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MINISTRY OF HEALTH MALAYSIA

GUIDELINES FOR TRADITIONAL AND COMPLEMENTARY MEDICINE HEALTHCARE FACILITIES AND SERVICES IN MALAYSIA

FIRST EDITION

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Foreword

By The Director-General of Health

Assalamualaikum wbt, Salam Sejahtera, and *Salam Malaysia Madani*.

I would like to extend my deepest congratulations and appreciation to the Traditional and Complementary Medicine (T&CM) Division, Ministry of Health Malaysia for their dedication and effort in developing the Guidelines for Traditional and Complementary Medicine Healthcare Facilities and Services in Malaysia.

There are various private health care facilities in Malaysia that provide a myriad of health services to the people. The Private Healthcare Facilities and Services Act 1998 [*Act 586*] provides for the regulation and control of private hospitals, private medical clinics, and private dental clinics as well as other services such as hospices, ambulatory care centres, and nursing homes. However, private T&CM healthcare facilities and services are not regulated by this Act and are currently self-regulated.

The Ministry of Health is moving towards the regulation of T&CM healthcare facilities and services. The statutory regulation of T&CM healthcare facilities and services will be governed by a new law, that is the T&CM Healthcare Facilities and Services Act.

The process of creating a new law will take time and thus, we hope that the guidelines can serve as a source of reference for operators and practitioners of T&CM healthcare facilities who wish to provide T&CM services during this period of self-regulation. The guidelines will not only be useful for operators of new T&CM healthcare facilities but to existing T&CM facilities as well. The best practices and recommendations provided in the guidelines can be adopted to continuously improve the operational management and delivery of T&CM services from time to time.

I would like to express my gratitude to the Ministry of Local Government Development (KPKT), the local authorities (PBT), and the T&CM Practitioner Bodies who have worked closely with the Ministry of Health in developing the guidelines. Congratulations and thanks to all those involved who contributed their ideas, knowledge, and expertise to make the publication of the guidelines a success. We hope that the guidelines can be optimised as much as possible by all stakeholders to ensure that T&CM services are effective, safe, and of high quality for all.

Datuk Dr. Muhammad Radzi bin Abu Hassan
Director-General of Health
Ministry of Health Malaysia

Foreword

By The Deputy Director-General of Health (Medical)

Assalamualaikum wbt, Salam Sejahtera, and *Salam Malaysia Madani*.

Congratulations to the Traditional and Complementary Medicine (T&CM) Division, Ministry of Health Malaysia for successfully producing the Guidelines for Traditional and Complementary Medicine Healthcare Facilities and Services in Malaysia.

The guidelines will be an important reference for new and existing private T&CM healthcare service providers in Malaysia. The guidelines can also be used as a guide for local authorities when approving new applications or renewals for business licences. It can also be referred to when conducting inspections on T&CM facilities to ensure that the operation of T&CM healthcare facilities and the provision of T&CM services are in accordance with the standards and requirements set by the Ministry of Health and the relevant authorities.

It is planned that the guidelines are to be implemented through engagement sessions with the relevant stakeholders such as the local authorities, operators of T&CM healthcare facilities, and T&CM practitioners to raise awareness towards the guidelines and educate them on the statutory requirements and voluntary standards aimed to enhance operational management and delivery of T&CM services.

I would like to thank the Ministry of Local Government Development (KPKT) for their enthusiasm in collaborating with the Ministry of Health to develop the guidelines. I would also like to thank all other Ministries, Divisions under the Ministry of Health, and T&CM practitioner bodies that are directly or indirectly involved in the development process. I am very proud that the Ministry of Health had succeeded in fostering inter-agency collaboration to make this important project a success. It is hoped that this collaboration will continue into the future, especially when the guidelines become widely implemented by all stakeholders.

Congratulations again to all.

Dato' Dr. Asmayani binti Khalib
Deputy Director-General of Health (Medical)
Ministry of Health Malaysia

Foreword

By The Director of the T&CM Division

Salam Malaysia Madani and greetings to all.

I am pleased that the Guidelines for Traditional and Complementary Medicine Healthcare (T&CM) Facilities and Services in Malaysia have been successfully developed. Congratulations to the Traditional and Complementary Medicine Division, Ministry of Health especially the Inspectorate and Enforcement Section for successfully preparing the guidelines.

There are many private T&CM healthcare facilities that provide T&CM services to the general public. Currently, the T&CM healthcare facilities that provide T&CM services are self-regulated. Existing laws such as the Traditional and Complementary Medicine Act 2016 [*Act 775*] regulate T&CM practitioners only. The purpose of Act 775 is to ensure that all T&CM practitioners in the recognised practice areas are registered with the T&CM Council. Currently, there are seven T&CM practice areas recognised in Malaysia, namely Traditional Malay Medicine, Traditional Chinese Medicine, Traditional Indian Medicine, Islamic Medical Practice, Homeopathy, Chiropractic, and Osteopathy.

Accordingly, the T&CM Division has taken the initiative to prepare guidelines for operators and practitioners of private T&CM healthcare facilities who wish to provide T&CM services in Malaysia. The guidelines was also developed as a reference for local authorities in the application and renewal of business licences. Although compliance with the guidelines is voluntary, the Ministry of Health sincerely hopes that the use of the guidelines can be optimised as much as possible by all relevant stakeholders.

The guidelines consist of two main parts. The first part of the guidelines highlights the statutory requirements that are mandatory for all T&CM healthcare facilities to operate legally in Malaysia. The second part of the guidelines consists of voluntary standards or best practices that all T&CM healthcare facility operators and practitioners are encouraged to adopt in their business operations.

It is hoped that the guidelines serve as a useful reference for T&CM service providers to ensure that quality and safe T&CM services are continuously provided to their clients or patients.

