LICENCE CONDITIONS FOR OUTPATIENT MEDICAL SERVICE AND AMBULATORY SURGICAL CENTRE SERVICE LICENSEES PROVIDING OR INTENDING TO PROVIDE LIPOSUCTION

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

1 Application

- 1.1 These licence conditions ("**LCs**") apply to:
 - (1) all persons that have been licensed under the Healthcare Services Act 2020 (the "**HCSA**") to provide:
 - (a) an ambulatory surgical centre service ("**ASCS**"); and/or
 - (b) an outpatient medical service ("**OMS**");
 - (2) that provide or intend to provide, as part of the aforementioned service or services, Liposuction (as defined in paragraph 2.1(1)) in premises which are not part of an acute hospital.

(such persons referred to as "Licensees").

- 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:
 - suspension or revocation of the Licensee's licence(s) to provide ASCS and/or OMS;
 - (2) shortening the term of the Licensee's license(s) to provide ASCS and/or OMS;
 - (3) a direction requiring the Licensee to rectify the contravention, or prevent a recurrence of the contravention; and/or
 - (4) a direction requiring the Licensee to pay a financial penalty.

- 1.4 For avoidance of doubt, these LCs do not override a healthcare professionals' 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) "Liposuction" means the surgical removal of localised fat deposits by aspiration, for the purposes of treating deposits of subcutaneous fat that are distributed in aesthetically unpleasing proportions, or for injecting or transferring such fat into another part of the body. Techniques of Liposuction include but are not limited to:
 - (a) Syringe lipoaspiration;
 - (b) Conventional liposuction;
 - (c) Power-assisted liposuction;
 - (d) Ultrasound-assisted liposuction; and
 - (e) Laser-assisted liposuction.
 - (2) **"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) **"Session**" means one continuous period of time, during the course of a day, whereby Liposuction is provided to a patient.
 - (4) **"Per Session Volume**" means the total volume of supernatant fat being removed from a patient per Session.

3 Specific Requirements and Restrictions relating to Liposuction

- 3.1 Licensees shall not provide Liposuction under the following circumstances:
 - (1) if Liposuction is provided to a patient as the sole or primary treatment for weight-reduction;

- (2) if Liposuction involves or results in a Per Session Volume of more than 2 litres; and
- (3) if a patient receiving Liposuction has a Body Mass Index ("**BMI**") of more than 28.
- 3.2 Subject to paragraph 3.1, Licensees shall only provide Liposuction to patients in accordance with the following:
 - (1) Licensees that are only licensed under the HCSA to provide OMS can only provide Liposuction to a patient if:
 - (a) the Per Session Volume is less than 100 millilitres;
 - (b) only local anaesthesia ("**LA**") is administered to that patient for the Liposuction;
 - (c) only syringe lipoaspiration is used for the Liposuction; and
 - (d) the Liposuction is provided via the 'permanent premises' mode of service delivery;
 - (2) the Liposuction shall be provided to a patient only in conjunction with an appropriate weight-reduction programme that includes supervised exercise and diet control regimes;
 - (3) there shall be a period of at least 14 calendar days between any two consecutive Sessions provided to a patient during which no Liposuction or other surgical procedure shall be performed on that patient; and
 - (4) unless otherwise specified in these LCs, Licensees shall comply with the relevant licensing conditions issued under the HCSA relating to the use of sedation and anaesthesia in ambulatory settings when sedation and anaesthesia are used in Liposuction.

4 Personnel Performing Liposuction

A. <u>Medical Practitioners</u>

- 4.1 Licensees shall ensure that Liposuction is provided to a patient only by a medical practitioner who is accredited by the Ministry of Health (the "**MOH**") to provide Liposuction for the Per Session Volume being removed from that patient. Accreditation by MOH will be made in accordance with the framework set out in the <u>Annex</u>.
- 4.2 Licensees shall ensure that if general anaesthesia or sedation (including oral sedatives) is used on a patient during Liposuction:

- (1) a medical practitioner who is registered under the Medical Registration Act 1997 ("MRA") by the Singapore Medical Council (the "SMC") as a specialist in anaesthesiology (the "Anaesthesiologist"); or
- (2) a medical practitioner who is trained and maintains currency in Advanced Cardiac Life Support, provided that the Licensee is licensed to provided ASCS,

must be present at all times until that patient is assessed as fit for discharge in accordance with paragraph 5.14 below.

B. <u>Nurses</u>

- 4.3 Licensees shall ensure that when Liposuction is provided to a patient, there shall be at least one person present during the Liposuction who shall:
 - (1) assist the medical practitioner providing the Liposuction at all times;
 - (2) be a Registered Nurse; and
 - (3) have at least two years of relevant training and experience in assisting inside the operating theatre.

