

LICENCE CONDITIONS FOR

OUTPATIENT MEDICAL SERVICE LICENSEES

PROVIDING OR INTENDING TO PROVIDE

ELECTROCARDIOGRAPHY STRESS TESTING

IMPOSED UNDER SECTION 13(1) OF

THE HEALTHCARE SERVICES ACT 2020

1 Application

- 1.1 These licence conditions (“**LCs**”) apply to all persons which have been licensed under the Healthcare Services Act 2020 (the “**HCSA**”) to provide an outpatient medical service (“**OMS**”) and provide, or intend to provide, as part of the service, Electrocardiography Stress Testing (as defined in paragraph 2.1(1) below) (such persons referred to as “**Licensee(s)**”).
- 1.2 For avoidance of doubt, the defined terms as used in these LCs shall have the meaning ascribed to them in the HCSA and any Regulations made thereunder, unless otherwise stated.
- 1.3 A breach of these LCs may result in regulatory action being taken against Licensees under section 20 of the HCSA, including but not limited to:
- (a) suspension or revocation of the Licensee’s licence(s) to provide OMS;
 - (b) shortening the term of the Licensee’s licence(s) to provide OMS;
 - (c) a direction requiring the Licensee to rectify the contravention, or prevent a recurrence of the contravention; and/or
 - (d) a direction requiring the Licensee to pay a financial penalty.
- 1.4 For avoidance of doubt, these LCs do not override a healthcare professional’s duty to make clinical decisions that are in the best interests of each patient.
- 1.5 For avoidance of doubt, the requirements in these LCs are without prejudice, and in addition to the requirements imposed under the HCSA as well as any Regulations and other applicable licensing conditions, directions, and codes of practice made thereunder.

2 Definitions

- 2.1 The following definitions shall apply to these LCs:

- (1) **“Electrocardiography Stress Testing”** or **“EST”** means the procedure of subjecting a patient to physiological stress applied or induced by methods such as subjecting the patient to physical stress using equipment such as a treadmill or an ergometer in order to elicit evidence of ischemic heart disease, arrhythmias and/or to assess cardiac functional status.
- (2) **“EST Equipment”** has the meaning in paragraph 8.1 below.
- (3) **“EST Performing Staff”** means a Medical Practitioner, Registered Nurse, medical technologist or a suitably trained assistant who is responsible for performing EST on a patient.
- (4) **“Medical Practitioner”** means an individual who:
 - (a) is registered under the Medical Registration Act 1997 (the **“MRA”**) as a registered medical practitioner; and
 - (b) holds a valid practising certificate that is issued under the MRA to practise as a registered medical practitioner.
- (5) **“Supervising Medical Practitioner”** means any Medical Practitioner who is appointed by the Licensee to be responsible for overseeing the operation and provision of EST.
- (6) **“Registered Nurse”** means a person who:
 - (a) is registered under the Nurses and Midwives Act 1999 (the **“NWA”**) as a registered nurse; and
 - (b) holds a valid practising certificate that is issued under the NWA to practise as a registered nurse.

3 Modes of Service Delivery for EST

- 3.1 The Licensee shall only provide EST in its approved permanent premises (as defined in the HCSA) and/or its approved conveyances (as defined in the HCSA), and no other service delivery mode.

4 Licensee’s Obligations as regards Supervising Medical Practitioners and EST Performing Staff

- 4.1 Supervising Medical Practitioner. The Licensee shall appoint at least one Supervising Medical Practitioner and shall ensure that at all times during its provision of EST:
 - (a) at least one Supervising Medical Practitioner is present at the premises at which EST is provided; and

- (b) the Supervising Medical Practitioner(s) is/are in sufficiently close proximity (i.e., within vicinity) to the patient receiving EST such that the Supervising Medical Practitioner(s) can be called upon immediately to do resuscitation in the event of an emergency.

