuity of care of patients would not be adversely affected by its cessation of services, and to observe relevant laws and codes of practice. Besides, before the closure of the hospital, the DH had scrutinised the hospital's weekly submission of service data, as well as conducted inspections of the hospital to monitor its service provision and closure arrangements.

2.32 As closure of a private hospital is unprecedented in Hong Kong, Audit encourages the DH to learn from this incident and develop guidelines to assist private hospitals in the closure arrangements. The DH may also use the guidelines to assist its staff in the conduct of the related inspection work.

Audit recommendations

2.33 **Audit has *recommended* that the Director of Health should:**

(a) **formulate guidelines to assist private hospitals in the closure arrangements in case they intend to cease operation; and**

(b) **develop procedures to assist DH staff in the inspection work concerning closure of private hospitals.**

Response from the Administration

2.34 The Director of Health welcomes the audit recommendations. She has said that:

(a) the DH has started formulation of guidelines to assist private hospitals in closure arrangements; and

(b) procedures are also being developed to assist DH staff in inspection work concerning closure of private hospitals.

PART 3: MONITORING OF SENTINEL EVENTS AND COMPLAINTS

3.1 This PART examines the DH's monitoring of sentinel events (see Note 3 to para. 1.7) and complaints in private hospitals. Audit has found room for improvement in the following areas:

(a) monitoring sentinel events in private hospitals (paras. 3.2 to 3.24); and

(b) handling complaints against private hospitals (paras. 3.25 to 3.39).

Monitoring sentinel events in private hospitals

3.2 Under the COP, private hospitals should comply with the requirements on the management of medical incidents (including sentinel events). Management of such incidents includes designation of a senior staff to coordinate the immediate response to the incident, establishment of procedures to communicate the nature of the incident to patients and their families, notification of the incident to the DH, investigation of the incident, and implementation of recommendations to prevent future occurrence.

3.3 Since 1 February 2007, the DH has set up a sentinel event reporting system. Under the system, all private hospitals are required to report a sentinel event to the DH within 24 hours upon occurrence of the event. The objectives of the reporting system are, among others, to:

(a) identify events that require immediate remedy;

(b) understand the causes that underlie the event, and on changing the organisation's system and procedures, to reduce the probability of occurrence of such an event in the future;

(c) disseminate the lessons learnt to other private hospitals; and

(d) facilitate the DH to monitor the performance of private hospitals.

According to the DH, in designing the reporting system, reference has been made to the guidelines issued by the World Health Organisation, i.e. successful sentinel event reporting systems should be non-punitive and confidential, and lead to constructive responses. Reporting of sentinel events under the system was therefore voluntary and the DH encourages private hospitals to report sentinel events so that lessons learnt could be shared among hospitals and healthcare workers. Appendix D shows the list of sentinel events reportable to the DH.

3.4 Upon receipt of the notification of a reportable sentinel event, the DH will gather preliminary information from the hospital concerned. If the event constitutes high public health risk, the DH will visit the hospital and conduct its own investigation. The private hospital concerned is required to submit a full investigation report (Note 10) within 4 weeks upon occurrence of the event. The DH will examine the investigation report and follow up on the implementation of the remedial measures during subsequent inspections. The DH will also disseminate information on the lessons learnt and the recommended improvement measures to facilitate learning among private hospitals.

3.5 From 2007 to 2011, the DH received 137 reports of sentinel events from private hospitals (see Table 4), and conducted on-site investigations on 17 of them. Since January 2010, the DH has revised the list of reportable sentinel events, in order to tally with that of the Hospital Authority (HA) to allow for better comparison.

Note 10: *The full investigation report should indicate whether a root cause of the event has been identified, include a remedial action plan setting out the proposed improvement measures, and state the mechanism to be put in place for monitoring the implementation of the improvement measures.*

Table 4

Sentinel events reported by private hospitals (2007 to 2011)

Sentinel event	Number of cases					
	2007	2008	2009	2010 (Note)	2011 (Note)	Total
1. Unanticipated death or serious injury or complications during or shortly after operation or interventional procedures	11	12	15	2	2	42
2. Maternal death/serious maternal injury	2	8	12	3	0	25
3. Perinatal death/serious injury	14	4	19	3	1	41
4. Unintended retention of foreign bodies after surgery or interventional procedures	1	2	1	0	1	5
5. Wrong site surgery/ interventional procedures	0	1	1	0	0	2
6. Others	11	6	4	0	1	22
Total	39	33	52	8	5	137

Source: DH records

Note: With effect from 2010, the DH has revised the list of reportable sentinel events, which has in particular, excluded common birth trauma and common surgical complications. Therefore, the reduction in the number of reported cases in 2010 and 2011 should not be interpreted as a decrease in medical incidents.

3.6 Given the voluntary nature of the sentinel event reporting system, there is a risk of under-reporting. Therefore, there are limitations inherent in the statistics so compiled, and should only be taken as one of the indicators to monitor the quality of the private hospitals in providing healthcare services.

Reporting of sentinel events and submission of investigation reports

3.7 Under the sentinel event reporting system, a private hospital is required to:

(a) report to the DH a sentinel event within 24 hours upon occurrence of the event (see para. 3.3); and

(b) submit to the DH a full investigation report within 4 weeks upon occurrence of the event (see para. 3.4).

These requirements have also been incorporated into the COP.

3.8 Audit analysis of DH records revealed that:

(a) a few private hospitals had reported more sentinel events than the others. For example, in 2009, the number of sentinel events reported by two hospitals had accounted for 60% of the total 52 sentinel events reported in the year by all private hospitals (Note 11). Owing to the voluntary nature of the reporting system, no conclusion can be drawn solely based on the statistics compiled, but the results call for the DH's attention; and

(b) in many cases, it took a long time for private hospitals to report sentinel events or submit full investigation reports to the DH. Details are shown in Table 5.

Note 11: *In 2010 and 2011, one of the two hospitals continued to account for a high ratio of the total 8 and 5 sentinel events reported by all private hospitals in the two years.*

Table 5

Time taken to report sentinel events and submit investigation reports (2007 to 2011)

	Number of sentinel events (a)	Reporting of sentinel events (Number of cases)		Submission of investigation reports (Number of cases)	
		Within 24 hours (b)	Not within 24 hours (c) = (a) − (b)	Within 4 weeks (d)	Not within 4 weeks (e) = (a) − (d)
2007	39	0	39 (Note 1)	17	22 (Note 1)
2008	33	12	21	17	16
2009	52	24	28	17	35
2010	8	5	3	2	6
2011	5	2	3	2	3
Total (2008 to 2011)	98 (100%)	43	55 (56%) (Note 2)	38	60 (61%) (Note 3)

Source: Audit analysis of DH records

Note 1: Prior to 2008, private hospitals were required to report a sentinel event to the DH within 3 days and submit a full investigation report within 2 weeks upon occurrence of the event. For 5 cases in 2007, no full investigation reports were submitted (see para. 3.10).

Note 2: Excluding one extreme case (which took 259 days — see Case 2 in para 3.9), the average time taken for the 54 (55 − 1) cases was 12.8 days, ranging from 2 to 115 days.

Note 3: Excluding two extreme cases (which took 37.9 and 40 weeks), the average time taken for the 58 (60 − 2) cases was 8.2 weeks, ranging from 4.1 to 26.4 weeks.

