LICENCE CONDITIONS FOR ACUTE HOSPITAL SERVICE, AMBULATORY SURGICAL CENTRE SERVICE, AND/OR OUTPATIENT MEDICAL SERVICE LICENSEES PROVIDING OR INTENDING TO PROVIDE TREATMENT FOR SEXUAL STERILISATION

IMPOSED UNDER SECTION 13(1) OF THE HEALTHCARE SERVICES ACT 2020

1 Application

- 1.1 These licence conditions ("**LCs**") apply to all persons who:
 - (a) have been licensed under the Healthcare Services Act 2020 (the "**HCSA**") to provide:
 - (a) an acute hospital service ("AHS");
 - (b) an ambulatory surgical centre service ("ASCS"); and/or
 - (c) an outpatient medical service ("OMS"); and
 - (b) are providing or intending to provide, as part of the aforementioned services or services, treatment for sexual sterilisation;

(such persons referred to as "Licensees").

- 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 an AHS, ASCS, and/or OMS;
 - (b) shortening the term of the Licensee's licence(s) to provide an AHS, ASCS, and/or 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:

- (a) the defined terms as used in these LCs shall have the meanings ascribed to them in the Voluntary Sterilisation Act 1974, HCSA and any Regulations made thereunder, unless otherwise stated;
- (b) these LCs do not override a healthcare professional's duty to make clinical decisions that are in the best interests of each patient; and
- (c) 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:

"registered medical practitioner" has the same meaning as in the Medical Registration Act 1997;

"Registered Nurse" means a person who:

- (a) a nurse registered under the Nurses and Midwives Act 1999 (the "NMA") and holds a valid practising certificate under the NMA;
- (b) holds a valid practising certificate that is issued under the NMA to practise as a registered nurse;
- (c) is not an enrolled nurse who is enrolled under the NMA; and
- (d) is not a midwife who is registered under the NMA.

"treatment for sexual sterilisation" means the surgical sterilisation of a male or female that does not involve removal of the reproduction glands or organs unless such removal is necessary for medical or therapeutic reasons.

"**Specified Website**" means the Healthcare Application and Licensing Portal of the Ministry of Health at https://halp.moh.gov.sg.

3 Specific Requirements and Restrictions relating to Treatment for Sexual Sterilisation

3.1 Licensees shall:

(a) not provide any treatment for sexual sterilisation as a service other than as part of the provision of AHS, ASCS, or OMS;

- (b) ensure that any treatment for sexual sterilisation provided as an AHS is provided by a Licensee licensed under the HCSA to provide an AHS;
- (c) ensure that any treatment for sexual sterilisation provided as an ASCS is provided by a Licensee licensed under the HCSA to provide an ASCS;
- (d) ensure that any treatment for sexual sterilisation provided as an OMS is provided by a Licensee licensed under the HCSA to provide an OMS;
- (e) ensure that (i) no treatment for sexual sterilisation provided to females is provided as an OMS and (ii) no treatment for sexual sterilisation involving the use of general anaesthesia, regional anaesthesia or intravenous sedation, is provided as an OMS; and
- (f) ensure that any treatment for sexual sterilisation provided to patients as an OMS are provided via the 'permanent premises' mode of service delivery and in compliance with paragraph 11 of these LCs.

4 Consent

- 4.1 Before carrying out any treatment for sexual sterilisation, Licensees shall ensure that the registered medical practitioner provides a full and reasonable explanation as to the meaning and consequence of the treatment to the patient, patient's spouse, parent or guardian in the course of (a) obtaining the patient's consent in the case of a married or unmarried person who does not lack mental capacity within the meaning of section 4 of the Mental Capacity Act 2008; (b) obtaining the parent or guardian's additional informed written consent in the case of an unmarried person below the age of 21 and who does not lack mental capacity within the meaning of section 4 of the Mental Capacity Act 2008; or (c) preparing the medical report to support the application by a spouse, parent or guardian for a Court Order (as defined in clause 6.1(b) of these LCs) in the case of a person who lacks mental capacity within the meaning of section 4 of the Mental Capacity Act 2008, as the case may be.
- 4.2 Licensees shall ensure that the consent to any treatment for sexual sterilisation provided to a person who does not lack mental capacity within the meaning of section 4 of the Mental Capacity Act 2008 is in writing and contains the following information:
 - (a) in all cases:
 - (i) the name, registration number and signature of the registered medical practitioner carrying out the treatment;
 - (ii) name of the health institution;
 - (iii) whether the treatment for sexual sterilisation is being provided under AHS, ASCS or OMS;

