

MH: 71:03/2

28 July 2015

Licensees/ Authorised Persons/ Managers for all licensed HCIs

SPECIFIC LICENSING TERMS AND CONDITIONS (LTCs) ON MEDICAL RECORDS FOR HEALTHCARE INSTITUTIONS

The Ministry of Health (MOH), in consultation with medical practitioners, professional bodies and agencies, has developed a set of Specific Licensing Terms and Conditions (LTC) on Medical Records for healthcare institutions so as to provide healthcare practitioners/ providers (i.e. Public and private hospitals, nursing homes and medical /dental clinics) with a better and clearer understanding of the minimum standards on clinical documentation and management of medical records.

- 2. The LTC on Medical Records will take effect from 1 September for your compliance. A copy of the LTC is available in Annex A.
- 3. The LTCs on Medical Records will supercede the existing medical records guidelines which are part of the "Guidelines under the Private Hospitals and Medical Clinics (PHMC) Act (1980) and Regulations (1991)" last revised on 1 October 2007.
- 4. Should you require further clarification, please send us your queries via email to eLIS@moh.gov.sg

PETER LEE

DEPUTY DIRECTOR (LICENSING, INSPECTION & AUDIT BRANCH)
REGULATORY COMPLIANCE AND ENFORCEMENT DIVISION
for DIRECTOR OF MEDICAL SERVICES











Ministry of Health, Singapore College of Medicine Building 16 College Road Singapore 169854 TEL (65) 6325 9220 FAX (65) 6224 1677 WEB www.moh.gov.sg

SPECIFIC LICENSING TERMS AND CONDITIONS ON MEDICAL RECORDS FOR HEALTHCARE INSTITUTIONS

IMPOSED PURSUANT TO SECTION 6(5) OF THE PRIVATE HOSPITALS AND MEDICAL CLINICS ACT (CAP. 248) ("PHMCA")

1. Application

- 1.1 These licensing terms and conditions apply to all healthcare institutions licensed under the PHMCA and shall come into effect on 1 September 2015.
- 1.2 A breach of these licensing terms and conditions may attract potential consequences under the PHMCA, including but not limited to:
 - (a) Suspension or revocation of healthcare institution licence; and
 - (b) Prosecution.

2 Definition of Medical Record

- 2.1 A medical record is a detailed manual or electronic record of all the medical care, medical investigations and treatment provided by a healthcare institution to a patient. Where a healthcare institution provides both in-patient and out-patient care, a medical record shall include a patient's medical care and treatment in both settings.
- 2.2 All electronic medical records are considered medical records for the purposes of these licensing terms and conditions.

3 General Terms and Conditions on Medical Records

3.1 Medical Records shall be Comprehensive and Accurate

3.1.1 The licensee shall ensure that all medical records are current, accurate and complete.

3.2 Medical Records shall be Well-Organised and Legible

- 3.2.1 The licensee shall ensure that all medical records are well-organised and allow a patient's medical information to be retrieved quickly and with ease.
- 3.2.2 The licensee shall be accountable for all entries made in the medical records by any person working in the licensed healthcare institution.

- 3.2.3 The licensee shall ensure that all entries made in all medical records are legible.
- 3.2.4 The licensee shall ensure that all entries made in all hardcopy medical records are permanently inked and non-erasable.
- 3.2.5 The licensee shall ensure that correction tape or fluid is not used to correct any errors in hardcopy medical records. Any correction to any hardcopy medical record must be made by drawing one or more lines across the part of the record to be corrected.
- 3.2.6 The licensee shall ensure that any person who makes any retrospective corrections / entries to any medical record shall append his signature and the date on which the corrections/entries are made.
- 3.2.7 In the case of electronic medical records, the licensee shall ensure that a system is in place to track all amendments made to such medical records.

3.3 Medical Records shall be kept Securely

- 3.3.1 The licensee shall ensure that medical records are kept securely at all times and can only be accessed by authorised staff.
- 3.3.2 The licensee shall ensure that there is proper and secure storage and retrieval of medical records in order to prevent the loss of, unauthorised access to, and tampering of the medical records. Where there are electronic records, there must be sufficient protocols in place to ensure that only authorised personnel are granted access to such records (e.g. through the use of passwords). Where the records are in paper form, there must be adequate safeguards for ensuring that the medical records are kept under lock and key when the authorised staff are not present and/or when the records are not in use (e.g. by keeping them in dedicated metal filling cabinets under lock and key).
- 3.3.3 The licensee shall brief its staff and any other person who may have access to the medical records on the relevant guidelines and policies.
- 3.3.4 The licensee shall ensure that, where appropriate, any incident involving the loss of, unauthorised access to or tampering with any medical record is reported to the Police promptly upon detection of any such incident.