3.9 As can be seen from Table 5, 56% of the sentinel events in private hospitals from 2008 to 2011 were not reported to the DH within 24 hours of their occurrence. The longest time taken for reporting a sentinel event was 259 days (see Case 2).

Case 2

Long time taken for reporting a sentinel event

1. In December 2007, one private hospital found that a patient had bowel perforation after a surgical operation, but the case was not reported to the DH until August 2008. The following shows a chronology of key events:

13 December 2007	The patient had a laparoscopic gynecological surgery.
17 December 2007	The patient presented symptoms of suspected bowel perforation.
18 December 2007	Perforation of transverse colon was found. An emergency surgery was performed.
25 March 2008	A follow-up surgery was performed for the patient.
30 April 2008	The patient was discharged.
14 August 2008	The patient lodged a complaint against the hospital.
28 August 2008	The hospital notified the case to the DH as a sentinel event.
18 September 2008	The hospital submitted an investigation report to the DH.

2. In investigating this case, the DH made verbal enquiry with the hospital. No visit to the hospital was conducted. No written enquiry was issued. According to the "Summary of Sentinel Event Investigation" compiled by the DH, this case was classified as a sentinel event under the category of "Other complications during or shortly after operation/interventional procedures", resulting in serious harm to the patient. The root cause was identified as "Complications of surgery". The DH did not issue any advisory/warning letter to the hospital.

Audit comments

3. Although this medical incident was a reportable sentinel event according to DH guidelines, the hospital did not report it to the DH promptly in December 2007. It only reported the case to the DH in August 2008, after receiving a complaint from the patient. This was not in line with the requirements of the sentinel event reporting system.

4. Despite the long time taken (259 days after occurrence of the event) by the hospital to report this sentinel event to the DH, the DH had only made verbal enquiry with the hospital about the case, without follow-up in writing or paying a visit to the hospital to further investigate into the case. The DH did not issue any advisory/warning letter to the hospital in this regard. Audit considers that there is room for the DH to strengthen its monitoring of sentinel events.

Source: DH records

3.10 Table 5 also shows that, from 2008 to 2011, in 60 (61%) of the 98 reported cases of sentinel events, private hospitals did not submit the full investigation reports to the DH within 4 weeks of the occurrence of the events. In five cases relating to sentinel events that occurred in 2007 (after the implementation of the sentinel event reporting system in February 2007 — see para. 3.3), the hospitals concerned had not submitted any investigation reports to the DH. Audit could not find evidence that the DH had taken adequate follow-up actions on these five cases.

3.11 The primary objective of the sentinel event reporting system is to identify areas for improvement in the quality and safety of healthcare services. Through the reporting system, the DH monitors the operation of private hospitals and ensures that they take prompt actions in accordance with established mechanisms so as to minimise the harm caused to patients. The long time taken by private hospitals to report sentinel events and to submit full investigation reports to the DH undermines the effective operation of the sentinel event reporting system. Notwithstanding this, the DH seldom issued advisory/warning letters to the hospitals concerned to remind them to strictly follow the required procedures. From 2008 to 2011, the DH only issued three regulatory letters in respect of the 55 cases of delays in reporting of sentinel events. For example, in one of the cases, a newborn sustained a head injury during delivery in a private hospital on 4 October 2011, and the hospital concerned had not immediately reported the event to the DH as required. Subsequently, there were media reports about the case. On 31 October 2011, the DH issued a regulatory letter to the hospital urging it to report sentinel events in a timely manner in the future. There is a need for the DH to closely monitor the effective implementation of the sentinel event reporting system, including issuing advisory/warning letters to private hospitals when they do not follow the procedures as required under the system, and ensuring that they take prompt remedial actions.

Regulatory actions on sentinel events

3.12 In February 2010, the Independent Commission Against Corruption (ICAC) completed an assignment study on the DH's registration and inspection of private hospitals and nursing homes. The assignment report stated that:

(a) in enforcing the regulatory provisions of the Ordinance, the DH adopted a strategy of "partnership approach" towards private hospitals. When investigating reports on sentinel events, the DH only issued advisory or warning letters to the private hospitals concerned if the cases were

substantiated, and the number of such letters issued was few. The DH did not refer cases involving the professionalism of doctors and nurses to the Medical Council of Hong Kong (MCHK) or the Nursing Council of Hong Kong (NCHK) for action. So far, the DH had not refused any registration or re-registration of private hospitals, nor had it prosecuted any party under the Ordinance. In view of growing public concerns about the standard of healthcare services and the monitoring of sentinel events, the DH's enforcement strategy was a cause for concern; and

(b) the study had identified that one of the major shortfalls in the system under study was that the offences and sanctions provided under the Ordinance were grossly inadequate to deter attempts to breach the registration conditions. Breaches relating to registration conditions and sentinel events normally only resulted in the issue of advisory or warning letters, which had little impact on private hospitals.

3.13 The ICAC therefore recommended, among others, that:

(a) the Administration should review the offences and sanctions under the Ordinance with a view to bringing them up-to-date, and making provisions for sanctions to deter breaches of the registration conditions; and

(b) the DH should refer the cases of sentinel events concerning the professionalism or conduct of doctors or nurses to the MCHK or the NCHK for investigation as appropriate.

3.14 The Legislative Council (LegCo) Panel on Health Services (LegCo Panel) also discussed the mechanism for handling sentinel events at its meetings held in November 2009, June 2010 and November 2011. Members expressed concerns that private hospitals would not be penalised for non-compliance with the requirements on management of sentinel events, other than issue of advisory or warning letters from the DH based on the severity of the case. They urged the Administration to review the Ordinance to increase the deterrent effect against non-compliance. In November 2011, the Administration informed the LegCo Panel that it agreed to conduct a review of the Ordinance (see para. 6.6).

3.15 Regarding the ICAC's recommendation on referral of cases of sentinel events to the MCHK or the NCHK for investigation (see para. 3.13(b)), the DH informed the ICAC in June and August 2010 that:

(a) the DH considered that the referral of cases to the MCHK or the NCHK might impinge on patient privacy. Apart from privacy issues, the complainant was also required to provide first-hand information of the incident and be prepared to be a witness at a public inquiry should it become necessary; and

(b) hence, the DH was not in a position to directly refer cases to the MCHK or the NCHK. Nevertheless, the DH would make known to complainants all channels for making such complaints and would render its assistance where appropriate.

3.16 Audit reviewed some cases of sentinel events monitored by the DH. Audit noted that for those cases which might involve professional misconduct/substandard performance, the DH had made known to the complainants the proper channels for lodging their complaints. With a view to further enhancing the regulatory control of the private hospital services and upholding the professional standard of personnel working therein, the DH should consider directly referring cases of sentinel events involving professional misconduct/substandard performance to the MCHK or the NCHK for investigation and follow-up.

Public disclosure of sentinel events

3.17 Upon receipt of the notification of a sentinel event, the DH will gather preliminary information from the hospital concerned and assess whether there is a need to disclose details of the event to the public. From 2007 to 2011, the DH issued only three press releases relating to sentinel events in private hospitals. Besides, the DH also uploads an aggregated figure of sentinel events onto its website on a quarterly basis. However, identities of the private hospitals concerned and details of the sentinel events other than the category they fall into (see Table 4 in para. 3.5) are not disclosed.

