

LICENCE CONDITIONS FOR OUTPATIENT MEDICAL SERVICE LICENSEES PROVIDING OR INTENDING TO PROVIDE ENDOSCOPY SERVICE

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**”) that provide, or intend to provide, as part of the OMS, Endoscopy service (such persons referred to as “**Licensee(s)**”).
- 1.2 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 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.
- 1.3 For avoidance of doubt:
- (1) the defined terms as used in these LCs shall have the meanings ascribed to them in the HCSA and any Regulations made thereunder, unless otherwise stated;
 - (2) these LCs do not override a healthcare professional’s duty to make clinical decisions that are in the best interests of each patient; and
 - (3) 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, codes of practice made thereunder.

2 Definitions

- 2.1 The following definitions shall apply to these LCs:
- (1) “**Diagnostic and Minor Therapeutic Endoscopic Procedure**” refers to any endoscopic procedure which:
 - (a) may or may not be accompanied with a minor surgical procedure;

- (b) may involve accompanying biopsy and/or removal of small tissues or foreign body;
- (c) may or may not involve sedation; and
- (d) does not require general anaesthesia.

Examples of Diagnostic and Minor Therapeutic Endoscopic Procedure include, but are not limited to: (i) ENT endoscopic examinations (i.e., Nasopharyngoscopy, video-laryngostroboscopy); (ii) Sigmoidoscopy; (iii) Gastroscopy; (iv) Colonoscopy; (v) Cystoscopy with or without injection of collagen/ Botulinum toxin; and (vi) Cystoscopy with or without removal of foreign body such as ureteric stent or bladder/urethral stones.

- (2) **“Endoscope”** refers to refers to a thin, tube-like instrument with a light and a lens for examining the inside of a body. Instruments such as proctoscope, otoscope, colposcope and capsule endoscopy are not considered Endoscopes.
- (3) **“Endoscopy”** or **“Endoscopic Procedure”**, is the inspection of body organs or cavities using an Endoscope, where the Endoscope is introduced into the body through any of the following five (5) body orifices: (1) mouth; (2) nostrils; (3) anus; (4) urethra; and (5) vagina.
- (4) **Sedation** refers to any of the following:
 - (a) Minimal Sedation, which means a drug-induced state of a patient – (i) during which the patient can respond normally to verbal commands; and (ii) where the patient’s cognitive function and physical coordination may be impaired, but the patient’s airway, ventilation and cardiovascular functions are unaffected; or
 - (b) Moderate Sedation, which means a drug-induced depression of a patient’s consciousness – (i) during which the patient can respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation; (ii) where no intervention is required to maintain a patent airway and spontaneous ventilation of the patient is adequate; and where the patient’s cardiovascular function is usually maintained without any pharmacologic intervention; or
 - (c) Deep Sedation, which means a drug-induced depression of a patient’s consciousness – (i) during which, the patient cannot be easily aroused but will respond purposefully following repeated or painful stimulation; (ii) where the patient’s ability to independently maintain ventilatory function may be impaired; (iii) where the patient may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate; and (iv) where the patient’s cardiovascular function is usually maintained.

(5) “**Therapeutic Endoscopic Procedure**” refers to any endoscopic procedure which:

- (a) is accompanied with the provision of anaesthesia (including general anaesthesia);
- (b) is accompanied with surgical treatment in an operating theatre (including open surgery and minimally invasive surgery); and
- (c) involves sedation.

Examples of Therapeutic Endoscopic Procedure include but are not limited to: (i) laparoscopic surgery; (ii) intragastric balloon placement via endoscopy (elipse balloon); (iii) endoscopic ultrasound-guided fine-needle biopsy; (iv) endoscopic retrograde cholangiopancreatography; and (v) endoscopic submucosal dissection.