3.4 Medical Records shall be maintained in a Manner that ensures Continuity of Care

3.4.1 The licensee shall ensure that all medical records are updated and kept in a manner that enables:

- (a) the attending medical practitioner or other healthcare professional(s) to provide continuing care for the patient;
- (b) any authorised personnel to retrieve any information that may be required for utilisation review or quality assurance activities.
- 3.4.2 The licensee shall ensure that a system is put in place to ensure that any abnormal results in a patient's medical records are brought to the attention of relevant healthcare professional(s) for their appropriate follow-up.

3.5 Retention Period of Medical Records

3.5.1 All original medical records (i.e. both paper and electronic) in the private hospitals, nursing home and medical clinics shall be retained for an appropriate length of time¹.

4 Specific Licensing Terms and Conditions on Medical Records for Hospitals

- 4.1 The licensee shall ensure that each patient's registration record includes the following particulars:
 - (a) the patient's name, identity card/birth certificate/passport number/ foreign identification number (FIN)/ hospital registration number (HRN), gender, date of birth and residential address;
 - (b) the name(s) of the medical practitioner(s) providing the care and treatment or requesting investigations;
 - (c) the dates and times of consultation, admission, investigations, discharge or death;
- 4.2 The licensee shall ensure that each patient's medical record includes the following:
 - (a) the details of admission;
 - (b) the patient's medical history, and any referral documents;
 - (c) clinical findings, diagnosis(es) and progress notes;
 - (d) details of clinical management and care plan (e.g. medical/surgical treatment, nursing care, allied health, etc.);

¹ In determining the appropriate retention period, the licensees may refer to the MOH <u>Guidelines for the Retention</u> Periods of Medical Records 2015.

- (e) record of allergies, if any;
- (f) records of adverse events, if any, and actions taken;
- (g) reports of all laboratory tests, radiological and other investigations performed;
- (h) signed consent forms (where applicable) of which a copy shall be given to the patient upon request;
- (i) Do Not Resuscitate (DNR) Form, if applicable;
- (j) documents on advanced care plan, if applicable;
- (k) communication records between hospital and patient/patient's next-of-kin;
- (I) document of possible/final cause of death, if applicable;
- (m) the Certificate of Cause of Death (CCOD), if applicable;
- (n) the post-mortem report, if available;
- (o) a discharge summary (including information on police report made (if any), condition on discharge and recommendations and arrangements for future care); and
- (p) a copy of any medical certificate issued to the patient, which shall include the hospital's name, the attending medical practitioner's name and signature and the date upon which the medical certificate was issued.
- 4.3 The licensee shall ensure that, for every patient who is to undergo or has undergone a surgical procedure [i.e. Table of Surgical Procedures (TOSP) 2 and above²], his medical records shall contain the following:
 - (a) the anaesthetic record (i.e. only applicable to sedation and general anaesthesia procedure), which shall include details of the pre-operative assessment, type and duration of anaesthesia and/or sedation used, and the name of the doctor in charge of administering the anaesthesia/sedation and monitoring the patient;
 - (b) the operation report, including the date of surgery, pre-operative and post-operative diagnosis, the indication for surgery, type of procedure, , surgery start and end times, the procedure summary which shall include a description of findings, complications during procedure, if any, technique used, tissue/ organ removed or transplanted;

² The Table of Surgical Procedures is available at the MOH website: https://www.moh.gov.sg/content/moh-web/home/costs and financing/schemes subsidies/medisave/Withdrawal Limits/updated-table-of-surgical-procedures.html