3.18 In discussing the mechanism for handling sentinel events in private hospitals in November 2011 (see para. 3.14), LegCo Members expressed concerns that the criteria for disclosing sentinel events and their details in private hospitals were different from those for public hospitals. The HA would consider disclosing a sentinel event in a public hospital if such event had immediate major impact on the public or involved a patient's death. On the other hand, the DH would only consider disclosing a sentinel event in a private hospital if such event had major impact on the public healthcare system, or if it constituted a persistent public health risk or involved a large number of patients.

3.19 LegCo Members also noted that under the sentinel event reporting system, private hospitals were required to develop their own policies and mechanisms to manage sentinel events, including whether to disclose the events to the public. Members were of the view that the Administration should devise a uniform mechanism for all private hospitals to follow. Members considered that the DH should require private hospitals to make public all sentinel events without compromising the privacy of patients concerned.

3.20 Audit considers that the FHB needs to consider how best to further align the criteria for disclosing sentinel events in both private and public hospitals as far as practicable. The DH also needs to consider issuing guidelines to private hospitals for the surveillance, reporting and management of sentinel events and the setting up of relevant policies and procedures, particularly the criteria for disclosing such events to the public. The voluntary reporting of sentinel events is also an issue that needs to be addressed in the future review of the Ordinance (see para. 1.8).

Audit recommendations

3.21 **Audit has *recommended* that the Director of Health should:**

Reporting of sentinel events and submission of investigation reports

(a) **closely monitor the effective implementation of the sentinel event reporting system, including issuing advisory/warning letters to private hospitals when they do not follow the required procedures and ensuring that they take prompt remedial actions;**

Regulatory actions on sentinel events

(b) **consider directly referring cases of sentinel events involving professional misconduct/substandard performance to the MCHK or the NCHK for investigation and follow-up;**

Public disclosure of sentinel events

(c) **consider issuing guidelines to private hospitals for the surveillance, reporting and management of sentinel events, as well as the setting up of relevant policies and procedures, particularly the criteria for disclosing sentinel events to the public; and**

(d) **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.**

3.22 **Audit has also *recommended* that the Secretary for Food and Health should, in collaboration with the Director of Health, consider aligning the systems and practices for disclosing sentinel events in both private and public hospitals as soon as possible.**

Response from the Administration

3.23 The Director of Health accepts the audit recommendations in paragraph 3.21. She has said that:

(a) the DH will closely monitor the effective implementation of the sentinel event reporting system and issue regulatory letters to non-compliant private hospitals;

(b) for cases of sentinel events involving professional misconduct or substandard performance of significant public health impact, the DH would refer the cases to professional boards and councils for investigation and follow-up; and

(c) in designing the disclosure mechanism, the DH will make reference to the international practices, such as the guidelines issued by the World Health Organisation, which states that successful reporting systems should be non-punitive and confidential, and lead to constructive responses (see para. 3.3).

3.24 The Secretary for Food and Health accepts the audit recommendation in paragraph 3.22.

Handling complaints against private hospitals

3.25 Under the COP, private hospitals are required to set up a mechanism for handling complaints made by patients or their representatives. The mechanism consists of procedures for receiving, investigating and responding to complaints. The COP also requires private hospitals to provide to the ORHI a complaint digest on a monthly basis. The complaint digests show a brief description of the complaints received, their nature, the results of investigation, and the actions taken by the hospitals. Upon receipt of complaint digests from private hospitals, the ORHI will screen the digests for any potential sentinel events and cases that require further investigation and action.

3.26 From 2009 to June 2011, private hospitals received a total of 2,063 complaints (see Table 6).

Table 6

Analysis of complaints received by private hospitals (2009 to June 2011)

Category of complaint	2009 (Number)	2010 (Number)	2011 (six months — Note) (Number)
Staff performance (see para. 3.37)	408	347	155
Staff manner	127	94	58
Communication	7	29	10
Inadequate staffing	0	2	1
Environment	23	29	10
Facilities and equipment	13	21	5
Charges (see para. 3.37)	153	140	58
Administrative procedure	69	48	24
Others	72	115	45
Total	872	825	366
		2,063	

Source: *DH records*

Note: *At the time of audit fieldwork in August 2012, statistics with detailed analysis of complaints were only available up to June 2011.*

An analysis of the complaints received by private hospitals for the period shows that a few hospitals had received a disproportionately high number of complaints. For example, complaints for one hospital accounted for 37%, 43% and 46% of the total complaints received by all private hospitals in 2009, 2010 and 2011 respectively. This calls for the DH's attention.

3.27 Members of the public may also lodge a complaint with the ORHI about the services of private hospitals. Apart from requiring private hospitals to submit investigation reports for review, the ORHI will also conduct its own investigations into these cases.

3.28 From 2009 to 2011, the ORHI received 246 complaints concerning private hospitals' services (see Table 7), and conducted follow-up visits for 17 complaints, and issued 11 advisory or warning letters.

Table 7

Analysis of complaints received by ORHI (2009 to 2011)

Category of complaint (Note)	2009 (Number)	2010 (Number)	2011 (Number)
Staff performance (see para. 3.37)	54	48	38
Staff manner	6	1	5
Communication	0	19	10
Inadequate staffing	0	4	5
Environment	2	4	4
Facilities and equipment	3	4	3
Charges (see para. 3.37)	16	9	16
Administrative procedure	14	26	14
Others	3	5	5
Overall (Note)	83	89	74
		246	

Source: DH records

Note: A complaint may cover one or more categories of complaint.

An analysis of complaints received by the ORHI from 2009 to 2011 also shows that 64% of the complaints related to four private hospitals. This again calls for the DH's attention.

3.29 Where there is a possibility that a complaint case involves professional misconduct or substandard performance, the ORHI will make known to the complainant all proper channels (e.g. the MCHK and the NCHK) for lodging the complaint and will render assistance as appropriate.

Submission of complaint digests

3.30 Audit reviewed the submission of complaint digests (see para. 3.25) by private hospitals from January 2011 to March 2012, and noted that five private hospitals had not always submitted the complaint digests monthly as required. These hospitals submitted the complaint digests on a quarterly to half-yearly basis. For example, it was only in February 2012 when the ORHI received the complaint digest from one hospital relating to the complaints it received during the period from July to December 2011. Late submission of complaint digests will delay the process of DH in screening the digests for any sentinel events unreported and cases that require further investigation (see para. 3.25). There is a need for the DH to ensure that all private hospitals submit their complaint digests monthly in accordance with the COP.

Issuing advisory/warning letters for complaint cases

3.31 According to DH guidelines, the DH will issue an advisory letter to the private hospital concerned if the complaint issues are substantiated and/or where one or more of the following irregularities are noted in the course of the ORHI's investigation of the complaint:

(a) non-compliance with established policies and procedural guidelines;

(b) repeated reporting of a similar event within a short period of time;

(c) lack of guidelines/protocols on essential procedures that link to patient safety; or

(d) inadequacies that require prompt rectification or improvements.

If the above irregularities concern accommodation, staffing or equipment, a warning letter will be issued.

3.32 Audit found that although the DH noted irregularities in the course of its investigation of a number of complaint cases, it did not issue advisory or warning letters to the private hospitals concerned. Case 3 is an example.