3 Service Delivery Modes and Restrictions on Endoscopy

- 3.1 The Licensee may provide any Diagnostic and Minor Therapeutic Endoscopic Procedure at their approved permanent premises or using their approved conveyances.
- 3.2 The Licensee shall only provide Diagnostic and Minor Therapeutic Endoscopic Procedures that do not involve any sedation, biopsy, and/or removal of foreign body, such as Nasopharyngoscopy and Cystoscopy, at premises other than their approved permanent premises (i.e., “**Temporary Premises**”).
- 3.3 For avoidance of doubt, the Licensee shall not provide any Therapeutic Endoscopic Procedure by any service delivery mode, as Therapeutic Endoscopic Procedure may only be provided by licensees who provide ambulatory surgical centre service or acute hospital service, and at their approved permanent premises.

4 Requirements Relating to Personnel

Medical Practitioners

- 4.1 The Licensee shall ensure that the medical practitioner(s) performing the endoscopy has been accredited by the Specialists Accreditation Board (“**SAB**”) and is registered as a specialist, under a specialty that commensurate with the type of endoscopic procedure to be performed.
- 4.2 The Licensee shall ensure that the medical practitioner(s) performing the endoscopy has adequate training, experience and competence as set out in the relevant prevailing practice guidelines issued by the Academy of Medicine, Singapore.

Other Personnel

- 4.3 For endoscopy that does not require the use of sedation but requires the use of endoscopic equipment other than the endoscope, the Licensee shall ensure that there is at least one trained personnel employed or engaged by the Licensee to assist in the handling of the endoscopic equipment during the endoscopy.
- 4.4 For endoscopy that requires the use of sedation, the Licensee shall ensure that the personnel required for the applicable level of sedation are in accordance with the Licence Conditions for Assisted Reproduction Service, Radiological Service, Outpatient Medical Service, Outpatient Dental Service, Nuclear Medicine Service, Ambulatory Surgical Centre Service, Community Hospital Service and Contingence Care Service Licensees Providing or Intending to Provide Sedation or General Anaesthesia.

5 Selection of Patients

- 5.1 The Licensee shall ensure that there are documented established indications in respect of each endoscopic procedure provided by the Licensee.
- 5.2 The Licensee shall ensure that each patient undergoing endoscopy is assessed to be fit to undergo the procedure by the medical practitioner in charge of the patient.

6 Facilities

- 6.1 Paragraph 6 shall apply only to Licensees providing endoscopy service at their approved permanent premises or using their approved conveyances.

Pre-procedure Area

- 6.2 The Licensee shall ensure that there is a waiting area with adequate space and privacy for patients to undergo the required pre-operative preparation.
- 6.3 Where a change of attire by a patient is required prior to the endoscopic procedure, the Licensee shall ensure that there are changing facilities for patients' use in the waiting area.

Procedure Area

- 6.4 The Licensee shall ensure that the area where endoscopy is performed ("**Procedure Area**") is spacious enough to accommodate all personnel, fittings and equipment, and allow all endoscopic procedures to be carried out in a proper, effective, safe and comfortable manner.

- 6.5 The Licensee shall ensure that environmental cleaning of the Procedure Area is performed at the end of each procedure and at the end of the day using an appropriate surface disinfectant solution.

Post-procedure Recovery

- 6.6 For endoscopy that requires the use of sedation, the Licensee shall ensure that there is an area available for patients to recover post-procedure (**“Recovery Area”**).
- 6.7 The Licensee shall ensure that the Recovery Area consists of all of the following:
- (a) At least one recovery bed available for immediate post-sedation monitoring by the time the procedure is expected to be completed;
 - (b) At least one enrolled nurse or one registered nurse to monitor the patient; and
 - (c) Adequate space for staff movement while monitoring the patient and for the treatment of complications, if any.

7 Patient Care

- 7.1 The Licensee shall ensure that each patient is observed for an adequate duration of time after the procedure which commensurate with the sedation and endoscopic procedure performed.
- 7.2 The Licensee shall ensure that the medical practitioner in charge of each patient undergoing endoscopy performs a fitness-for-discharge review to determine if a patient is fit for discharge or requires to be transferred to an Acute Hospital Service for further management.
- 7.3 The Licensee shall ensure that there are adequate arrangements made in advance for the transfer to and further management of patients at an Acute Hospital Service should unexpected complications arise following the endoscopy.