4.2 EST Performing Staff. The Licensee shall ensure that at all times during its provision of EST:

- (a) at least one EST Performing Staff is present with the patient at all times in the exercise room during the EST in order to ensure patient safety; and
- (b) each and every EST Performing Staff employed or engaged by the Licensee is proficient in the use of EST Equipment, which includes, at the minimum, the EST Performing Staff knowing (i) when and how to terminate the EST and (ii) how to analyse Electrocardiogram (“**ECG**”) rhythms. If the EST Performing Staff is not sufficiently proficient in analysing ECG rhythms and there are no other EST Performing Staff around who is proficient in analysing ECG rhythms, the Licensee shall ensure that a Supervising Medical Practitioner is present for each EST.

4.3 The Licensee shall ensure that the final interpretation and reporting of EST results are performed by either (a) a cardiologist, or (b) a Medical Practitioner who has been approved by the Academy of Medicine, Singapore (“**AMS**”) to be on the EST registry of competent non-cardiologists¹ who may perform the final interpretation and reporting of EST results.

5 Education and Training

5.1 The Licensee shall ensure that all of its personnel who are involved in the provision of EST, including the Supervising Medical Practitioner(s) and EST Performing Staff, are familiar with their roles and are suitably trained and qualified to ensure the proper monitoring of patient health status and the management of any emergencies, including being suitably trained in the use of external defibrillators.

Supervising Medical Practitioner

5.2 The Licensee shall ensure that all of its Supervising Medical Practitioners complete an MOH-approved course on the standards on provision of EST² before performing any EST, unless he/she:

¹ Non-cardiologists who have passed the EST accreditation test administered by AMS and who have co-reported a minimum of 200 EST results with a cardiologist as part of his or her EST training can apply to AMS to be on the EST registry of competent non-cardiologists who may perform the final interpretation and reporting of EST results.

² An example of such a course is the “*Understanding the Standards on Provision of Electrocardiography Stress Testing (EST) – A Short Course on Meeting the New Requirements*” course organised by the AMS.

- (a) is a specialist in cardiology, respiratory or sports medicine; or
- (b) is a family physician with MMed (Family Medicine).

5.3 The Licensee shall ensure that all of its Supervising Medical Practitioners are (a) Basic Cardiac Life Support (“**BCLS**”)-certified, (b) trained in the use of an Automated External Defibrillator (“**AED**”) or Manual External Defibrillator, and (c) trained and proficient in the use of EST Equipment, Emergency Equipment (as defined in paragraph 8.5(b) below), and the drugs listed in paragraph 8.7 below.³

EST Performing Staff

5.4 The Licensee shall ensure that all of its EST Performing Staff who are Medical Practitioners and Registered Nurses are BCLS-certified, and that all of its EST Performing Staff who are not Medical Practitioners or Registered Nurses are at least Cardiopulmonary Resuscitation (“**CPR**”)-certified.

5.5 The Licensee shall also ensure that in addition to the requirements in paragraph 5.4 above, all of its EST Performing Staff are (a) trained in the use of an AED or Manual External Defibrillator, and (b) proficient in the use of EST Equipment, which includes knowing when and how to terminate the EST. The Licensee shall ensure that a Supervising Medical Practitioner is present for an EST if the EST Performing Staff performing that EST is not proficient in analysing ECG rhythms.

5.6 The Licensee may allow its Supervising Medical Practitioner(s) to perform the role of an EST Performing Staff, as long as the Supervising Medical Practitioner(s) fulfil(s) all of the criteria in paragraphs 5.4 and 5.5 above. In the event that a Supervising Medical Practitioner performs the role of an EST Performing Staff, the Licensee shall ensure that there is at least one personnel engaged or employed by the Licensee (aside from the Supervising Medical Practitioner performing the role of an EST Performing Staff) who is in sufficiently close proximity (i.e., within vicinity) to the patient receiving EST and who is at least (a) CPR-certified and (b) trained in the use of an AED or Manual External Defibrillator such that that personnel can be called upon immediately to perform resuscitation in the event of an emergency.