Case 3

No advisory or warning letter issued to a hospital for irregularities noted

From 2009 to 2011, the ORHI received a total of 32 complaints against the services of one private hospital. The ORHI's investigation results for 3 of these complaint cases are as follows:

Complaint 1: In March 2009, the DH received a complaint alleging that a patient was given a triple dose of the recommended dosage of an oral medication during the stay in the hospital. After investigation, the ORHI found that the dispensing guidelines were not followed. However, the ORHI did not issue any advisory letter/warning letter to the hospital. The case was closed in July 2009.

Complaint 2: In March 2011, the ORHI received a complaint concerning a patient being mistakenly provided with a bag of take-home drugs, which bore another patient's name. After investigation, the ORHI found the case substantiated. However, the ORHI did not issue any advisory letter/warning letter to the hospital. The case was closed in May 2011.

Complaint 3: In December 2011, there was a media report that the parents of a patient were dissatisfied with the hospital's medical staff who had not obtained their consent prior to blood collection from the patient. The ORHI's investigation of the case found that the medical staff concerned did not follow the hospital's guidelines on blood collection. Although the ORHI found the case substantiated, it did not issue any advisory or warning letter to the hospital. The case was closed in January 2012.

Source: DH records

3.33 As the irregularities in Case 3 highlighted non-compliance with established procedural guidelines or inadequacies that required prompt rectification, it would appear that the DH should issue advisory or warning letters to the hospital concerned in accordance with its guidelines (see para. 3.31).

Analysing causes of complaints to identify systemic issues

3.34 Complaints are a valuable source of information to reveal substandard service or malpractice (if any) of a private hospital for the DH's attention. DH management should regularly receive and critically review reports regarding handling of complaints on private hospitals' services. Such reports should include analysis of the causes of complaints to identify systemic issues for the DH's and hospital management attention as well as areas where service improvements are needed.

3.35 According to DH guidelines, the ORHI has to submit, on a quarterly basis, a summary of complaints it handled to Assistant Director (Health Administration and Planning). In practice, the ORHI prepares monthly a summary of complaints (showing the statistics of complaints and highlighting the important cases) for discussion at its monthly meetings and for submission to the Assistant Director for review. Audit noted that the summary of complaints covered only those complaints on private hospitals' services which the ORHI directly received (i.e. complaints received by private hospitals were not included — see para. 3.36).

3.36 Regarding complaints received by private hospitals, the DH has not provided any guidelines on whether the ORHI has to compile regularly a summary of such complaints (mainly based on the complaint digests submitted by private hospitals) to DH management for review. Audit found no record showing that the ORHI had prepared any analysis or summary of complaints (or other similar reports) for submission to DH senior management. There is a need for the DH to formulate relevant guidelines in this regard.

3.37 Tables 6 and 7 (see paras. 3.26 and 3.28) show that "staff performance" and "charges" are the two major areas about which complaints were made against private hospitals. As a good practice, the DH needs to critically analyse the causes of complaints to identify systemic issues for management attention. The DH also needs to regularly disseminate its analysis results for facilitating private hospitals to make improvements on their services.

Audit recommendations

3.38 **Audit has *recommended* that Director of Health should:**

Submission of complaint digests

(a) **take measures to ensure that private hospitals submit their complaint digests to the ORHI monthly in accordance with the COP;**

Issuing advisory/warning letters for complaint cases

(b) **issue advisory or warning letters to private hospitals when serious irregularities are detected during investigation of complaints;**

Analysing causes of complaints to identify systemic issues

(c) **provide guidelines requiring the ORHI to submit regularly (e.g. monthly) a summary of complaints received by private hospitals to DH senior management for review, and ensure that the guidelines are properly followed;**

(d) **critically analyse the causes of complaints on a regular basis to identify systemic issues for management attention as well as areas where service improvements are needed; and**

(e) **disseminate the analysis results in (d) above for private hospitals to share the lessons learnt and make further improvements on their services.**

Response from the Administration

3.39 The Director of Health accepts the audit recommendations.

PART 4: PRICE TRANSPARENCY IN HOSPITAL CHARGES

4.1 This PART examines the Government's efforts in enhancing price transparency in the fees and charges of private hospitals.

Fees and charges information required of private hospitals

4.2 According to the COP, patients have the right to know the fees and charges prior to consultation and any procedures in private hospitals. The COP requires that private hospitals have to prepare a schedule of charges in respect of room charges, investigative and treatment procedures, medical supplies, medicines, medical report, photocopy of medical records, and any charges that will be levied. The schedule should be available for reference by patients at the admission office, cashier and wherever appropriate. The COP also requires that the schedule of charges is updated when there is a change in the charges, and that patients are informed of the charges of services where practicable.

4.3 Besides, the DH requires private hospitals to report to it information on their fees and charges on an annual basis and to make further reporting once there is any change. During its inspections of private hospitals, the DH checks the hospitals' compliance with the COP requirements. From 2009 to June 2012, the DH detected no non-compliant case regarding provision of charging information by private hospitals.

Communicating price information to patients

4.4 In recent years, there had been growing public concerns about the level and increase of private hospital charges, and the lack of price transparency in private hospitals. According to the Medical Claims Statistics (Note 12) compiled by the Hong Kong Federation of Insurers, the billed amounts for in-patient claims for private, semi-private and ward accommodation had increased by 6.5%, 3.8% and 6.5% respectively in 2009 as compared to 2008.

Note 12: *The statistics were compiled based on data provided by 18 of the largest medical underwriters in Hong Kong, which represented a total of 86% of the market earned premium in 2009. The statistics included only group medical insurance policies.*

4.5 According to a survey published by the Consumer Council in December 2011 regarding charges for maternity package (including items for maternal and baby care), there was a big increase in the number of complaints lodged with the Council concerning obstetric services of private hospitals (Note 13). These complaints were mainly on the unexpected price increase, and ambiguous or unreasonable charges (Note 14). Some usual miscellaneous items (e.g. spouse attendance at time of delivery or caesarean section, fetal heart monitoring during labour, forceps delivery or vacuum extraction, and incubator or phototherapy for the baby) were not included in the packages of some private hospitals and could end up as a huge sum in the bill.

4.6 Charges have always been a common source of complaints against private hospitals. Of the 2,063 complaints received by private hospitals from 2009 to June 2011, 351 (17%) related to charges. As for the 246 complaints received by the ORHI concerning private hospitals' services from 2009 to 2011, 41 (17%) related to charges. Audit examined some of such complaint cases handled by the DH and noted that the complaints were mainly on unexpected price increase, unreasonable charges, and price information (including doctor fees) not communicated in advance to patients.

4.7 Although the COP requires private hospitals to make available a schedule of charges for patients' reference and to inform them of any changes (see para. 4.2), there are no detailed requirements on the extent of information to be provided and the means for communication of such information to patients. Besides, because the COP does not form part of the Ordinance and has no legal backing, the DH can only encourage and remind private hospitals to communicate price information (covering all items) to the patients prior to any procedures or operations. The DH also needs to take follow-up actions (e.g. issue of advisory/warning letters) on those private hospitals failing to effectively communicate price information to patients.

Note 13: *The number of complaint cases had increased from 2 and 3 respectively in 2009 and 2010, to 25 during the first 10 months in 2011.*

Note 14: *For example, in one case, the complainant's wife opted for caesarean section package which he estimated to cost around $45,000. It was not until he saw the bill that he realised the actual charge was over $70,000. This was because an additional sum of $5,000 was charged for emergency caesarean section performed an hour in advance upon the request of the attending doctor, and there were also additional charges of various medical items, along with an administration fee of $15,000.*

Promoting price transparency

4.8 Transparent price information on the fees and charges of private hospitals helps consumers anticipate their health costs and reduce the possibility of unexpected expenses. It also helps consumers make more informed choices about their healthcare.