Dr. Goh Cheng Soon
Director
Traditional and Complementary Medicine Division
Ministry of Health Malaysia

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1.0 INTRODUCTION

1.1 TRADITIONAL AND COMPLEMENTARY MEDICINE (T&CM)

The use of traditional and complementary medicine (T&CM) is widespread in Malaysia. Although conventional medicine is at the heart of the Malaysian healthcare system, T&CM remains socio-economically significant as it has always been used to prevent or treat health disorders among Malaysians. Due to the cultural and ethnic diversity of the country, there is a wide variety of T&CM practices in Malaysia.

In Malaysia, the practice of T&CM, as defined in the T&CM Act 2016 [*Act 775*], is a form of health-related practice that is intended to prevent, treat or manage ailments or diseases or to maintain the mental and physical well-being of a person. Medical and dental practices used by doctors and dentists respectively are excluded.

The T&CM Act 2016 is a law that provides for the establishment of the T&CM Council to regulate T&CM services in Malaysia and to oversee related matters. Currently, seven (7) T&CM practice areas are recognised in Malaysia. These are Traditional Malay Medicine (TMM), Traditional Chinese Medicine (TCM), Traditional Indian Medicine (TIM), Islamic Medicine, Homeopathy, Chiropractic and Osteopathy. The purpose of the Act is to ensure that all T&CM practitioners in the recognised practice areas are registered with the T&CM Council. The Act also aims to set professional standards for T&CM practitioners to ensure that the provision of T&CM services in Malaysia is of the highest safety and quality. The T&CM Act 2016 is currently in Phase 2 of implementation and is expected to be fully enforced by 2024.

1.2 REGULATION OF T&CM HEALTHCARE FACILITIES AND SERVICES

The Malaysian government, through the Ministry of Health (MOH), aims to transform the T&CM industry to realise its potential as a professional T&CM services hub that promotes the country's economic, health and socio-cultural progress.

To achieve this goal, the existing gaps in the T&CM regulatory landscape need to be addressed. While the T&CM Act 2016 regulates the practice of T&CM, there is no clear authority to oversee the regulation of T&CM facilities. There is also a lack of standards for private T&CM facilities, which can impact the safety and quality of T&CM services. Currently, T&CM facilities only need to obtain a business licence from the local authority to operate.

The MOH is moving towards regulating T&CM facilities, an agenda that is enshrined in various national strategies. Statutory regulation of T&CM health facilities and services will be governed by a new law, the T&CM Healthcare Facilities and Services Act.

The process to create a new law takes between 5 and 10 years, leaving the industry largely without regulation during this time. The Guidelines for T&CM Healthcare Facilities and Services in Malaysia will play an important role during this interim to promote the self-regulation of T&CM facilities.

1.3 GUIDELINES FOR T&CM HEALTHCARE FACILITIES AND SERVICES IN MALAYSIA

The Guidelines for T&CM Healthcare Facilities and Services in Malaysia have been developed by the Traditional and Complementary Medicine Division (T&CMD) of the MOH. The Guidelines should be read in conjunction with the applicable laws and regulations and other relevant legislation, as appropriate, governing the related aspects of T&CM in Malaysia.

The Guidelines consist of two main components, namely the statutory requirements and the voluntary standards.

The statutory requirements are mandatory obligations set out in the relevant laws and regulations of Malaysia. T&CM healthcare facilities must adhere to the statutory requirements in order to operate legally in Malaysia.

The second part of the Guidelines consists of voluntary standards for T&CM healthcare facilities. The voluntary standards are best practices that T&CM healthcare facility operators and practitioners are encouraged to apply to their business operations. The adoption of these voluntary standards will enable the MOH to evaluate the adequacy of the recommended standards and facilitate compliance by the T&CM industry to the new Act.

The T&CMD is responsible for the Guidelines and may make amendments to the Guidelines from time to time and as required.

2.0 OBJECTIVES

The Guidelines aim to:

- Provide guidance to operators and practitioners of T&CM healthcare facilities on the operational management and delivery of T&CM services; and
- Encourage the operation of T&CM healthcare facilities and the provision of T&CM services to be in accordance with the standards and requirements set by the MOH and relevant authorities to ensure the highest level of patient safety and quality of care.

3.0 SCOPE OF THE GUIDELINES

The Guidelines provide the minimum requirements and standards for inpatient and outpatient healthcare services provided by private T&CM healthcare facilities. Inpatient healthcare services include the admission of patients who require an overnight stay at the T&CM healthcare facility, such as a T&CM hospital. Outpatient healthcare services involve patients being diagnosed and treated during operating hours without having to stay overnight at the T&CM healthcare facility.

The first part of the Guidelines highlights the statutory requirements that are mandatory for all T&CM healthcare facilities to operate in Malaysia.

The second part of the Guidelines consists of voluntary standards or best practices that all T&CM healthcare facility operators and practitioners are encouraged to adopt in their business operations.

4.0 STATUTORY REQUIREMENTS

- The operator of the T&CM healthcare facility is responsible for ensuring that the business complies with the laws and regulations governing the practice of T&CM in Malaysia.
- The T&CM healthcare facility must adhere to the following statutory requirements in order to legally operate according to the laws of Malaysia.

4.1 BUSINESS REGISTRATION

- Depending on the business entity, T&CM healthcare facilities must be registered with the Companies Commission of Malaysia (CCM) unless otherwise exempted by law such as the Registration of Business Act 1956, Companies Act 2016 and Limited Liability Partnerships Act 2012.
- The certificate of registration from the CCM proves that the business is valid and legally authorised to conduct its business activities and enter into contracts with banks, government agencies and non-governmental entities.
- The certificate of registration issued in respect of a business registered under the Registration of Business Act 1956 must be displayed in a conspicuous place accessible to all staff and recipients of care at the T&CM healthcare facility.
- The T&CM healthcare facility is responsible to comply with all requirements issued by the relevant legislation. For example, companies registered under the Companies Act 2016 must display its registered name and company registration number at every place its business is carried out where records of information are kept and on all official documents issued by the company.