6 Summary of Roles, Qualifications and Training Requirements for Licensee’s Personnel

6.1 A summary of the roles, qualification and training requirements required of the Licensee’s Supervising Medical Practitioners and EST Performing Staff is set out in **Annex A**. For avoidance of doubt:

³ Additional training in Advanced Cardiac Life Support (ACLS) is optional.

- (a) Annex A is intended to provide a broad overview of the requirements in paragraphs 4 and 5 above. When in doubt, Licensees shall refer to the requirements in paragraphs 4 and 5 above; and
- (b) in the event of any conflict between the requirements in paragraphs 4 and 5 above and the requirements in Annex A, the requirements in paragraphs 4 and 5 above shall prevail.

7 Patient Management

Selection of Patients

7.1 The Licensee shall ensure that:

- (a) every Medical Practitioner who performs EST at the Licensee's premises ensures that patients who are selected to undergo EST must have a clinical risk assessment and/or a cardiac risk score. Some examples of cardiac risk score include but are not limited to, the Framingham Risk Score or the Pooled Cohort Atherosclerotic Cardiovascular Disease Risk Equations;
- (b) prior to the performance of any EST, the Supervising Medical Practitioner in charge of a patient checks the patient's history, examines the patient, and reviews the patient's resting ECG, to exclude any unstable condition(s) that might be present for which EST is contraindicated or inappropriate;
- (c) the selection of its patients for EST is in line with the current local or international guidelines including but not limited to guidelines from the American Heart Association, American College of Cardiology or European Society of Cardiology ("**Patient Selection Criteria**"); and
- (d) in the event that it offers EST to any patient who does not satisfy the Patient Selection Criteria referred to in paragraph 7.1(c) above (including patients who have requested for EST or referrals from insurance companies that require EST to be included as part of the health screening process), the Licensee shall ensure that the Supervising Medical Practitioner in charge of the patient (i) informs the patient that he or she does not fall within the Patient Selection Criteria and (ii) obtains the patient's express consent to undergo EST notwithstanding that he or she does not fall within the Patient Selection Criteria.

Pre-EST Assessment

- #### 7.2 The Licensee shall ensure that EST is conducted only after a comprehensive assessment of a patient has been conducted. Such comprehensive assessment includes but is not limited to the (a) conduct of a clinical examination of the patient, (b) evaluation of the patient's medical history, and

(c) assessment of the patient's cardiovascular risk factors and calculation of the patient's cardiac risk score.

- 7.3 The Licensee shall be allowed to provide EST to a patient as an optional test as part of a general or executive screening package. If the Licensee does so, the Licensee shall ensure that a proper risk assessment is completed by the Supervising Medical Practitioner in charge of the patient to determine if EST is indicated for the patient as per current cardiology guidelines.

8 Facilities, Equipment and Supplies

- 8.1 The Licensee shall ensure that the equipment used for EST in its premises shall comprise all of the following:

(a) a motorised treadmill / braked ergometer capable of providing measured increases in speed and gradient in accordance with the test protocol. Treadmills shall have at least a front rail and be fitted with an emergency stop button;

(b) a suitable 12-lead ECG recording system capable of continuous monitoring; and

(c) blood pressure ("**BP**") monitoring,

(collectively, the "**EST Equipment**").

- 8.2 The Licensee shall ensure that the EST Equipment used in its premises is registered with the Health Sciences Authority of Singapore ("**HSA**") under the Health Products Act 2007.

- 8.3 The Licensee shall ensure that the EST Equipment is serviced on a regular basis in accordance with the EST Equipment's manufacturer's instructions.

- 8.4 The Licensee shall ensure:

(a) that there is sufficient space in the room adjacent to the treadmill/ergometer referred to in paragraph 8.1(a) above to facilitate CPR in the event of an emergency; and

(b) easy access for a standard ambulance patient trolley for patient evacuation in the event of an emergency.