4.9 In July 2012, Audit reviewed the websites of the 12 private hospitals (Hospitals A to L) to ascertain the availability of their charging information to the public, with a focus on room charges and charges for operations. Audit found that there was still scope for improvement in promoting price transparency for individual private hospitals. Audit findings are summarised in Table 8.

Table 8

Charging information provided on the 12 private hospitals' websites (July 2012)

Hospital	Room charges	Obstetric packages (Note 1)	Operations (excluding obstetric packages) offered at packaged charges	Operations other than those offered at packaged charges
A	✓	✓	✓ (Note 2)	×
B	✓	Not applicable	×	×
C	✓	✓	✓ (Note 2)	✓ (Note 3)
D	✓	✓	×	✓ (Note 4)
E	✓	✓	✓ (Note 2)	×
F	✓	✓	✓ (Note 2)	×
G	✓	✓	✓ (Note 2)	✓ (Note 4)
H	✓	✓	×	×
I	✓	✓	×	×
J	✓	✓	✓ (Note 2)	×
K	✓	Not applicable	×	×
L	✓	✓	✓ (Note 2)	×

Source: Audit research

Note 1: Other than two hospitals which did not provide obstetric services, the other 10 hospitals provided price information on obstetric service packages (vaginal delivery and caesarean section). For vaginal delivery, general obstetric services such as basic labour ward facilities and general observation and care were included in the package. For caesarean section, services such as pre-operative preparation care, operation room fee and post-operative routine nursing care and observation were included. However, in both vaginal delivery and caesarean section, doctor fees were often not included.

Note 2: These hospitals provided information on packaged charges for various operations. The number of packages offered by each hospital varied significantly, ranging from 1 to over 80 packages. Packages offered by most hospitals often did not include doctor fees. However, for Hospital G, such fees were often included.

Note 3: Operation charges (such as charges for operating theatre) for more than 30 types of operations were provided. However, doctor fees were not included.

Note 4: These two hospitals were able to provide comprehensive price information regarding some common operations. They provided statistical information such as the mean, median, maximum and minimum charges for operating theatres, doctor fees, hospital charges (e.g. room charges, medication fees and investigation fees), and total invoice amounts for common operations performed in the past.

4.10 The price information available on the websites of the private hospitals listed in Table 8 varied considerably. Apart from services which were offered at packaged charges, most hospitals could not provide comprehensive price information for their services. Hospitals D and G demonstrate that it is possible to provide comprehensive price information regarding some common operations. There is a need for further promoting price transparency of private hospitals.

4.11 Besides reviewing the 12 private hospitals' websites, Audit staff also anonymously visited their admission offices in May 2012 to ascertain the availability of charging information for a selected surgery. Audit staff requested price information on cholecystectomy (a common surgery) by laparoscopic and/or open procedures. Audit found that, of the 12 hospitals:

(a) 5 could provide information on the total charges (covering room charge, operation charge, doctor fee and anaesthetist fee) for laparoscopic and/or open procedures;

(b) 3 could provide information on the charges (covering room charge and operation charge) for laparoscopic and/or open procedures. However, doctor and anaesthetist fees were not included in the charges; and

(c) 4 indicated that the relevant information could only be provided after consulting the specialists.

4.12 Audit staff's visits of the 12 private hospitals revealed that only 5 hospitals could provide complete price information on the surgery concerned. Besides, the price information available varied among the hospitals. This did not facilitate price comparison, nor did it help customers make informed choices about their health care.

4.13 Audit noted that the HA made available comprehensive price information regarding private services provided by its hospitals (see Example 1). Audit also conducted research on the provision of price information, and identified some good practices adopted overseas (see Examples 2 and 3).

Example 1

Provision of price information by the HA

1. The HA publishes its charges for private patients in the Gazette and on its website. The published information includes in-patient fee per day, intensive care ward charge per day, and charges for various services (e.g. pathology services, radiology services, diagnostic/therapeutic procedures, operations, and rehabilitation and outreach services).

2. For operation charges, the HA classifies operations into different categories (i.e. minor, intermediate, major and ultra-major). A price range is specified for each category. The charges cover surgeon fee, administration of anaesthetics, medicines used in operation, and operating theatre expenses.

Source: Audit research

Example 2

Provision of price information in Singapore

1. Since January 2011, the Ministry of Health in Singapore has requested all private hospitals to submit their bill size data for the most common medical conditions for publication on its website. The published information include number of admission cases, average length of stay, and the 50th percentile (Note 1) and the 90th percentile (Note 2) bill size according to different ward classes of private hospitals. The published bill sizes reflect all hospital charges including doctors' professional fees.

2. Besides, the manager of a private hospital is required by law to ensure that every patient should be informed, on or before his admission to the hospital, of the estimated total charges which are likely to be incurred in respect of his hospitalisation and treatment.

Source: Audit research

Note 1: This means that 50% of patients pay the published amount or less, and 50% pay more than that amount. The figure provides an estimate of the typical bill sizes for patients.

Note 2: This means that 90% of patients pay the published amount or less, and 10% pay more than that amount. The figure provides an estimate of the upper range of bill sizes.

Example 3

Provision of price information in the USA

1. In the USA, a number of states have enacted some form of healthcare price transparency legislation, which makes price information available to consumers (e.g. requiring all hospitals, including private hospitals, to make information available upon request or requiring hospitals to submit price information to a state agency that makes the information publicly available). Besides, according to a report by America's Health Insurance Plans (an industry group), at least 25 states have price transparency initiatives that provide publicly accessible websites with healthcare price information.

2. For example, in Wisconsin, the state contracted with the Wisconsin Hospital Association to collect and disseminate hospital information. Information on hospital charges for the 75 most common procedures is available on a website called "Price Point" which is run by the Wisconsin Hospital Association. The website displays information such as the number of discharges, the average length of stay, and the average and median charges for hospital services (Note) for individual hospitals, alongside state and county averages.

Source: Audit research

Note: Physician charges such as those for a surgeon or anaesthesiologist are not included.

4.14 In April 2012, the Government invited tenders from interested parties for developing new private hospitals at two sites and included a set of special requirements for hospital development (see paras. 1.6 and 6.7). To improve price transparency and better protect patients' interests, the Government requires new private hospitals to publish a comprehensive services price list, which provides charging information on room charges, diagnostic procedures, therapeutic services/procedures, nursing care, medication, consumables and equipment, and other miscellaneous items as advised by the Government. Such price list should be made available to the public, including through publication on the new hospitals' websites, and by making printed materials readily available and displaying the price list at major facilities within the hospitals such as admission offices and shroffs. Besides, the Government also requires that at least 30% of the in-patient bed days taken up in new hospitals each year must be for services provided through standard beds at packaged charges.

4.15 Audit welcomes the Government's initiative to improve price transparency in the charges of private hospitals. However, the new requirements are only applicable to new private hospitals. There remains much room for improving the price transparency in the charges of existing private hospitals for better protection of patients' interests. The Administration needs to explore ways to enhance the price transparency of existing private hospitals, taking into account the good practices adopted locally and overseas.