4.2 BUSINESS AND SIGNBOARD LICENCES

- Following the Local Government Act 1976, T&CM healthcare facilities must obtain the necessary licences, permits or approval letters from the relevant licensing department of the local authority or *Jabatan Perlesenan Pihak Berkuasa Tempatan* in relation to the location and nature of the business.
- A business licence shows that the T&CM healthcare facility is a credible business that is responsible for its activities and does not cause harm to public health and safety.

- T&CM healthcare facilities must display the business licence in a place that is accessible to all staff and patients.

- The size of the signboard must comply with the specifications set by the local authority and the content must meet the requirements of the Institute of Language and Literature or *Dewan Bahasa dan Pustaka (DBP)*.

4.3 MEDICAL DEVICES

- All medical devices used in the T&CM healthcare facility must be approved by the Medical Device Authority (MDA) unless otherwise exempted under the Medical Device Act 2012.

4.4 T&CM MEDICATION

- T&CM medication consists of any drugs, products or medicinal materials prescribed by registered T&CM practitioners and dispensed to patients for the treatment or prevention of diseases, whether taken internally or applied externally.

- According to Control of Drugs and Cosmetics Regulations 1984, all drugs, products, and medicinal materials manufactured, sold, supplied, imported, possessed, or administered in the T&CM healthcare facility must be registered with the relevant authorities such as the National Pharmaceutical Regulatory Agency (NPRA) or the Food Safety and Quality Division (FSQD) of the MOH, unless an exemption applies.

- According to Poisons Act 1952, the T&CM healthcare facility must not possess for sale, sell, or supply any of the scheduled poisons listed in the Poisons List of the First Schedule of the Poisons Act 1952 and its Regulations.

- Expired, contaminated or discontinued drugs, products, and medicinal materials shall be properly disposed of in accordance with the T&CM healthcare facility's policy and any written law governing such disposal

- The storage, packaging, labelling and dispensing of all drugs, products, and medicinal materials must be in accordance with the relevant guidelines and written laws. For example, according to the Code of Professional Conduct for T&CM Practitioners, the patient dispensing pack for T&CM medication shall contain the following information:

- Name and address of the T&CM premise/ practitioner;
- Generic name of the medication/ name of the active ingredient;
- Patient's name;
- Date when the medication was supplied or sold;
- Reference number of the patient in the patient medical record; and
- Complete instructions on how to take the medication.

4.5 EMPLOYMENT OF STAFF

- Employment of staff must be in accordance with relevant legislation such as the Employment (Amendment) Act 2022.
- T&CM practitioners and other entitlements of staff such as Social Security Protection (SOCSO) and Employees Provident Fund (EPF) must comply with the relevant law such as the Employees' Social Security Act 1969 and the Employees Provident Fund Act 1991.

4.6 T&CM PRACTITIONERS

- All T&CM practitioners in the Recognized Practice Areas (RPAs) under Act 775 who intends to practice at T&CM healthcare facilities in Malaysia shall register with the T&CM Council and hold a valid Registered Practitioner's Practising Certificate/ RPPC (for local T&CM practitioners) or Temporary Practising Certificate/ TPC (for foreign T&CM practitioners).
- Foreign T&CM practitioners or assistant practitioners are also required to obtain a valid expatriate Employment Pass (EP) from the Immigration Department of Malaysia (IDM).
- The employer hiring foreign T&CM practitioners or assistant practitioners must apply for the expatriate EP through a centralised online platform known as Xpats Gateway which can be accessed via the Expatriate Services Division (ESD) website at esd.imi.gov.my. The application process for the expatriate EP involves obtaining a feedback/ supporting letter from the T&CM Division. The foreign T&CM practitioner is then required to apply for a TPC from the T&CM Council after

obtaining the expatriate EP from the IDM. Interested parties can refer to the Application Guideline For Feedback Letter For Foreign T&CM Assistant Practitioners and Registration Guideline for Foreign T&CM Practitioners for further information.

- The RPPC/ TPC must be displayed in a conspicuous place accessible to all staff and patients of the facility.

4.7 FIRE AND SAFETY REQUIREMENTS

- According to the Fire Services Act 1988, the T&CM healthcare facility must have a fire certificate issued by the Malaysian Fire and Rescue Department and renewed annually.

- Under the Fire Services (Designated Premises) (Amendment) Order 2020, a fire certificate is required if the building meets the criteria of a 'designated premise'. For example, a hospital with a total floor area of 2,000 square metres or more or 5 storeys or more requires a fire certificate. Shops with a total floor area of 3,000 square metres or more also require a fire certificate.

- A fire certificate is given to a building to certify that it has passed the fire safety audit and complies with the Fire Services Act 1988 and its regulations. This includes working fire extinguishers, unobstructed exits and clear signages.

4.8 STANDARDS OF HYGIENE AND CLEANLINESS

- T&CM healthcare facilities must comply with standards of hygiene and cleanliness set by the relevant authorities.

- Examples include the Policies and Procedures on Infection Prevention and Control by the Ministry of Health, the National Cleanliness Policy by the Ministry of Housing and Local Government, and the Guidelines on the Handling and Management of Clinical Wastes in Malaysia by the Department of Environment (DOE), Ministry of Natural Resources, Environment and Climate Change of Malaysia.

4.9 ADVERTISEMENT FOR T&CM HEALTHCARE FACILITIES AND SERVICES

- According to the Medicines (Advertisements and Sales) Act 1956, advertisements include any notice, circular, report, commentary, pamphlet, label, wrapper or other document, and any announcement made orally or by any means of producing or transmitting light or sound.

- Physical forms of advertisements include name cards, flyers, buntings, posters, and signboards. Digital forms of advertisements include websites, blogs, posts on social media such as Facebook and Instagram, videos on content sharing sites such as YouTube, TikTok etc.