- (c) if surgical specimens (e.g. tissue or body fluid) were removed for further investigation, the histopathology report;
- (d) if a medical device (i.e. Class C and above³) is used, the type, serial number and name of medical device used and follow-up care plan, if applicable;
- (e) the names of the surgeon(s), proceduralist(s) and assistant(s) involved in the operation; and
- (f) the consent form signed by the patient prior to the procedure.
- 4.4 The licensee shall ensure that, where maternity services are provided, the patient's medical record contains the following particulars:
 - (a) the labour record;
 - (b) date, time and type of delivery, and whether the result was a live birth, stillbirth or abortion;
 - (c) number of live birth, stillbirth or foetus aborted;
 - (d) sex, weight and height of the newborn, circumference of head and condition of newborn at birth;
 - (e) name(s) of person(s) attending to the patient during delivery;
 - (f) name(s) of person(s) who tagged the newborn;
 - (g) condition of mother and newborn on discharge;
 - (h) name, address and relationship of the person who received the newborn from the private hospital on discharge.
- 4.5 The licensee shall ensure that each patient's allergy in hardcopy or electronic medical record is set out in RED⁴ and other risk factors are also prominently reflected and conspicuous according to international color coding. The licensee shall indicate the medication(s) to which the patient is allergic and the risk factor(s) pertaining to that patient (e.g. risk of falling, risk of suicide, G6PD deficiency, etc.), respectively.

³ The medical device is regulated under the Health Products Act 2007 /Health Products (Medical Devices) Regulations by the Health Science Authority (HSA). http://www.hsa.gov.sg/content/hsa/en/Health Products Regulation/Medical Devices/Overview/Regulatory Fram ework.html

⁴ Allergy to medication will be reflected in RED according to the MOH Circular (*MH Cf* 36:08) issued on 8 August 1994.

4.6 The licensee shall ensure that medical records can be accessed by the attending healthcare professional(s) at all times. The licensee shall ensure that, where electronic medical records are used, an IT system is in place to ensure that all records are backed-up electronically and remain accessible at all times.

5 Specific Licensing Terms and Conditions on Medical Records for Nursing Homes

- 5.1 The licensee shall ensure that each resident's record contains the following particulars:
 - (a) the resident's name, identity card/birth certificate/passport number/ foreign identification number (FIN), gender, date of birth, residential address and photography of the resident;
 - (b) name of the attending healthcare professional(s) providing the care and treatment or requesting for the investigations;
 - (c) dates and times of consultation, admission, investigations, discharge or death.
- 5.2 The licensee shall ensure that each resident's medical record (which includes a nursing care record) contains the following:
 - (a) the details of admission:
 - (b) the resident's medical history, and any referral documents:
 - (c) resident's assessment record and care plans (e.g. skin care and pressure ulcers, nutritional status, pain management needs, fall risk, continence status, psychosocial/mental health status, etc.);
 - (d) clinical findings and progress notes;
 - (e) details of medication, care plan and clinical management (e.g. medical/surgical treatment, nursing care, allied health, etc.);
 - (f) resident's medication records
 - (g) record of allergies and other factors requiring special consideration, if any;
 - (h) records of adverse events (e.g. wrong medication, falls, physical abuse), if any, and actions taken;
 - (i) reports of all laboratory tests, radiological and other investigations ordered by the attending healthcare professional (s) in the nursing home, if any;

- (j) signed consent forms (where applicable) of which a copy shall be given to the resident's main caregiver upon request;
- (k) Do Not Resuscitate (DNR) form, if applicable;
- (I) documents and/ or communication records on advanced care plan, if applicable;
- (m) communication records between nursing home and resident/resident's next-of-kin;
- (n) document of possible/ final cause of death, if applicable;
- (o) the Certificate of Cause of Death (CCOD), if applicable;
- (p) the post-mortem report, if available;
- (q) a discharge summary [including information on police report made (if any), condition on discharge and recommendations and arrangements for future care].
- 5.3 The licensee shall ensure that each patient's allergy in hardcopy or electronic medical record is set out in RED⁵ and other risk factors are also prominently reflected and conspicuous according to international color coding. The licensee shall indicate the medication(s) and food to which the resident is allergic and the risk factor(s) pertaining to that resident (e.g. risk of falling, risk of suicide, G6PD deficiency, etc.), respectively.
- 5.4 The licensee shall ensure that medical records can be accessed by the attending healthcare professional(s) at all times. The licensee shall ensure that, where electronic medical records are used, an IT system is in place to ensure that all records are backed-up electronically and remain accessible at all times.