Audit recommendations

4.16 **Audit has *recommended* that the Director of Health should:**

(a) **remind private hospitals to effectively communicate price information (covering all items) to patients prior to any procedures or operations; and**

(b) **take follow-up actions (e.g. issue of advisory letters) on those private hospitals failing to effectively communicate price information to patients.**

4.17 **Audit has also *recommended* that the Secretary for Food and Health should, in collaboration with the Director of Health, take measures (e.g. by revising the COP) to further enhance the price transparency of private hospitals, taking into account the good practices adopted locally and overseas (see paras. 4.8 to 4.15).**

Response from the Administration

4.18 The Director of Health agrees with the audit recommendations in paragraph 4.16.

4.19 The Secretary for Food and Health agrees with the audit recommendation in paragraph 4.17.

PART 5: PERFORMANCE MEASUREMENT AND REPORTING

5.1 This PART examines performance measurement and reporting in respect of the DH's regulatory work on private hospitals.

Performance measures

5.2 Performance measurement, including developing and reporting performance measures, helps enhance government performance, transparency and accountability. According to the Financial Services and the Treasury Bureau's guidelines, Controlling Officers should, among other things:

(a) focus on targets measured preferably in terms of intended outcome when developing their performance measures; and

(b) indicate the extent to which the departments' operational objectives are being achieved.

5.3 In the 2012-13 Controlling Officer's Report (COR), the DH has only reported two performance measures, comprising one target and one indicator, in respect of its work on licensing of healthcare institutions (including private hospitals). Details are shown in Table 9.

Table 9

Performance measures in 2012-13 COR

Target	Target	2010 (Actual)	2011 (Actual)	2012 (Plan)
Inspections of licensed institutions registered under the Ordinance not less than once a year	100%	100%	100%	100%
Indicator		**2010 (Actual)**	**2011 (Actual)**	**2012 (Estimate)**
Number of inspections of licensed institutions registered under the Ordinance (Note)		205	246	220

Source: DH records

Note: The number of inspections covered inspections of private hospitals, maternity homes and nursing homes.

5.4 While Table 9 shows that the target set for inspections of licensed institutions was met, Audit found that improvements could be made in the DH's performance measurement and reporting.

5.5 The performance measures used by the DH focus mainly on output, and are inadequate for measuring the efficiency and effectiveness of the DH's regulatory work on private hospitals. Audit considers that there is a need for the DH to develop appropriate effectiveness/outcome indicators for publication in the COR. Such indicators might include number of complaints received on private hospitals' services, and regulatory actions taken by the DH (e.g. number of advisory/warning letters issued).

5.6 As shown in Table 9, the DH conducted 205 and 246 inspections of healthcare institutions in 2010 and 2011 respectively. However, there was no breakdown of the number and type of inspections carried out for each type of healthcare institution (e.g. private hospital and nursing home). To enhance transparency and accountability, the DH needs to consider providing a breakdown of inspections in the COR.

Audit recommendations

5.7 **Audit has *recommended* that the Director of Health should:**

(a) **develop appropriate effectiveness/outcome indicators in respect of the DH's regulatory work on private hospitals for publication in the COR; and**

(b) **consider providing a breakdown of inspections conducted for each type of healthcare institution in the COR.**

Response from the Administration

5.8 The Director of Health accepts the audit recommendations. She has said that the FHB and the DH have commenced a review of the existing Ordinance and the DH will take into account the audit recommendations about developing appropriate effective performance/outcome indicators when conducting the review.

PART 6: WAY FORWARD

6.1 This PART examines the way forward for the regulation of private hospitals.

Review of the existing regulatory framework

6.2 Private hospitals in Hong Kong are subject to regulation by the DH under the Ordinance on matters of accommodation, staffing and equipment. In December 2000, the DH completed a review of legislation, including the Ordinance, regulating private hospitals and other healthcare institutions (the 2000 review). The review found, among others, that:

(a) the Ordinance was enacted in 1936. Except for the amendment to bring the originally exempted private hospitals within the ambit of this Ordinance in 1966, there was no major review since it was enacted. One of the major weaknesses of the existing regulatory framework was that it tended to focus on physical facilities rather than quality of care provided to patients;

(b) the few sanctions provided in the Ordinance, which were mainly limited to certain areas (see para. 2.18(a)), were clearly insufficient. Although the regulatory authority could cancel the registration of a healthcare institution when it was not performing satisfactorily in certain areas, this arrangement was not totally satisfactory as it was on an all-or-none basis; and

(c) there was a trend in overseas countries to tighten up control over healthcare institutions, including private hospitals. Laws regulating private hospitals were written in greater details in some overseas countries (e.g. Singapore and Australia). Standards in respect of design and construction, facilities and equipment, staffing, clinical standards, infection control, and clinical records, etc. were prescribed in the main statute, regulations or codes of practice which were legally binding.

6.3 The 2000 review also found that in Hong Kong, there were establishments in which invasive procedures were carried out on the human body that did not come under regulation, which demonstrated that the current legislation did not cater for

rapid introduction of new procedures or treatment modalities. The review identified the following principles to be adopted in developing the future legislative framework for the regulation of private healthcare facilities:

(a) ***Responsiveness to the changing needs and expectations of the community.*** Overseas experience then showed that legislation on the regulation of healthcare facilities was unable to keep pace with the development of medical technology and practice;

(b) ***Timeliness in the protection of public health.*** The pace of development of medical advances coupled with the motivation in the commercial sector to adopt whatever devices or treatment modalities for financial gain had led to a scenario that the laws could not provide sufficient protection towards the consumers;

(c) ***Risk-based approach.*** The degree of regulation on different types of healthcare facilities should be commensurate with the potential risk such facilities would pose to the public if the services they provided did not conform to professional or hygienic standards;

(d) ***Quality-focused.*** Emphasis should be placed on ensuring the quality of services to be provided in addition to meeting the basic physical and staff requirements; and

(e) ***Responsibility of the licensee.*** The management of institutions had shared responsibility in ensuring that services provided therein were up to standards and of a quality acceptable to the clients and community in terms of professional standards and customer services.

6.4 In the 2000 review, the DH considered that there was a need to introduce major changes in the regulation of healthcare institutions in terms of scope and regulatory standards. Unfortunately, the review of the Ordinance was subsequently held in abeyance.

6.5 The subject of monitoring of private hospitals had also been discussed at a number of LegCo Panel meetings. LegCo Members were most concerned about a lack of effective control over the performance of private hospitals. The major concerns raised at LegCo Panel meetings are summarised in Table 10:

Table 10

Major concerns raised at LegCo Panel meetings (1998 to 2011)

Date of LegCo Panel meeting	Major concerns
September 1998	Members expressed concern that the level of penalty stipulated in the Ordinance, which was last amended in 1966, as being inadequate and called for a review of the Ordinance.
November 2011	Members expressed concern that private hospitals were not adequately penalised for non-compliance with the requirements on the management of sentinel events. They urged the Administration to review the Ordinance to increase the deterrent effect against non-compliance with the Ordinance.
December 2011	Members expressed concern that while compliance with the requirements under the COP was a condition for the registration of private hospitals, the DH had no statutory power to impose penalty on private hospitals for non-compliance with the COP. They considered the existing regulatory mechanism ineffective and that the cause of the problem lay in the deficiencies of the Ordinance which lacked deterrent effect. They urged the Administration to formulate a comprehensive policy and review the Ordinance in order to regulate private hospitals effectively, particularly in the areas of service standards, mechanism for handling sentinel events, transparency of medical charges, and penalty for non-compliance.