- T&CM healthcare facility operators and practitioners who wish to advertise their facilities or services should abide by:

    - Existing laws and regulations pertaining to the advertising of health care facilities and services, such as:

        - Prohibition of making spurious claims and false or misleading representations in relation to T&CM services provided by the registered practitioner under the T&CM Act 2016;

        - Prohibition of advertising certain diseases, abortions and skills or services under the Medicines (Advertisements and Sales) Act 1956;

        - Prohibition of the use of the term "clinic" or "dispensary" or "hospital" or the equivalent of any of these terms having the same meaning in the name of a business or company under the Medical Act 1971; and

        - Prohibition of the use of the title "Pharmacist", "Chemist", "Druggist" or the equivalent of any of those terms having the same meaning in the name of a business or company or dispensary under the Registration of Pharmacists Act 1951.

    - Code of Professional Conduct for T&CM practitioners; and

    - Relevant guidelines (e.g., Advertisement Guidelines for T&CM Practitioner) and directives (e.g., Notification of the List of Prohibited Titles and Abbreviations 2022) issued by the T&CM Council.

- The statements made in the advertisements must be factually correct and substantiated.
- They must not be exaggerated, false, misleading or deceptive so as to give the public a false impression of the capabilities or services of the practitioners in the T&CM healthcare facility.

5.0 VOLUNTARY STANDARDS

In addition to meeting the statutory requirements, T&CM healthcare facility operators and practitioners are encouraged to adopt the following best practices to improve the safety and quality of care provided at the T&CM healthcare facility.

5.1 MANAGEMENT OF PERSONNEL AND OPERATIONS

5.1.1 ORGANISATIONAL PLAN

- All T&CM healthcare facilities should have an organisational plan that includes an organisational chart that should be displayed in a prominent place in the facility.
- The organisational plan should define the functions, authority and responsibilities of each category of staff.
- All registered T&CM practitioners and support staff should be considered part of the organisation.
- The plan should be in writing and easily accessible to all staff in the facility.

5.1.2 PERSON IN CHARGE

- The licensee of a T&CM healthcare facility should appoint a registered T&CM practitioner as the person in charge.
- The responsibilities of the person in charge of a T&CM healthcare facility include:
    - Managing the T&CM healthcare facility and the provision of all services;
    - Supervising all persons employed or engaged in the T&CM healthcare facility and all services provided;
    - Ensuring that all T&CM services given to recipients of care are provided by registered T&CM practitioners and records of their qualifications, practising licence, training, skills and experience are maintained;

- Encouraging and supporting the continuous learning and professional development of all staff and T&CM practitioners;

- Ensure that the T&CM healthcare facility is equipped with safe and functional aids and equipment for staff and those in need of care, such as wheelchairs, grab rails, wheelchair ramps, etc.;

- Ensure the storage, packaging, labelling, and dispensing of all drugs, products, and medicinal materials comply with the requirements of the relevant guidelines and written laws; and

- Performing other duties and responsibilities deemed necessary to ensure that the T&CM healthcare facility and the services provided meet the standards and requirements established by the relevant authorities to maintain the highest level of safety and quality of care.

5.1.3 T&CM PRACTITIONER

- The licensee of the T&CM healthcare facility should be responsible for ensuring all T&CM practitioners employed to provide T&CM services in the recognised practice areas are registered with the T&CM Council.

- All T&CM practitioners employed in the facility must hold a valid Annual Practising Certificate (APC) or Temporary Practising Certificate (TPC) once the T&CM Act 2016 is fully in force.

- The practising certificates must be displayed in a conspicuous place accessible to all staff and patients of the facility.

- All T&CM practitioners must ensure that all details of their registration, qualification, training, skill and experience are provided to the person in charge of the T&CM healthcare facility.

- All T&CM practitioners should undertake continuous professional training activities to maintain, update or develop their knowledge, skills and attitudes to their practice.

- All T&CM practitioners should display their name when performing their duties.

5.1.4 OPERATIONS MANUAL

- An operations manual should be made available and readily accessible to all facility staff.
- The operations manual should contain instructions but not be limited to the following:
    - Operational management of the T&CM healthcare facility (e.g., person in charge, organisational chart, staff reporting procedures, hours of operation).
    - Management of staff and their records (e.g., standards for personal hygiene and appearance, application procedures for staff benefits such as leave and training, guidelines for registration/ consultation/ diagnosis/ treatment of patients).
    - Management of patients and their records (e.g., guidelines for accessing the medical records system, important patient information to be recorded, obtaining consent, maintaining confidentiality).
    - Hygiene and cleanliness standards (e.g., guidelines for cleaning and disinfecting designated areas, air/ temperature/ vector control).
    - Management of medical equipment (e.g., preparation area/ trolley set-up, storage system, planned maintenance).
    - Safety of the T&CM healthcare facility, staff and patients (e.g., emergency plan, emergency contacts, infection control, incident reporting mechanism).
    - Management of T&CM products and medicinal materials (e.g., procurement, T&CM prescription guidelines, storage area/ system, scheduled audit).

5.1.5 HUMAN RESOURCES MANUAL

- A human resources manual should be made available and readily accessible to all staff in the facility.
- The human resources manual should include information but not be limited to the following:
    - Organisational chart;
    - Job description of staff;
    - Staff training and development;
    - Staff welfare; and
    - Staff handbook detailing benefits and leave, confidentiality agreement, privileges etc.

5.1.6 STAFF REGISTER

- The person in charge of the T&CM healthcare facility should keep a staff register containing the following:
    - The name, age, designation and qualifications of all staff, including T&CM practitioners, medical staff, technical staff, ancillary staff and staff responsible for the care and treatment of patients and, where applicable, the professional registration number and practising certificate numbers of each staff member; and
    - Records of leave and sick leave, the date and source of references received and issued, and the results of the most recent staff appraisal, which shall be confidential but made available to staff.
- The person in charge shall maintain a similar register for temporary staff or volunteers if their services are used at the T&CM healthcare facility.

5.2 MANAGEMENT OF PATIENT AND SERVICE PROVISION

5.2.1 PATIENT REGISTER

- The person in charge of a T&CM healthcare facility should keep and maintain an attendance, referral and death register for all patients. A referral is an act of referring someone to the referred facility for consultation, review or further treatment.