- (iv) the name, identity card or passport number, residential address and signature of the person undergoing the treatment;
- (v) a declaration by the medical practitioner carrying out the treatment that he has given a full and reasonable explanation as to the meaning and consequence of the treatment to the patient undergoing the treatment;
- a declaration by the person undergoing the treatment that he clearly understands the meaning and consequence of the treatment; and
- (vii) the date of the consent;
- (b) in the case of any treatment provided to an unmarried person below the age of 21:
 - (i) the name, identity card or passport number, residential address and signature of the parent or guardian giving consent to the person undergoing such treatment;
 - (ii) the relationship of the parent or guardian giving consent to the person undergoing such treatment;
 - (iii) the date that the consent of the parent or guardian was provided;
 - (iv) a declaration by that medical practitioner that he or she has given a full and reasonable explanation to the parent or guardian giving consent to the person undergoing such treatment; and
 - (v) a declaration by the parent or guardian giving consent to the person undergoing such treatment that he or she clearly understands the meaning and consequence of the treatment.

5 Sexual sterilisation of unmarried persons below the age of 21

- 5.1 Licensees shall only provide treatment for sexual sterilisation to any unmarried person below the age of 21 and who does not lack mental capacity within the meaning of section 4 of the Mental Capacity Act 2008, if, and only if, the following conditions are satisfied:
 - (a) the person, and at least one parent or guardian of the person, both give consent to such treatment;
 - (b) that person's case has been referred to a clinical ethics committee (CEC) licensed under the Healthcare Services Act as soon as reasonably practicable; and

(c) no active steps have been taken to administer any treatment for sexual sterilisation on that person until the CEC has rendered its decision on such case.

6 Treatment for sexual sterilisation of patients who lack mental capacity

- 6.1 Licensees shall only provide treatment for sexual sterilisation on any person who lacks mental capacity within the meaning of section 4 of the Mental Capacity Act 2008 if, and only if,
 - (a) the person undergoing the treatment has been certified by the registered medical practitioner carrying out the treatment to lack mental capacity within the meaning of section 4 of the Mental Capacity Act 2008 and that such treatment is necessary in the best interests of that person; and
 - (b) the court has made an order declaring that such treatment is necessary in the best interests of that person (the "Court Order"), and the relevant spouse, parent or guardian of such person has furnished a copy of such Court Order to the Licensee.

7 Personnel providing treatment for sexual sterilisation

A. <u>Registered Medical Practitioners</u>

- 7.1 Each Licensee shall ensure that treatment for sexual sterilisation to patients provided as part of AHS or ASCS is provided only by registered medical practitioners who are accredited by that Licensee to provide sexual sterilisation.
- 7.2 Licensees shall ensure that treatment for sexual sterilisation to patients provided as part of OMS is provided only by registered medical practitioners who are registered under the MRA by the SMC as a specialist in one of the following branches of medicine:
 - (a) Urology;
 - (b) Obstetrics and Gynaecology; or
 - (c) General Surgery.

B. Nurses

- 7.3 Licensees shall ensure that when treatment for sexual sterilisation is provided to a patient as part of OMS, there shall be at least one person:
 - (a) present during the treatment who is a Registered Nurse with relevant operating experience of not less than six (6) calendar months, to assist in the surgical procedures; and

(b) who is a Registered Nurse with the requisite competencies to oversee the nursing care of the patient.

8 Register

- 8.1 Licensees shall keep and maintain a register of all treatment for sexual sterilisation provided to patients, where such register shall contain the following information:
 - (a) the name of operating theatre, the address of the operating theatre, and the name of the acute hospital, ambulatory surgical centre, or outpatient medical clinic where the treatment has been carried out at;
 - (b) the name and registration number of the registered medical practitioner who carried out such treatment:
 - (c) the name of the person who underwent such treatment, as indicated in identity card or passport;
 - (d) the identity card or passport number of the person who underwent treatment;
 - (e) the date that the treatment was carried out;
 - (f) the method of sterilisation;
 - (g) the reasons for the treatment;
 - (h) where the treatment for sexual sterilisation was provided to a married person who does not lack mental capacity within the meaning of section 4 of the Mental Capacity Act 2008, a copy of the consent provided by that person; and
 - (i) where the treatment for sexual sterilisation was provided to an unmarried person who does not lack mental capacity within the meaning of section 4 of the Mental Capacity Act 2008 and is below the age of 21, a copy of the consent from the parent or guardian;
 - (j) where the treatment for sexual sterilisation provided to a person who lacks mental capacity within the meaning of section 4 of the Mental Capacity Act 2008,
 - (i) the name of the applicant of the Court Order, his identity card or passport number, residential address and signature;
 - (ii) the relationship of the person applying for the Court Order, to the person undergoing treatment;
 - (iii) a declaration by the medical practitioner that he has given a full and reasonable explanation as to the meaning and consequence

- of the treatment to the spouse, parent or guardian (as the case may be) applying for the Court Order;
- (iv) a declaration by the spouse, parent or guardian (as the case may be) that he or she clearly understands the meaning and consequence of the treatment;
- (v) a copy of the medical report in support of the application for the Court Order; and
- (vi) a copy of the Court Order, including the date upon which it was issued.