Source: LegCo Panel papers

6.6 At the LegCo Panel meetings held in November 2011, the DH agreed that the scope and depth of the existing Ordinance had failed to meet the rising public expectation for a mechanism that could effectively monitor the performance of private hospitals. At another LegCo meeting in November 2011, the Secretary for Food and Health said that a review of the Ordinance would be conducted so as

to enhance price transparency and quality service in the provision of private healthcare services. It would appear that in resuming the review of the Ordinance, the FHB needs to take into account those findings and recommendations of the 2000 review (see paras. 6.2 and 6.3).

Recent developments

6.7 ***Special requirements for new private hospital development.*** In April 2012, the Government invited tenders from interested parties for developing private hospitals at two of the four sites reserved for private hospital development (see para. 1.6). To ensure that the services of the new hospitals are of good quality and will cater for the needs of the general public, the Government had included a set of special requirements for the private hospital development at the two sites, covering the following aspects:

(a) ***Land use:*** restriction on land use primarily for hospital service while allowing at most 30% of the total gross floor area for non-clinical supporting services or facilities;

(b) ***Date of commencement of operation:*** commencement of operation within 60 months from the date of execution of the agreement;

(c) ***Bed capacity:*** provision of no less than 300 beds to ensure optimal use of the land;

(d) ***Service scope:*** provision of mix of specialties without slanting towards any particular types of services;

(e) ***Packaged charge and price transparency:*** provision of at least 30% of in-patient bed days taken up in a year for services provided at packaged charges through standard beds, and making available comprehensive charging information of services for easy reference by the public and patients;

(f) ***Service target:*** provision of at least 50% of in-patient bed days taken up in a year for services to local residents;

(g) ***Service standard:*** requirement to attain hospital accreditation on a continuous basis to ensure service standard and quality; and

(h) ***Reporting:*** requirement for the hospital to regularly report to the Government on its compliance with the obligations as set out in the tender documents.

6.8 To facilitate monitoring of the operations of the new private hospitals, the successful tenderers will be required to enter into, in addition to the land lease, a service deed with the Government. The service deed, which will be co-terminus with the land lease, will incorporate the successful tenderer's proposal for the operation of the new private hospital. A number of measures are available to the Government if the successful tenderer breaches any of its obligations. Such measures include the right to require the successful tenderer to implement a cure plan and pay liquidated damages, the right to exercise step-in rights to temporarily take partial or total control of the hospital, and the right to terminate the service deed. The Government also has resort to the performance guarantee and bank bond provided by the successful tenderer.

6.9 The tender exercises for the two private hospital sites closed in July 2012. The Government expects that the result of the tender exercises will be announced in early 2013.

6.10 ***Review on the regulatory regime for private healthcare facilities.*** On 11 October 2012, the Government announced the setting up of a steering committee (Note 15) to conduct a review on the regulatory regime for private healthcare facilities. It will cover, among others, a review of the Ordinance, and is expected to be completed within a year. The Government would then consult the public on the proposal put forward by the steering committee. Subject to the views from the trade and the public, the Government would consider commencing the relevant legislative process.

Overall conclusions

6.11 The existing Ordinance has become outdated and failed to meet the rising public expectation for a mechanism that could effectively monitor and enforce the good performance of private hospitals. As early as December 2000, the DH found in its review that there were deficiencies in the existing regulatory framework

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Note 15: *The steering committee is chaired by the Secretary for Food and Health and comprises 16 non-official members and four ex-officio members. Non-official members comprise personalities from a wide range of backgrounds and interests, including the trade, academia, regulatory bodies, patient groups and civil societies. Ex-officio members include representatives from the FHB, the DH and the HA.*

(see paras. 6.2 and 6.3). It was only until October 2012 when the Government commenced a review of the Ordinance (see para. 6.10). It is important for the Administration to complete the review within the set timeframe and initiate public consultation and legislative process as soon as practicable.

6.12 This audit has revealed room for improvement in the regulatory control of private hospitals. In conducting the review on the regulatory regime for private healthcare facilities, the Administration needs to take the audit observations and recommendations into account. Given the long lead time which may be required by the Administration to review and introduce legislative amendments to the Ordinance, the Administration needs to explore ways to strengthen its regulatory control of private hospitals in the interim. For example, the Administration may consider enhancing public disclosure of performance information of private hospitals (e.g. the number and type of sentinel events and complaints for each hospital, and the late reporting of sentinel events of hospitals), and encouraging private hospitals to continue improving price transparency.

6.13 Audit welcomes the Government's initiative to include a set of special requirements for the development of new private hospitals at the two reserved sites (see para. 6.7). The initiative helps ensure that the services of new hospitals are of good quality and cater for the needs of the general public. However, these special requirements do not apply to existing private hospitals. The Administration needs to explore the possibility of extending these requirements to existing private hospitals, for example through legislative amendments or other administrative measures (including revision of the COP) to ensure that the public interest is safeguarded.

Audit recommendations

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

(a) **take into account the audit observations and recommendations in this Audit Report, and take on board the findings and recommendations of the 2000 review when conducting a review on the regulatory regime for private healthcare facilities;**

(b) **pending amendments to the Ordinance, explore interim measures to strengthen the regulatory control of private hospitals; and**

(c) **explore the possibility of extending the set of special requirements (which are applicable to new private hospital developments) to existing private hospitals, for example through legislative amendments or other administrative measures (including revision of the COP).**

Response from the Administration

6.15 The Secretary for Food and Health agrees with the audit recommendations, and thanks Audit for undertaking a detailed review. He has said that:

(a) the audit observations and recommendations will assist the Administration in further improving the regulation of private hospital services; and

(b) the Administration has commenced a review of the Ordinance (see para. 1.8). The review will take into account the audit observations and recommendations. The Administration expects to complete the review within a year. The Administration will then undertake a public consultation and prepare the necessary legislative amendments to update the Ordinance and implement the improvement measures. In the meantime and before the amendment of the legislation, the DH will take measures with reference to the audit recommendations to enhance and strengthen the supervision and regulation of private hospitals.

6.16 The Director of Health welcomes the audit recommendations. She has said that the DH will take proactive measures to enhance the regulatory control of private hospitals.

Appendix A
(para. 1.9 refers)

List of registered private hospitals
(1 January 2012)

Private hospital	Year opened	Operating as a charitable institution?	Number of in-patient beds
Canossa Hospital (Caritas)	1929	Yes	174
Evangel Hospital	1965	Yes	60
Hong Kong Adventist Hospital	1971	Yes	152
Hong Kong Baptist Hospital	1963	Yes	877
Hong Kong Central Hospital (Note)	1966	Yes	85
Hong Kong Sanatorium & Hospital Limited	1922	No	485
Matilda & War Memorial Hospital	1907	Yes	99
Precious Blood Hospital (Caritas)	1937	Yes	176
Shatin International Medical Centre Union Hospital	1994	No	410
St. Paul's Hospital	1898	Yes	356
St. Teresa's Hospital	1940	Yes	1,050
Tsuen Wan Adventist Hospital	1964	Yes	174
		Total	4,098

Source: DH records

Note: Hong Kong Central Hospital ceased operation in September 2012.