- The following information should be entered into the register each time a patient is seen or followed up:

    - Full name;
    - Identification card number;
    - Date and time of visit;
    - Gender;
    - Age;
    - Nationality;
    - Contact number;
    - Referral details, if any; and
    - Death, if any.

- For patient referrals, the referral forms should contain the following information and a copy of the referral form should be filed in the patient's medical record at the referring facility:

    - Name, address, date of birth and gender;
    - Identification card number;
    - Referring T&CM healthcare facility and place of referral;
    - Date of referral;
    - Provisional diagnosis at the time of referral;
    - Current medication, if any;

- Known allergies and drug hypersensitivities, if any;
- Patient's condition during transfer;
- Name and signature of referring practitioner; and
- Notes or any reports sent with the patient, if any.

5.2.2 PATIENT MEDICAL RECORD SYSTEM

- The person in charge of the T&CM healthcare facility should have an appropriate system for maintaining patient medical records that includes the facilities, procedures and mechanisms for organising and maintaining patient medical records.
- Each patient's medical record should have an appropriate registration number.
- The patient's medical record should be protected from loss, tampering or use by unauthorised persons.

5.2.3 PATIENT MEDICAL RECORD

- Each patient’s medical record should contain the following information:
  - Registration number;
  - Name, address, date of birth and gender;
  - Name and contact details of next of kin or legal guardian; and
  - Relevant medical details of the patient, including clinical history, investigations, medical orders signed by the registered medical practitioner (if any), current medication, results of diagnostic tests, etc. A medical order by a registered medical practitioner is a diagnostic or treatment directive that may or may not include a drug prescription.

- A patient medical record may only be taken from the T&CM healthcare facility on court order. If it is taken by court order, the facility shall retain a copy of the record. The original record should be returned at the conclusion of the court proceedings.

- All entries in the patient medical record should be 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 relates and must be legibly written in ink or typewritten or recorded by a computer.

- The patient's medical record must be retained for an appropriate period of time as determined by the relevant authorities such as the National Archives of Malaysia or *Arkib Negara*.

5.2.4 PRIOR DISCLOSURE OF MEDICAL INTERVENTION

- The attending T&CM practitioner should adequately inform the patient about the diagnosis, treatment, or medication to be administered.

- The information should include, but not be limited to, justifications for the diagnosis, treatment or medication, the risks of the procedure, possible adverse effects, and any alternatives, if available.

5.2.5 PATIENT CONSENT FOR TREATMENT

- The patient should give his/ her consent for treatment.

- A patient consent form should be provided for the patient to confirm their consent in writing before treatment is initiated.

- For minors, consent should be obtained from the patient's next of kin or legal guardian as noted in the patient's medical record.

- If the patient is incapacitated due to injury or illness, the consent of the patient's next of kin or legal guardian may be obtained as noted in the patient's medical record.

- The T&CM practitioner should not proceed with treatment without the patient’s consent.

- The patient's consent form shall be properly filed when completed and signed.

5.2.6 DIAGNOSIS AND TREATMENT OF PATIENT

- Diagnostic procedures, treatment and medication preparation for the patient should only be done on the medical order of a registered T&CM practitioner. The medical order should be legibly written and signed by the T&CM practitioner.

- The names of prescribed medication should be written in full before any abbreviation is used in the patient medical record.

- Patients should be informed of possible adverse effects when medications are prescribed. Prescribed medication must be appropriately packaged and properly labelled.

- All medications used in the T&CM healthcare facility must be registered according to the standards and requirements of the Ministry of Health, unless other exceptions apply.

- Treatment of patients shall be carried out by registered T&CM practitioners or a person acting on the T&CM practitioners' explicit instructions. For example, Traditional Indian Medicine (TIM) treatments should only be carried out by a TIM assistant practitioner under the supervision of a TIM practitioner.

- The person in charge of a T&CM healthcare facility must ensure that at least one registered T&CM practitioner is on duty at all times during the facility's operating hours.

5.2.7 USAGE OF MEDICAL EQUIPMENT

- The use of medical equipment in the provision of T&CM services should be in accordance with best practice. For example, acupuncture needles and needles used for wet cupping or *bekam basah* treatment should be of single-use and must not be reused to ensure the highest level of patient safety.

5.2.8 CONFIDENTIALITY

- The patient's medical record should only be accessible by authorised personnel of the T&CM healthcare facility.
- In the event of a civil lawsuit brought by or against the T&CM healthcare facility and its practitioners, access to the patient's medical record should be granted to the T&CM practitioner who provided or caused to be provided any care to the patient or who caused written notes to be made in the patient's medical record while providing care to the patient so that it may be used for the purposes of the civil lawsuit.
- The practitioners in the facility should have the right to inspect the patient's medical record.

5.2.9 INCIDENT REPORTING

- Any unforeseen or unanticipated incident that occurred at the T&CM healthcare facility should be recorded and reported in writing to the relevant authorities within the prescribed time frame after the incident or after the facility has reasonable cause to believe that the incident has occurred.
- Reporting of unforeseen or unanticipated incidents should include, but not be limited to:
    - National Pharmaceutical Regulatory Agency (NPRA)
        - Adverse reactions to T&CM products or medicinal materials.
    - Royal Malaysia Police (RMP)
        - Deaths of patients from unexplained causes or in suspicious circumstances requiring a police report.
        - Assault or bodily injury of patients by staff or vice versa.
    - Malaysian Fire and Rescue Department (JBPM)
        - Fires in the facility resulting in death or personal injury.

- Medical Device Authority (MDA)
    - Malfunction or intentional misuse of equipment that has or would have a significant adverse effect on the patient or facility staff if not averted.

5.2.10 PATIENT GRIEVANCE PLAN

- The person in charge of the T&CM healthcare facility should establish a patient grievance plan that includes a method for educating each patient about their rights to raise their grievances and the grievance procedures.