8 Reprocessing of Endoscope

- 8.1 The Licensee shall ensure that all equipment and accessories required for the provision of any endoscopic procedures are effectively reprocessed in accordance with the manufacturer’s instructions.
- 8.2 The Licensee shall ensure that any endoscopic equipment and accessories requiring reprocessing via sterilisation or high-level disinfection shall be carried

out in accordance with the prevailing recommendations set out in the infection control guidelines issued by the Ministry of Health¹.

8.3 Where manual or automated reprocessing using a high-level disinfectant or sterilant is required, the Licensee shall, at the minimum, perform the following processes:

- (a) Pre-cleaning: Pre-cleaning of the endoscope must be done in the Procedure Area immediately after the removal of the endoscope from the patient and prior to disconnecting the endoscope from the power source. Pre-cleaning of the endoscope should be done in accordance with the manufacturer's instructions.
- (b) Leak testing: A leak test must be done before immersing the endoscope in reprocessing solutions to minimise damage to parts of the endoscope that are not designed for fluid exposure. Leak testing shall be done in accordance with the endoscope's and leak testing equipment's manufacturers' instructions for use. If an endoscope fails a leak test, the Licensee shall remove the endoscope from service and send it for repair or replacement.
- (c) Manual cleaning: Thorough manual cleaning of the endoscope and accessories, including the brushing of all channels and valves, must be done to ensure that all mucous, blood and other biologic products are removed after each use. Manual cleaning is done using an appropriate detergent solution at a specified concentration in accordance with the manufacturer's instructions.
- (d) Manual or automated reprocessing: After manual cleaning, the endoscope shall be reprocessed with the appropriate high-level disinfectant or sterilant in accordance with the manufacturer's instructions. High level disinfection or sterilisation may be done either manually or via an automated endoscope reprocessor ("**AER**"). The effectiveness of the high-level disinfectant or sterilant must be monitored in accordance with the manufacturer's instructions. For manual high-level disinfection, endoscopes must be rinsed thoroughly with sterile water according to the disinfectant's and endoscope's manufacturers' instructions for use.

¹ The National Infection Prevention and Control Guidelines For Endoscopy Centres can be found on: <https://www.moh.gov.sg/hpp/all-healthcare-professionals/guidelines/GuidelineDetails/infection-prevention-and-control-guidelines-and-standards>

- (e) Drying: Endoscopes shall be flushed with 70% or 90% ethyl or isopropyl alcohol prior to being dried with pressurised, filtered air by AER or manually.
- (f) Storage: Endoscopes shall be stored hanging in a dry and well-ventilated area with valve and channel caps removed. The storage area shall have sufficient height, width and depth to allow endoscopes to be hung vertically or for horizontal storage.

9 Quality Assurance

9.1 The Licensee shall ensure that there is a documented system to ensure that the cleanliness and sterility of the endoscope(s) are maintained. The documented system shall allow traceability of the following information pertaining to the reprocessing of the endoscope(s):

- (a) the date and time of reprocessing;
- (b) the identities of the endoscope and accessories;
- (c) the method of high-level disinfection or sterilisation used;
- (d) the results of the efficacy of the high-level disinfectant or sterilant used; and
- (e) the identity of the personnel performing the reprocessing of the endoscope.

9.2 The Licensee shall ensure that every personnel involved in the high-level disinfection or sterilisation of endoscopes are trained and competent in the reprocessing of endoscopes via high-level disinfection or sterilisation. The Licensee shall also properly document and maintain the records of the training course(s) and competency test(s) completed by every personnel.

9.3 The Licensee shall implement the following quality assurance measures in relation to the Licensee's provision of endoscopy services:

- (a) Review and document all complications and clinical incidents arising from the Licensee's provision of endoscopy services;
- (b) Conduct periodic monitoring of and document the clinical performance of the endoscopic procedures;
- (c) Implement and document policies and Standard Operating Procedures ("**SOPs**") to ensure safe provision of the endoscopy service;
- (d) Review regularly and document the policies and SOPs referred to in paragraph 9.3(d) above.

- 9.4 The Licensee shall submit all documentation in relation to the quality assurance measures set out in paragraph 9.3 above to the Director-General of Health as and when required.