6 Specific Licensing Terms and Conditions on Medical Records for Medical Clinics

- 6.1. Every medical clinic shall maintain a Register of Patients specifying in detail the following for each entry/visit:
 - a. the patient's name, identity card/birth certificate/passport number/ foreign identification number (FIN)/ clinic registration number, gender, date of birth and residential address;
 - name of the medical practitioner(s) providing the care and treatment;

⁵ Allergy to medication will be reflected in RED according to the MOH Circular (*MH Cf 36:08*) issued on 8 August 1994.

- c. date and time of consultation;
- d. drugs that are dispensed;
- e. type of procedure performed and/or treatment provided.
- 6.2 The licensee shall ensure that the medical record of each patient shall include the following information:
 - (a) the patient's name, identity card/birth certificate/passport number/ foreign identification number (FIN)/ clinic registration number, gender, date of birth and residential address;
 - (b) the patient's medical history, and any referral documents;
 - (c) the clinical findings;
 - (d) the names and doses of drugs prescribed;
 - (e) the financial counselling details, if applicable;
 - (f) a description of all procedures performed and/or treatment provided;
 - (g) a record of allergies and other factors requiring special considerations (e.g. G6PD, drug contraindications), if any;
 - (h) a record of adverse events, if any, and actions taken;
 - (i) the reports of all laboratory tests, radiological and other investigations performed;
 - (j) signed consent forms (where applicable) of which a copy shall be given to the patient upon request; and
 - (k) information of medical certification granted to the patient (e.g. MC from 2 to 3 April 2010).
- 6.3 The licensee shall ensure that, where a significant surgical procedure [i.e. Table of Surgical Procedures (TOSP) 2 and above ⁶] has been performed, the medical records of each patient contain the following:
 - (a) the anaesthetic record (i.e. only applicable to sedation and general anaesthesia procedure), which shall include details of the pre-operative assessment, type and duration of anaesthesia and/or sedation used, and the

⁶ The Table of Surgical Procedures is available at the MOH website: https://www.moh.gov.sg/content/moh_web/home/costs_and_financing/schemes_subsidies/medisave/Withdrawal_ Limits/updated-table-of-surgical-procedures.html

- name of the doctor in charge of administering the anaesthesia/sedation and monitoring the patient;
- (b) the operation report, including the date of surgery, pre-operative and post-operative diagnosis, the indication for surgery, type of procedure, surgery start and end times, the procedure summary which shall include a description of findings, complications during procedure, if any, technique used, tissue removed;
- (c) if surgical specimens (e.g. tissue or body fluid) were removed for further investigation, the histopathology report;
- (d) if a medical device (i.e. Class C and above⁷) is used, the type, serial number and name of medical device used and follow-up care plan, if applicable; and
- (e) the names of the operating medical practitioner(s) and assistant(s), if any.
- 6.4 The licensee shall ensure that each patient's allergy in hardcopy or electronic medical record is prominently reflected and conspicuous in RED⁸ and indicate the medication(s) to which the patient is allergic.

6.5 Transfer of Medical Records upon the Cessation of Operation of a Medical Clinic

- 6.5.1 If a licensee intends to cease the operation of its medical clinic, the licensee shall ensure that each patient of the medical clinic is informed of its intention (e.g. by way of a door sign or notice) to do so with sufficient notice (i.e. at least 30 days) ahead of the intended cessation date, in order for its patients to make decisions regarding the transfer or disposal of their respective medical records.
- 6.5.2 The licensee shall ensure each patient's medical record or a detailed medical report is transferred/ relayed to another licensed healthcare institution. This shall apply only to patients who are on active follow-up within the preceding 1 year and need continuing follow up.
- 6.5.3 In the event that a patient cannot be contacted, the licensee shall ensure that that patient's medical record is disposed in a manner that would not compromise its confidentiality (i.e. the medical records shall be de-identified before being destroyed using cross-shredding machines or disposed through a proper disposal vendor, and not disposed in the wastepaper or recycling bins).

⁷ The medical device is regulated under the Health Products Act 2007 /Health Products (Medical Devices) Regulations by the Health Science Authority (HSA). http://www.hsa.gov.sg/content/hsa/en/Health Products Regulation/Medical Devices/Overview/Regulatory Fram ework.html

⁸ Allergy to medication will be reflected in RED according to the MOH Circular (*MH Cf 36:08*) issued on 8 August 1994.

Dated: 6 August 2015