

Grievance procedure

40. (1) Any grievance against a private healthcare facility or service may be submitted by any patient orally or in writing to the patient relations officer or to any healthcare professional of the private healthcare facility or service at any time.

(2) If the complaint is submitted to any healthcare professional of the private healthcare facility or service, it shall be forwarded to the patient relations officer by the next working day.

(3) The patient relations officer shall document all complaints received and resolve the matter and where the complaint cannot be resolved by the patient relations officer, the matter shall be referred to the licensee or person in charge immediately, but not later than three working days.

(4) The licensee or person in charge shall cause an investigation to be made and provide a reply which shall include result of the investigation to the complainant within ten working days after the complaint was received by the licensee or person in charge.

(5) The notification of the report of the investigation shall include an information to the complainant that if he is dissatisfied with the reply of the licensee or person in charge, the complainant may refer the matter in writing to the Director General.

(6) Upon receipt of the complaint, the Director General shall notify the complainant and the private healthcare facility or service of the complaint and the Director General shall investigate or cause to be investigated the complaint.

(7) The Director General shall inform the complainant and the private healthcare facility or service in writing of his findings or any recommendations he may have based on his finding.

Updating of plan and procedure

41. The licensee or person in charge of a private healthcare facility or service shall update the grievance mechanism plan and procedure and inform all healthcare professional of the updated plan and procedure.

PART VII**PATIENT'S MEDICAL RECORDS****Interpretation**

42. In this Part, unless the context otherwise requires—

“attending healthcare provider” means—

- (a) any registered medical practitioner or registered dental practitioner who attends to the patient in the private healthcare facility or service; or
- (b) the person in charge of the private healthcare facility or service if the registered medical practitioner or registered dental practitioner under paragraph (a) is deceased or unavailable;

“representative” means —

- (a) a person so authorized in writing by a patient;
- (b) a person so authorized in writing by a court order to act on behalf of a patient;
or
- (c) in the case of a deceased patient or where a patient is incompetent or unable to act on his own behalf, the legal representative of a patient.

Patient’s medical record system

43. (1) The licensee or person in charge of a private healthcare facility or service shall have an appropriate patient’s medical record system comprising of facilities, procedures and organization for keeping patient’s medical record.

(2) The licensee or person in charge of the private healthcare facility or service shall —

- (a) ensure that a separate patient’s medical record is kept for each patient where each patient is assigned with a registration number; and
- (b) be responsible to safeguard the information on the patient’s medical record against loss, tampering or use by unauthorized persons.

(3) The department in the private healthcare facility or service where a patient is referred or admitted to shall maintain its own patient’s medical record and the record shall be integrated with the patient’s overall medical record in the private healthcare facility or service.

(4) In the case of outpatient departments that belong to the private hospitals, private nursing homes, private psychiatric hospitals, private psychiatric nursing homes and private hospice, the outpatient medical records maintained shall be correlated with the facility or service patient’s medical record and the outpatient’s medical record shall be integrated with the patient’s overall medical record in the private healthcare facility or service.

(5) Any person who contravenes this regulation commits an offence and shall be liable on conviction to a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding three months or to both.

Patient’s medical record

44. (1) A patient’s medical record is the property of a private healthcare facility or service.

(2) No patient’s medical record shall be taken out from the private healthcare facility or service except under a court order and when taken out from the private healthcare facility or service under a court order, a copy of the records shall be retained by the private healthcare facility or service and the original records shall be returned to the private healthcare facility or service at the end of the proceedings for which the records were directed to be procured.

(3) The licensee or person in charge of the private healthcare facility or service shall ensure that for each admission, each patient's medical record shall have the information as specified in the Sixth Schedule.

(4) All entries in a patient's medical record shall be—

(a) dated and authenticated by the person who gave the order, provided the care or performed the observation, examination, assessment, treatment or other service to which the entry pertains; and

(b) legibly written in ink, typewritten or recorded on a computer terminal which is designed to receive such information and if recorded and stored in a computer, it may be stored on magnetic tapes, discs or other devices suited to the storage of data.

(5) All originals or copies of any patient's medical reports received from any other healthcare facility or service shall be filed in the patient's medical record in the private healthcare facility or service.

(6) Any person who contravenes subregulation (3), (4) or (5) commits an offence.

Retention of patient's medical record

45. (1) The licensee or person in charge of a private healthcare facility or service shall ensure that all original patients' medical records or documents relating to such records shall be preserved at least for the period as specified under any written law pertaining to limitation period.

(2) Where a private healthcare facility or service intends to cease operation, the licensee or person in charge of the private healthcare facility or service shall comply with such directions as the Director General may give with regard to the preservation of the patient's medical records and other records or reports on the patient care data.

(3) Where a licence of a private healthcare facility or service is transferred or assigned to a new licensee, the transferor or assignor shall ensure that the patient's medical records are also transferred or assigned to the new licensee.

Rights of healthcare professional to access or inspect patient's medical record for defence in any civil action brought against him

46. (1) A healthcare professional who had provided or who had caused to be provided any healthcare to a patient and who had made or caused to be made any written notations in a patient's medical record while providing such healthcare to such patient shall be allowed access to such notations in the patient's medical record in the custody of any licensed private healthcare facility or service specifically to be used for his defence in any civil action brought against him relating to the healthcare he had provided or caused to be provided.

(2) Such healthcare professional may, upon approval by the licensee or person in charge of a private healthcare facility or service and after consulting the attending healthcare provider, access other notations or documents relevant to the healthcare he had provided or caused to be provided by him including observation chart, referral letters or notes and nurses' notes relating to such patient which were made available to him when he was providing healthcare to such patient.

(3) Nothing in this regulation shall be construed so as to waive the responsibility of a healthcare professional from obtaining consent from a patient or patient's representative for access to the patient's medical record for purposes other than a civil action brought against him by such patient.

(4) Nothing in this regulation shall be construed so as to limit the right of a healthcare professional or his counsel to inspect the patient's medical record.

(5) Nothing in this Part shall be construed so as to waive the responsibility of a private healthcare facility or service or custodian of a patient's medical records to maintain confidentiality of such records in its possession.

PART VIII

CONSENT

Valid consent

47. (1) A licensee or person in charge of a private healthcare facility or service shall obtain or cause to be obtained valid consent from a patient before any procedure or surgery is carried out on the patient.

(2) The valid consent under subregulation (1) shall be obtained from—

- (a) the patient;
- (b) if the patient is mentally or physically disable, the spouse, parent or next of kin; or
- (c) if the patient is unmarried and below eighteen years of age, the parent or guardian.

(3) Consent obtained or caused to be obtained under this regulation shall be in writing.

(4) Any person who contravenes this regulation commits an offence and shall be liable on conviction to a fine not exceeding ten thousand ringgit or to imprisonment for a term not exceeding three months or to both.

When consent may be dispensed with

48. (1) A valid consent referred to in regulation 47 may be dispensed with if a surgeon believes that any delay caused in obtaining the consent would endanger the life of a patient provided that a consensus of the surgeon and another registered medical practitioner is obtained and the surgeon signed a statement stating that the delay would endanger the life of the patient.