5.2.11 GRIEVANCE PROCEDURE

- Any complaint against the T&CM healthcare facility should be made orally or in writing by any patient to any staff member of the T&CM healthcare facility.
- The staff should document all complaints received and forward them immediately to the person in charge of the T&CM healthcare facility by the next working day.
- The person in charge of the T&CM healthcare facility is responsible for either assigning someone or personally conducting an investigation of the complaint and providing a response to the complainant within the time limit specified in the patient grievance plan.
- The reply to the complainant should contain:
    - The result of the investigation;
    - Plan of action by the T&CM healthcare facility (if available);
    - Contact information for further communication if the complainant is dissatisfied with the response or the handling of their complaints.

5.3 SPACE REQUIREMENTS FOR T&CM HEALTHCARE FACILITIES

5.3.1 LOCATION OF T&CM HEALTHCARE FACILITY

- A T&CM healthcare facility should be located free from excessive noise.
- If the T&CM healthcare facility is located in a noisy area, the licensee or person in charge should take reasonable steps to ensure that noise is minimised to the extent that patients and staff of the T&CM healthcare facility are not disturbed.
- The location of a T&CM healthcare facility should not be exposed to excessive smoke, foul odour or dust.

5.3.2 DOORS, ENTRANCES AND EXITS

- Doors for the entrance area, storage room, and other doors through which wheelchairs, stretchers, large carts or bulk goods are transported should be sufficiently wide.
- Entrances and exits in a T&CM healthcare facility should be located in an area that causes minimal disruption to staff and patients.

5.3.3 LIFTS, STAIRS AND RAMPS

- The entrances and exits of the T&CM healthcare facility should be designed in a manner that patients can move easily in wheelchairs or on stretchers.
- If treatment or diagnosis is provided in multi-storey buildings, lifts, stairs or ramps should be installed where appropriate to facilitate patient movement.

5.3.4 DESIGNATED AREAS FOR T&CM SERVICE PROVISION

5.3.4.1 RECEPTION AND WAITING AREA

- The T&CM healthcare facility should have adequate reception and waiting areas that are appropriate to the capacity of the T&CM healthcare facility in terms of the number of staff, patients and visitors.
- The areas should be well lit, adequately equipped and have good ventilation. They should be kept clean at all times.
- The waiting area should have a suitable information corner for patients and visitors.

5.3.4.2 SCREENING ROOM

- The T&CM healthcare facility should have suitable screening rooms if required.
- The rooms should be well lit, adequately equipped and well ventilated. They should be kept clean at all times.

5.3.4.3 CONSULTATION ROOM

- The T&CM healthcare facility should have suitable consulting rooms if required.
- The set-up of the consultation room should be appropriate to the nature of practice. For example, Traditional Chinese Medicine (TCM) practitioners diagnose their patients based on the traditional 14-step diagnostic procedure. This diagnostic procedure may require the use of an examination bed.
- The rooms should be well lit, adequately equipped and have good ventilation. They should be kept clean at all times.

5.3.4.4 TREATMENT ROOM

- The T&CM healthcare facility should have suitable treatment rooms.

- The set-up of the treatment room should be appropriate to the nature of the practice. For example, in Shirodhara therapy, the patient usually lies on a treatment bed made of guava wood or other suitable material as prescribed by the Ayurvedic practice. The treatment bed should also be large enough to support a larger stature. Other considerations include treatment rooms segregated by gender and raised platforms for the massage bed (*pangkin*) in facilities offering traditional Malay medicine (TMM) services. TMM services should also be performed by practitioners of the same gender as the patients.

- Rooms should be well lit, adequately equipped and have good ventilation. They should be kept clean at all times.

- Treatment rooms should provide adequate privacy to patients (e.g., patient privacy screens, medical dividers, curtains, prohibited use of unauthorised video surveillance equipment etc.) in accordance to the rules and regulations set by the local authority.

5.3.4.5 PREPARATION AREA

- A preparation area is a secured room or space used to prepare medical equipment (e.g., for cupping therapy) or medication (consisting of drugs, products or medicinal materials) for patients.

- The medical equipment or medication preparation area should be equipped with the relevant facilities:

    - Appropriate cabinets, shelves or storage;

    - An adequate work area for the preparation of medical equipment or medication;

    - An adequate sink or facilities for washing hands or equipment;

- Dispensing machine for medicinal preparations;
- Appropriate tools for measurement;
- Appropriate tools for sterilisation;
- Appropriate equipment for temperature/ humidity control;
- Suitable facilities for waste disposal; and/or
- Refrigerator with thermometer used exclusively for medicinal preparations.

- General disinfectants, cleaning agents and other similar products should not be stored in the preparation area.

5.3.4.6 STORAGE AREA

- Medical equipment and medication (consisting of drugs, products or medicinal materials) should be stored in an environment free of pests and therefore the storage facility must be well designed to keep vectors out.
- The T&CM healthcare facility should have sufficient storage space for medical equipment and medication and the area should be clean, dry, free of odours and dust, and protected from sunlight.
- The storage room should have a system for classifying or organising medical equipment and medication [e.g., First In, First Out (FIFO) system] and the system used should be known to all staff.
- The T&CM healthcare facility should maintain an inventory record that includes, at minimum, information on the items under storage with their specifications, including dosage form, type, strength and quantity per pack, stock balance, etc.
- The inventory record should be updated regularly.
- Medical equipment and medication should be stored at an appropriate temperature and humidity. The temperature and

humidity of the different areas within the storage room should be consistently monitored.

5.3.4.7 TOILET AND BATHROOMS

- All T&CM healthcare facilities should provide toilets or bathrooms with appropriate features for use by staff and patients.
- For example, TIM healthcare facilities offering oil-based therapies should have appropriate bathrooms and showering facilities so that patients can shower after they have received oil therapy and have rested for an appropriate amount of time. The bathroom should have adequate seating and grab bars so that elderly patients can sit down while showering or bathing.
- The toilets or bathrooms should be kept in a clean and hygienic condition at all times.
- The toilets or bathrooms should be large enough to allow space for moving wheelchairs and to ensure patient privacy.
- The door of the toilet or bathroom should not swing outwards and if the toilet or bathroom is adjacent to a corridor, the door should open sideways.