5 Patient Management

- A. Patient Selection
- 5.1 Licensees shall maintain and use a patient selection criteria for Liposuction that is:
 - (1) clear and documented in writing; and
 - (2) is in accordance with the most recent edition of the Guidelines for Aesthetic Practices for Doctors as published by the Singapore Medical Council from time to time.

B. <u>Pre-Liposuction Assessment</u>

- 5.2 Licensees shall ensure that a medical practitioner carries out the following for each patient receiving Liposuction before the procedure is provided to them:
 - (1) to conduct and document a complete medical history of the patient;

- (2) to conduct physical examinations and the appropriate investigations for the patient based upon the patient's overall health and age;
- (3) to determine the appropriate technique of Liposuction to be used on the patient and the facility where the Liposuction will be provided at by taking into consideration:
 - (a) that patient's overall health and age; and
 - (b) the type of anaesthesia and anaesthetic drugs that will be used on that patient during the Liposuction.
- 5.3 Licensees shall ensure that the medical practitioner performing the acts set out in paragraph 5.2 above takes into consideration any common risks of surgery that may be presented by a patient, including but not limited to, bleeding disorders, potential drug reaction and drug interactions, which performing those acts.
- C. Patient Preparation and Consent Taking
- 5.4 Licensees shall ensure that each patient receiving Liposuction is appropriately and adequately (1) assessed, and (2) counselled, by a medical practitioner on the costs, risks and potential outcomes of Liposuction before the procedure is provided to them.
- 5.5 Subject to paragraph 5.7, if a patient expressly communicates a desire to receive Liposuction after the requirements set out in paragraph 5.4 are satisfied, Licensees shall ensure that a period of at least 7 calendar days ("Cooling-Off Period") has elapsed before Liposuction is provided to that Patient.
- 5.6 Subject to paragraph 5.7, during the Cooling-Off Period, Licensees shall ensure that it does not; and its representatives, and persons under its management and control do not:
 - (1) enter into any financial transaction or agreement with;
 - (2) contact; or
 - (3) place any inappropriate constraints on,

the patient receiving Liposuction, on any matter that may directly or indirectly induce or cause the patient to be induced to receiving Liposuction.

- 5.7 Notwithstanding paragraphs 5.5 and 5.6, Licensees do not need to observe the Cooling-Off Period if it is provided to Short-Term Visit Pass (STVP) holders who enter into Singapore for the primary purpose of receiving Liposuction.
- 5.8 Licensees shall not provide Liposuction to a patient if they are aware or have reason to suspect that such patient has:
 - (1) entered into any financial transaction or agreement with;
 - (2) been contacted by;
 - (3) been subjected to any inappropriate constraints by,

any party, on any matter that may directly or indirectly induce or cause the patient to be induced to receiving Liposuction.

- 5.9 After the end of the relevant Cooling-Off Period and before Liposuction is provided to a patient, Licensees shall obtain, in writing, the informed consent of that patient to undergo the procedure.
- 5.10 Licensees shall ensure that the informed consent described in paragraph 5.9 is recorded in a form which is in a format and language that is comprehensible to the patient receiving Liposuction and must include the following information:
 - (1) the name and description of the Liposuction technique to be used;
 - (2) the type of anaesthesia to be used during the Liposuction;
 - (3) if sedation is to be used during the Liposuction;
 - (4) the anticipated costs, benefits, and outcomes to that patient as a result of the Liposuction;
 - (5) the possible risks and complications that that patient may experience as a result of the Liposuction;
 - (6) if there are alternative procedures or treatments other than Liposuction for that patient's condition which Liposuction is being provided for;
 - (7) the full name, identification number and signature of that patient or that patient's legal representative, where relevant;
 - (8) the date that the that patient or that patient's legal representative signed the form, where relevant;

- (9) the full name and signature of the treating medical practitioner carrying out the Liposuction; and
- (10) the date that the treating medical practitioner carrying out the Liposuction signed the form.
- 5.11 Before Liposuction is provided to a patient, Licensees shall obtain the contact details of that patient, including but not limited to (1) his or her local or overseas address; and (2) his or her telephone or mobile number, and inform that patient to provide feedback to the Licensee after the Liposuction using **Form A**.
- 5.12 Licensees shall comply with the requirements set out in paragraphs 5.5 to 5.11 for each Session provided to a patient. Licensees shall ensure that a medical practitioner explains the implications and increased difficulty of repeat Liposuctions to that patient and documents the explanation given in that patient's medical records.

