PRIVATE HEALTHCARE FACILITIES AND SERVICES ACT 1998 [ACT 586]

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PRIVATE HEALTHCARE FACILITIES AND SERVICES (PRIVATE HOSPITALS AND OTHER PRIVATE HEALTHCARE FACILITIES) REGULATIONS 2006

INCIDENT REPORTING

Private Medical Practice Control Section (CKAPS)
Medical Practice Division
Ministry of Health Malaysia

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INCIDENT REPORTING

1. Charter
A private healthcare facility or service shall report to the Director General, or any person authorised by him any unforeseeable or unanticipated incidents as required under Section 37 of the Private Healthcare Facilities and Services Act 1998 [Act 586] and delineated in regulation 19 of the Private Healthcare Facilities and Services (Private Hospitals and Other Private Healthcare Facilities) Regulations 2006.

2. Goals

2.1. As a tool for improving the safety and quality of patient care.

2.2. To focus the attention of a healthcare facility or service that has experienced an “unforeseeable or unanticipated incident” on understanding the causes that underlie the event and on making changes in the healthcare facility or service’s systems and processes to reduce or eliminate the probability of the event occurring in the future.

2.3. To increase knowledge about incidents, their causes and strategies for their prevention and management.

2.4. To maintain and enhance public confidence in the quality and safety of care and services provided by private healthcare facilities and services.

3. Objectives

3.1. To systematically assess the quality and safety of private healthcare facilities and services by reporting any unforeseeable or unanticipated incidents as required by law.

3.2. To systematically review the information relating to incident reports, identify shortfalls in service and take remedial measures to prevent the future occurrence of similar incidents.

3.3. To evaluate the effectiveness of the remedial or preventative measures.
4. **Guiding Principles**

The Incident Reporting implementation procedures are bound by the following guiding principles:

4.1. **Confidentiality**

Absolute confidentiality of all the reports is assured and strictly adhered to. All identification data from the reports are expunged before being coded. They are then reviewed by the members of the Incident Reporting Working Committee (Ministry of Health) who thus have no knowledge of the origin of the cases.

4.2. **Non-punitiveness**

The inquiry looks at system problems and deficiencies. It does not apportion blame to any individual.

4.3. **Objectivity**

Each case is independently assessed by the Incident Reporting Working Committee members who are in no way connected with the “incident” case in question. They will then discuss these findings and make conclusions and recommendations.

5. **Monitoring and Evaluating the Implementation of Incident Reporting**

5.1. There is a need to systematically monitor and evaluate the implementation of Incident Reporting as well as assess their impact on the quality of care.

5.2. If similar Incidents recur at the facility, the Incident Reporting Working Committee will need to determine why this is so and if the previous recommendations had been ineffective or had not been implemented (and the reasons why they had not been implemented).

5.2. The notification, report and statistical summary of the incidents that occurred in the private healthcare facilities and services can be addressed to the Incident Reporting Secretariat, Ministry of Health Malaysia.

5.3. In addition, all licensed private healthcare facilities and services are encouraged to establish local Incident Reporting Committee.
6. **Methodology**

This is a reporting mechanism involving notification of all designated "incidents" that occur in the private healthcare facility or service.

6.1. **Definition**

"Incident" refers to any unforeseeable or unanticipated incidents stipulated in the Fifth Schedule of the Private Healthcare Facilities and Services (Private Hospitals and Other Private Healthcare Facilities) Regulations 2006 which requires mandatory notification.

6.2. **Policies and Procedures**

The private healthcare facility or service must establish –

(a) policies for requiring its employees to report unexpected or unanticipated incidents; and

(b) in-house policies/procedures as well as organisational structure for incident reporting, identifying root causes and rectifying such incidents.

6.3. **Notification and Data Collection for Incident Reporting**

6.3.1. It is the duty of the management or its representative(s) to –

(a) ensure that incidents are reported using Form IR-1 in writing and preferably via electronic means to the Director General of Health Malaysia or any other person authorised by the Director General in that behalf the next working day after the incident occurred or immediately after the time the private healthcare facility has reasonable cause to believe that the incident occurred;

(b) provide a statistical summary of unforeseeable or unanticipated incidents (refer Form IR2-A and IR2-B) as required by the Director General of Health, Malaysia at six (6) months’ interval; and

(c) ensure that information pertaining to investigation(s) of any incident and the finding(s) as well as the report and statistical summary submitted to the Director General of Health, Malaysia be retained at least for such period as specified under any written law pertaining to limitation period.
6.3.2. In addition, the Director-General of Health Malaysia may request further oral report or a written report of the incident if he determines a report is necessary for further investigation.

6.3.3. The notification forms can be accessed and downloadable at http://medicalprac.moh.gov.my

6.4. Follow-up of Notification and Data Collection for Incident Reporting
"Incidents" that have been notified are investigated using the Root Cause Analysis Methodology (London Protocol). Investigation of Incident is essential to determine contributory and root causes as well as to draw up and implement remedial measures to improve care systems, thus preventing the incident from recurring.

6.5. Fate of Incident Reporting Forms and Reports
All incident reporting forms including information about an incident investigation and its findings as well as the report and statistical summary shall be submitted to the Director General of Health, Malaysia. They will be retained at least for such period as specified under any written law pertaining to limitation period.

7. Incident Reporting at Facility Level
The formation of the above-mentioned committee at the facility level as well as unit levels is highly recommended for each healthcare facility or service. An incident reporting system which is primarily maintained at the individual location or unit but coordinated at the facility Director’s level will allow local managers to develop ownership and manage their own problems. It will also allow the person in charge to have a general overview or “bird’s eye view” of the facility’s strengths and weaknesses. Being coordinated by the person in charge, remedial measures can be more effectively implemented across units and services.

8. The Secretariat
The secretariat will consist of the staff of the Private Medical Control Practice Section (CKAPS), Medical Practice Division of the Ministry of Health (MOH). The Secretariat will be working closely in collaboration with the Section on Quality in Healthcare, Medical Development Division, MOH. The functions of the Secretariat include the following:

8.1. Receive notifications of “Incidents” as well as reports from the relevant private healthcare facilities and services.

8.2. Obtain further information from the relevant private healthcare facilities and services as per request.
8.3. Circulate feedback (conclusions and recommendations) to the relevant healthcare facilities and practitioners.

8.4. Assist in the analysis of Incident Reporting findings.

8.5. Monitoring of performances of the specific incidents reports as required by the Regulations.

8.6. Publish the Annual Reports.

8.7. Ensure the confidentiality by expunging the names of patients and facilities in the reports.

8.8. Ensure smooth review, monitoring and evaluation of the implementation of Incident Reporting recommendations at various levels of the private healthcare facilities.

9. **Access to the Incident Reporting Secretariat, MOH**

The Committee can be contacted through its Secretariat at the following:

Incident Reporting Secretariat  
Private Medical Practice Control Section  
Medical Practice Division  
Ministry of Health Malaysia  
Level 3, Block E1, Complex E  
Federal Government Administrative Centre  
62590 PUTRAJAYA

Tel: 03 - 8883 1302/1297  
Fax: 03 - 8881 0901/0902  
Email: ckkaps@moh.gov.my  
Website: http://medicalprac.moh.gov.my