5.3.5 WALL SURFACES

- Wall surfaces in the T&CM healthcare facility should be made of non-toxic material.
- In rooms used for the care or treatment of patients and in rooms where consumables and equipment for the care or treatment of patients are stored, assembled or processed, wall surfaces shall be smooth and washable. For example, to facilitate cleaning after oil-based therapies, walls should be painted with washable, glossy paint to facilitate removal of oil.
- In all rooms or areas exposed to splashes, the walls should have waterproof finish, up to above the splash line.

5.3.6 SIGNBOARD AND SIGNAGES

- An adequate signage and labelling system should be in place in all T&CM healthcare facilities.
- Signs that indicate no smoking or vaping should be posted in T&CM healthcare facilities.

5.3.7 HAND WASHING FACILITIES

- Every room should have hand washing facilities which include soap, hand washing appliances, and sanitary facilities for drying hands.
- All taps on all hand washing facilities in rooms used by patients and care recipients should be patient-friendly.

5.3.8 WATER SUPPLY

- The water supply used in the T&CM healthcare facility must meet the quality standards approved by the relevant authorities such as by the DOE.
- There should be sufficient water supply at all times to meet the needs of the T&CM healthcare facility.
- All water tanks should be properly maintained and constructed of materials approved by the relevant authorities.

5.3.9 PLUMBING SYSTEM

- All plumbing fixtures should be designed and installed in a manner that can be easily cleaned and maintained. For example, it is common for patients to have a wet shower or bathe with a special medicinal powder after an appropriate period of rest post-Ayurvedic treatment. Therefore, larger piping and grease traps are required for the bathroom to avoid clogging of the piping or sewerage system.

- Plumbing facilities shall be installed to prevent cross-contamination between safe and unsafe water supplies or reversal of flow direction that could cause contamination.

5.3.10 AIR CONTROL AND VENTILATION

- The installation of a ventilation or suction system in the T&CM healthcare facility should be appropriate to the nature of the practice.
- For example, in facilities offering moxibustion treatments, fumes may be released into the air which may trigger the conventional fire alarm system. Therefore, an adequate ventilation and exhaust system must be installed above the moxibustion treatment bed to prevent such fumes from escaping into the facility's environment.

5.4 MANAGEMENT OF LINEN AND WASTE

5.4.1 DOMESTIC WASTE

- Domestic waste should be kept in suitable containers (e.g., black refuse bin) and disposed of daily.
- Containers for domestic waste should be thoroughly cleaned each time the container is emptied.
- All staff should wash their hands thoroughly after handling waste.

5.4.2 CLINICAL WASTE

- The management of clinical waste must comply with the Environmental Quality Act 1974 and the Environmental Quality (Scheduled Wastes) Regulations 2005, which are overseen by the DOE.
- The person in charge should refer to the Guidelines on the Handling and Management of Clinical Wastes In Malaysia, Third Edition, 2009 issued by the DOE when handling and managing clinical waste. This obligation is also set out in the Code of Professional Conduct for Traditional and

Complementary Medicine (T&CM) Practitioners under Proper Management of Sharp Equipment and Clinical Waste.

- Clinical waste generated at the T&CM healthcare facility must be disposed of in accordance with established standards. Examples include:
    - Contaminated waste consisting of blood, body fluid waste, infectious waste or any material that has been used on or come into contact with the patient, such as cotton swabs, gloves, bandages, dressings, etc., must be thrown into the clinical waste bin for complete incineration.
    - Sharp waste such as acupuncture needles, blades, lancet needles, syringes with needles and glass must be thrown into the sharps waste container for complete destruction.
    - Unused, expired or contaminated medication in the form of tablets, liquids or powders must be thrown into the clinical waste bin for complete incineration.
    - Non-hazardous clinical waste such as containers, bottles and external packaging can be disposed of normally in the black refuse bin.
- The T&CM healthcare facility must carry out the storage, treatment and disposal of clinical waste using the prescribed transporter and premises licensed by the DOE. The list of licensed scheduled waste facilities/transporters can be referred at https://eswis.doe.gov.my/.
- The T&CM healthcare facility must keep an up-to-date inventory of clinical waste generated, treated and disposed of for notification to the DOE. The records should be kept for a period of 3 years.

5.4.3 LINEN SUPPLY

- Sufficient clean linen should be available to ensure the cleanliness and safety of patients at all times.
- Clean linen should always be used for the patients' examination and treatment beds.

- Dirty linen should be separated from contaminated linen. Dirty linen is linen that has been used but not soiled. It can be washed with detergent, rinsed, and dried in sunlight. Contaminated linen is linen that has been soiled by body fluids and secretions and poses a risk of infection. Such linen should be soaked in a 0.5% sodium hypochlorite solution for 30 minutes, washed with detergent, rinsed, and dried under sunlight.

- Contaminated linen should be changed immediately after use.

- Used linen should not be shaken to prevent the spread of harmful organisms.

- Appropriate personal protective equipment should be used when handling used linen.

- The storage area for used linen should be covered, e.g., using linen bags.

- Clean linen should be stored in a suitable place, e.g., in a closed cupboard or cabinet.

- Adequate records for the management and supply of linen should be kept and maintained appropriately. Such records may include linen stock register, maintenance of washing machines, charges for outsourced laundry services, daily use of cleaning agents etc.

5.5 MANAGEMENT OF SAFETY AND EMERGENCIES

5.5.1 EMERGENCY RESPONSE PLAN

- The person in charge of the T&CM healthcare facility should take precautions and place appropriate emergency measures for all emergencies that may occur in the T&CM healthcare facility such as fires, needle prick injuries, unconscious patients, etc.

- An emergency response plan should be provided in the T&CM healthcare facility and includes the emergency contact information of the person in charge, details of the nearest medical facility/fire brigade, a staff action plan, a referral mechanism, an evacuation plan, etc.