- 8.5 The Licensee shall ensure that:

(a) all of its facilities or premises used for the provision of EST ("**EST Facility**") is equipped to provide basic life support in the event of complications and cardiac arrest; and

- (b) the EST Facility is, at the minimum, equipped with the following emergency equipment:
 - (i) a defibrillator which is easily manoeuvred into place for easy defibrillation within the EST Facility;
 - (ii) a bag-valve mask;
 - (iii) oropharyngeal airways; and
 - (iv) intra-venous sets,

(collectively, “**Emergency Equipment**”).

8.6 The Licensee shall ensure that all Emergency Equipment is checked regularly and maintained in a state of readiness for emergencies.

8.7 The Licensee shall ensure that all the following drugs are available within the Licensee’s premises for emergencies:

- (a) atropine (in its intravenous form);
- (b) lignocaine or amiodarone (in their intravenous form);
- (c) sub-lingual nitroglycerine tablet or spray;
- (d) adrenaline (in its intravenous form);
- (e) antiplatelets approved by HSA for use in acute coronary syndromes such as aspirin, clopidogrel, ticlopidine, ticagrelor or prasugrel;
- (f) normal saline (0.9%) solution or 5% Dextrose saline solution; and
- (g) short-acting inhaled bronchodilator.

9 Documentation and Audit

9.1 The Licensee shall properly document and maintain the records of training and qualifications of the Licensee's personnel involved in the provision of EST, including the Supervising Medical Practitioner(s) and EST Performing Staff.

9.2 The Licensee shall ensure that where a patient has given his or her express consent pursuant to paragraph 7.1(d) above, such express consent is recorded in writing and kept in the patient’s medical records.

9.3 The Licensee shall ensure that records are kept for each patient in which EST is administered, and that the records are kept in a readily-accessible database which may be subject to audit for quality assurance. These records shall minimally include the following:

- (a) the patient's particulars, including full name, personal identification number, date of birth and gender;
- (b) name(s) of the Supervising Medical Practitioner(s) and personnel who have performed the EST (e.g. the EST Performing Staff);
- (c) date of EST conducted;
- (d) indications for EST;
- (e) any complication(s) during the EST; and
- (f) EST results/outcome.

9.4 The Licensee shall ensure that an up-to-date, dedicated register of patients who have undergone EST at its premises is available at all times.

Annex A: Summary of the Roles, Qualifications and Training Requirements for the Licensee’s Personnel

Personnel Involved in Performing EST	Roles	Qualification Requirements	Training Requirements
Supervising Medical Practitioner	<ol style="list-style-type: none"> 1. To oversee the operation and provision of EST. 2. At least one Supervising Medical Practitioner must be present for EST test when the EST Performing Staff is not sufficiently proficient in analysing ECG rhythms. 3. Must be in sufficiently close proximity (within the vicinity) to the patient to be called upon to do resuscitation in the event of an emergency. 4. Trained and proficient in the use of EST Equipment, Emergency Equipment and drugs listed in paragraph 8.7. 	<p>Must have completed an MOH-approved course on the standards on provision of EST before performing any EST unless he/she is a:</p> <ol style="list-style-type: none"> (a) Specialist in cardiology/respiratory/sports medicine; or (b) Family physician with MMed (Family Medicine). 	<ol style="list-style-type: none"> 1. BCLS certified and trained in the use of an AED or Manual External Defibrillator.
EST Performing Staff	<p>Must be with the patient in the exercise room during the EST at all times in order to ensure patient safety</p>	<p>Can be either a:</p> <ol style="list-style-type: none"> (a) Medical Practitioner (including a Supervising Medical Practitioner); 	<ol style="list-style-type: none"> 1. [Medical Practitioners and Registered Nurses] BCLS-certified

		<ul style="list-style-type: none"> (b) Registered Nurse; (c) Medical Technologist; or (d) A suitably trained assistant. 	<ul style="list-style-type: none"> 2. [Medical Technologists and suitably trained assistants] At least CPR-certified. 3. [All EST Performing Staff] Must be (a) trained in the use of an AED or Manual External Defibrillator and (b) proficient in the use of EST Equipment.
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