Appendix B
(para. 2.2 refers)

Extracts of the Code of Practice requirements

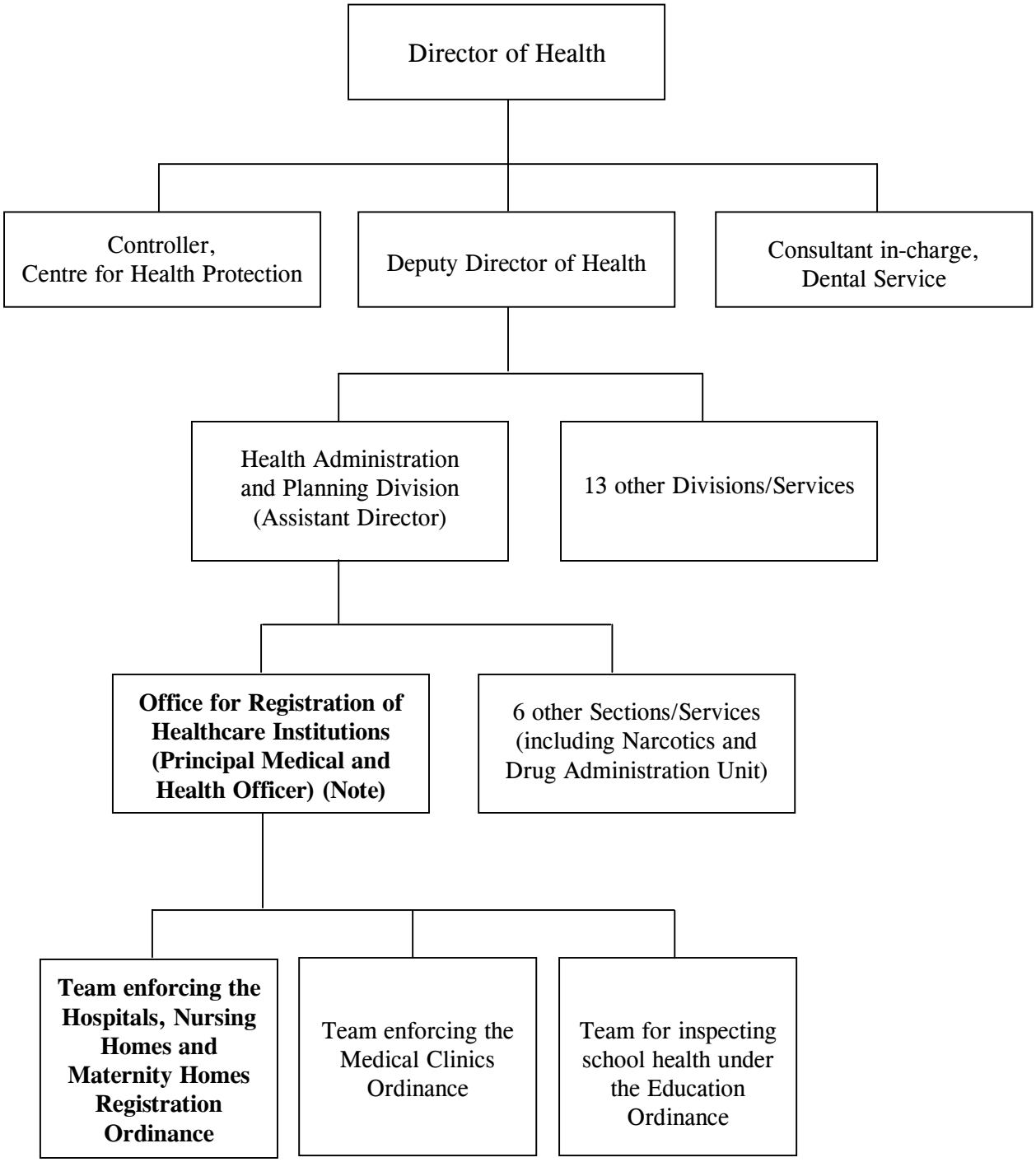
Aspect	COP requirement
Accommodation	• Lighting, temperature, humidity, ventilation and noise level are appropriate to the facilities. • The premises are kept clean and hygienic.
Equipment	• Equipment is to be installed and serviced according to the manufacturer's instruction. • Medical equipment intended for single use should not be reused.
Staff management	• There should be an appropriate number of suitably qualified and experienced persons in the establishment at all times. • A resident medical practitioner is available on immediate call within the establishment at all times to provide urgent patient care. • The nurse-in-charge in the intensive care units, operating theatres, and maternity unit, etc. should preferably have received relevant training. • There is a contingency plan for ensuring adequate nursing staff at all times.
Quality management of services	• A quality committee comprising members from multi-disciplinary services is set up to prescribe standards of care and service. • The quality committee implements a system for reviewing the quality of services at appropriate intervals.
Rights of patients	• There are written policies and procedures to protect the patients' rights (e.g. the right to obtain information on one's own diagnosis, treatment, progress and investigation results, and the right to know the fees and charges prior to consultation and any procedures). • A mechanism is in place for handling complaints made by patients.

Aspect	COP requirement
Risk management	• There are written risk management policies and procedures covering: (i) assessment of risks; (ii) identification, analysing and learning from adverse health events or near misses; and (iii) arrangement for responding to emergencies (e.g. fire evacuation, and cessation of water and electricity supply).
Reporting of sentinel events	• The management is required to inform the DH within 24 hours, with a full report within 4 weeks, of the occurrence of a sentinel event.
Pharmacy and dispensing service	• There should be clear labelling of medicines. Stock items sent to wards should have expiry dates. • There is a system to monitor the accuracy of dispensing and administration of medicines. • Where there is a cold chain requirement for maintaining the efficacy of medicines, there is a system to monitor and record the temperature of the transport and storage facilities.
Operating theatre service	• There are written policies and procedures for the running of operating theatres, covering staff arrangements, equipment, facilities and theatre practice. • An appropriate number of suitably qualified and experienced staff are in attendance during each surgical procedure.
Intensive care service	• All staff should be familiar with resuscitation procedures and nurses should be equipped with intensive care nursing skills. • The nurse to patient ratio shall be 1:1 at all times and increased to 2:1 in critical cases.
Obstetric and nursing service	• A midwife registered with the Hong Kong Midwives Council is appointed to take charge of the day-to-day operation of the obstetric service. • At least one nursing staff with certified training in advanced life support should be on duty at all times.

Source: DH records

Appendix C
(para. 2.3 refers)

Department of Health
Organisation chart (extract)
(1 September 2012)



Source: *DH records*

Note: *The Principal Medical and Health Officer also heads the Narcotics and Drug Administration Unit.*

Appendix D
(para. 3.3 refers)

List of reportable sentinel events

Events that lead to death or 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, or with 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 an unanticipated death or serious injury, or with significant public health risk

Source: DH records

Acronyms and abbreviations

Audit	Audit Commission
COP	Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes
COR	Controlling Officer's Report
DH	Department of Health
FHB	Food and Health Bureau
HA	Hospital Authority
ICAC	Independent Commission Against Corruption
LegCo	Legislative Council
MCHK	Medical Council of Hong Kong
NCHK	Nursing Council of Hong Kong
ORHI	Office for Registration of Healthcare Institutions