9 Reports

- 9.1 Licensees shall ensure that a registered medical practitioner who carries out treatment for sexual sterilisation to a patient who:
 - (a) is below 21 years of age and unmarried; or
 - (b) a patient who lacks mental capacity within the meaning of section 4 of the Mental Capacity Act 2008;

submits a report to the Director-General of Health in the form set out at the Specified Website within 30 calendar days after completing such treatment.

10 Certificate of Sexual Sterilization

- 10.1 Licensees shall ensure that:
 - (a) a registered medical practitioner, who has carried out treatment for sexual sterilisation on a patient who does not lack mental capacity within the meaning of section 4 of the Mental Capacity Act 2008, issues to that patient, upon his or her request, a Certificate of Sexual Sterilization in the form set out at the Specified Website;
 - (b) a registered medical practitioner, who has carried out treatment for sexual sterilisation on a patient who lacks mental capacity within the meaning of section 4 of the Mental Capacity Act, issues to that patient's spouse, parent or guardian who was the applicant for the Court Order, upon the applicant's request, a Certificate of Sexual Sterilization in the form set out at the Specified Website; and
 - (c) every registered medical practitioner retains a duplicate of any Certificate of Sexual Sterilization that he or she has issued.

11 Facilities and management of patients

11.1 Licensees who are licensed under the HCSA to provide an OMS shall ensure the availability of necessary facilities and equipment in relation to treatment for sexual sterilisation provided as an OMS, including but not limited to ensuring that:

(a) Pre-operative Area

- (i) there is an adequate waiting area for patients to receive the required pre-operative preparation; and
- (ii) adequate toilet facilities are available in each approved permanent premises; or
- (iii) assistance with toileting needs is provided to patients where needed;

(b) Operating Room

- (i) the operating room is large enough to accommodate all personnel, fittings and equipment and allows for all procedures and movements to be carried out in comfort and safely;
- (ii) the operating room is provided with emergency lighting, water, and power supply;
- (iii) the door to the operating room must be wide enough for the unhindered and free movement of equipment and wheelchairs;
- (iv) the operating room has the necessary facilities for performing the surgery, including but not limited to proper operating tables, operating lights, suction, diathermy, anaesthesia, resuscitation and monitoring equipment, good quality surgical instruments, and any other special equipment required for a particular surgery to be performed;
- (v) the operating room complies with internationally acceptable standards of air quality;
- (vi) the movement of soiled and clean supplies and equipment within the operating room follows a designated traffic pattern to ensure that there is no cross contamination of clean and dirty items;
- (vii) there is provision for effective and appropriate sterilisation of all surgical instruments and equipment by acceptable methods, such as autoclaving;

- (c) Emergency Life- Saving Measures
 - (i) there are up-to-date contingency plans and procedures for rapid evacuation of persons to the nearest permanent premises licensed under the HCSA to provide an AHS and equipped with appropriate facilities for resuscitation and monitoring;
 - (ii) there is a written standing arrangement with the nearest permanent premises licensed under HCSA to provide an AHS for emergency surgical consultations, and for direct ward or intensive care unit admission of patients when required;
 - (iii) the following drugs, supplies and equipment for resuscitation shall be available and easily accessible for prompt usage in the operating room at all times:
 - A. Injection Atropine;
 - B. Intravenous amiodarone:
 - C. Endotracheal intubation or supraglottic airways (such as laryngeal mask airways);
 - D. Motor suction apparatus;
 - E. Oxygen, and oxygen masks or cannula;
 - F. Resuscitative and monitoring facilities, including an automated external defibrillator that has been licensed by the relevant agencies; and
- 11.2 Licensees who are licensed under the HCSA to provide an OMS shall ensure that:
 - (a) all patients are observed after the surgery for an adequate length of time commensurate with the anaesthesia given and the surgical procedure performed;
 - (b) all patients are assessed by the registered medical practitioner-in-charge to determine if each patient requires a transfer to a hospital for continued management, where such review shall be clearly documented in that patient's medical notes, and where that patient requires a transfer to a hospital, the transfer process shall be initiated immediately and without delay; and
 - (c) where necessary, the appropriate verbal and written post-operative instructions for follow-up care, including possible adverse reactions, are provided to a patient.

12 Others

12.1 Licensees shall ensure that information is furnished to the Ministry of Health (MOH) from time to time as required by the MOH, regarding treatment for sexual sterilisation procedures provided as part of OMS and the clinical outcomes of such patients.