5.5.2 EMERGENCY CONTACT INFORMATION

- The emergency contact information should be posted in a conspicuous place in the T&CM healthcare facility for immediate and easy access by all staff and patients when needed.
- The emergency contact information should include the following:
    - Telephone numbers of the fire brigade and police;
    - Telephone number of ambulance service;
    - Name, address and telephone number of all staff who need to be called in an emergency; and
    - Telephone numbers of all hospitals in the locality of the T&CM healthcare facility.

5.5.3 EMERGENCY ESCAPE PLAN

- All T&CM healthcare facilities should have an appropriate emergency escape plan and signage.
- The emergency escape plan should be posted in a prominent location in the facility that is accessible to all staff and patients.

5.5.4 BASIC EMERGENCY CARE

- T&CM practitioners should refer their patients to the nearest medical facility if the patient suffers from an acute medical emergency during the course of treatment such as loss of consciousness, difficulty in breathing, wounds, bleeding, and musculoskeletal injuries. Additionally, T&CM practitioners should refer their patients to an appropriate medical facility if the patients' illness or condition is beyond the practitioners' competency or expertise.
- In cases of acute medical emergency, the T&CM practitioner should assess the patient's condition to determine the nature, urgency, and severity of the patient's immediate medical needs.

- If the patient's medical needs is immediate, the T&CM healthcare facility should arrange the referral as soon as possible by calling the ambulance and informing the referred medical facility of the impending transfer. If the patient is able to go to the nearest medical facility on his/her own, a suitable referral letter should be prepared.

- The T&CM healthcare facility may provide basic emergency care to the patient suffering from an acute medical emergency to resuscitate or stabilise the patient while pending transfer to the nearest medical facility to receive more advanced care.

- The nature and extent of basic emergency care that can be provided to the patient such as first aid, basic life support, Cardiac Pulmonary Resuscitation (CPR), and Automated External Defibrillation (AED) will depend on the capabilities of the T&CM healthcare facility.

- Based on the specified capabilities of the T&CM healthcare facility in providing basic emergency care, the facility should be equipped with the necessary medical equipment and supplies to stabilise the patient such as an emergency call system, first aid kit, airway management equipment (e.g., pocket mask, bag-mask device, laryngeal mask airway), AED/ manual defibrillator etc.

- Each T&CM healthcare facility should have at least one employee on duty during operating hours who is certified in providing first aid and/ or basic life support. A healthcare worker who is competent in providing first aid and basic life support has the skills to perform dressing and bandaging, CPR and AED, recovery position, Heimlich Manoeuvre, manage fractures, and handle casualties.

- Appropriate policies and procedures for providing basic emergency care as well as records of patients who received basic emergency care should be established.

5.5.5 FIRE SAFETY

- The T&CM healthcare facility should have adequate fire safety equipment that is commensurate with the capacity of the facility, such as smoke detectors, sprinklers, fire extinguishers, safety ladders, etc.

- Fire safety equipment should be maintained according to schedule.

- Fire safety equipment should be placed at strategic locations in the facility as required by the Malaysian Fire and Rescue Department.

5.5.6 INFECTION CONTROL

- The person in charge of the T&CM healthcare facility should be responsible for developing a facility-wide infection control system with measures to prevent, identify, and control the outbreak of infections in the facility.

- To prevent the outbreak of infections in the T&CM healthcare facility, the facility should meet the following requirements:

    - Comply with hand hygiene guidelines for alcohol-based handrub and handwashing with soap and water;

    - Screen patients for potentially infectious diseases before treatment;

    - Ensure that a patient carrying potentially infectious diseases is either referred to another medical facility or isolated from other patients to prevent the spread of infectious diseases;

    - Ensure all T&CM or patient care equipment or instruments that are single-use or disposable are used once only;

    - All T&CM or patient care equipment or instruments that are reusable must be cleaned and sterilised according to standard procedures (as indicated in MOH's Policies and Procedures on Infection Prevention and Control) before use for diagnostic or treatment procedures; and

    - All treatment rooms, diagnostic rooms, preparation rooms and the reception area should be clean and maintained at all times.

- The facility should establish a system for reporting all identified infectious disease outbreaks among patients, staff or the community in which the facility operates. Based on the Prevention and Control of Infectious Diseases Act 1988, all infectious diseases listed in Table 1 of the Act (e.g., avian influenza, measles, dengue fever, malaria, typhoid fever) must be reported immediately to the appropriate authorities. These authorities are:

    - District health officer;
    - Officials at government health facilities;
    - The nearest police station; or
    - Village head.

- To control the outbreak of infections, the facility should comply with the following requirements:
    - Ensuring that any staff who has contracted a contagious disease is removed from duty until they are cleared by a registered medical practitioner to resume work; and
    - Ensuring that any equipment contaminated during the treatment of a patient with a contagious disease cannot be used for other patients until it has been adequately disinfected.

- The person in charge of the T&CM healthcare facility should take appropriate measures to protect all staff, patients and the environment from biological hazards.

- The person in charge of the T&CM healthcare facility must comply with all Ministry of Health directives and guidelines on infection control in times of infectious disease outbreaks, such as during the COVID -19 pandemic.

5.5.7 PEST CONTROL

- The T&CM healthcare facility should be designed and maintained to prevent the entry and harbourage of rodents, lizards, and insects such as cockroaches and ants.

5.5.8 EMERGENCY POWER SUPPLY

- Emergency power generators should be available in case of interruption of normal power supply in T&CM healthcare facilities providing inpatient services.

- Emergency power generators should be considered for outpatient facilities as needed.

5.5.9 PLANNED PREVENTIVE MAINTENANCE

- Planned preventive maintenance of the T&CM healthcare facility and equipment should be carried out to ensure good working condition and safety for use.

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Business Registration Act 1956 and Regulations

Code of Professional Conduct for T&CM Practitioners. Traditional and Complementary Medicine Council (2021)

Companies Act 2016 and Regulations

Employment (Amendment) Act 2022 and Regulations

Environmental Quality Act 1974 and Regulations

Fire Services (Designated Premises) (Amendment) Order 2020

Fire Services Act 1988 and Regulations

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