D. <u>Post-Procedural Management</u>

- 5.13 After Liposuction is provided to a patient, Licensees shall ensure that:
 - (1) at least one of the medical practitioners who provided the Liposuction to that patient is available at all times to assess that patient until that patient is certified fit for discharge in accordance with paragraph 5.14 below;
 - (2) subject to paragraph 5.15, at least one Registered Nurse who is trained and proficient in monitoring the condition and recovery of patients' postsedation is stationed at all times in the recovery area to provide sufficient care and monitoring to all patients who have received Liposuction;
 - (3) subject to paragraph 5.15, that patient is monitored:
 - (a) for a period that is
 - (i) commensurate with the type and duration of sedation and anaesthesia given to that patient;
 - (ii) commensurate with the Liposuction technique used on that patient;
 - (iii) at least one hour;
 - (b) with respect to all of the following:
 - (i) vital signs;

- (ii) level of consciousness;
- (iii) pulse rate;
- (iv) respiratory rate;
- (v) oxygen saturation;
- (vi) blood pressure; and
- (vii) body temperature.
- 5.14 Subject to paragraph 5.15, Licensees shall ensure that a patient who received Liposuction is discharged only if the medical practitioner in charge of that patient or the Anaesthesiologist assesses and determines that the patient:
 - (1) has undergone a physical clinical assessment;
 - (2) does not demonstrate any abnormal vital signs and symptoms arising from the Liposuction or the sedation and anaesthesia administered;
 - (3) is capable of ambulating without assistance;
 - (4) is medically cleared of any possible danger to his well-being; and
 - (5) has been given appropriate verbal and written post-operative instructions, including but not limited to the possible adverse reactions and how to manage them.
- 5.15 Notwithstanding paragraphs 5.13(2), 5.13(3) and 5.14, the requirements set out thereunder do not apply to Licensees who are licensed to only provide OMS.

6 Facilities, Equipment and Devices

6.1 Licensees shall ensure the availability and sterility of the facilities and equipment necessary for Liposuction, and that all such facilities and equipment are maintained in good working order.

A. <u>Pre-operative Facilities</u>

- 6.2 Licensees shall ensure that there:
 - (1) is a waiting area for patients to receive the required pre-operative preparation; and
 - (2) are adequate changing facilities and toilets for patients.

7 Documentation

- 7.1 Subject to paragraph 7.3, Licensees shall ensure that detailed medical records of all pre-operative, intra-operative and post-operative procedures performed on a patient in relation to Liposuction, and the details of that patient's post-operative monitoring, are kept securely and minimally include the following:
 - (1) the particulars of the patient receiving Liposuction, including his height, weight and BMI;
 - (2) the names of the medical practitioner(s) and assistant(s) involved in the Liposuction;
 - (3) the patient's diagnosis and indication(s) for the Liposuction;
 - (4) the date, start and end times of the Liposuction;
 - (5) a summary of the Liposuction, including a description of any findings and complications during the procedure;
 - (6) the Liposuction technique used and any assisted technique used (i.e., ultrasound, laser, power);
 - (7) the number and type(s) of drains used during the procedure;
 - (8) the anatomical sites treated;
 - (9) the total volume of tumescent fluid infused during the Liposuction (where applicable);
 - (10) the total dosages and drugs utilised during the Liposuction;
 - (11) the Per Session Volume removed during the Liposuction;
 - (12) the total volume of aspirate from the Liposuction;
 - (13) the post-operative garment used; and
 - (14) the outcome of the Liposuction.
- 7.2 Subject to paragraph 7.3, Licensees shall keep securely all other records and reports that are relevant to any Liposuction provided to a patient, including but not limited to, the following:
 - (1) investigation reports;

- (2) completed consent forms;
- (3) anaesthesia records, including the following:
 - (a) details of pre-operative assessment;
 - (b) type and duration of anaesthesia and sedation used; and
 - (c) the name of the medical practitioner in charge of (i) administering the anaesthesia and sedation and (ii) monitoring the patient;
- (4) post-operative review reports of the patient by the medical practitioner in charge of the patient;
- (5) reports of adverse events, if any;
- (6) pre-discharge evaluation records;
- (7) patient feedback form; and
- (8) histopathology reports if tissue or body fluid is removed.
- 7.3 Notwithstanding paragraphs 7.1 and 7.2, the requirements set out thereunder do not apply to Licensees who are licensed to only provide OMS.

8 Quality Assurance

- 8.1 Licensees shall ensure that each medical practitioner providing Liposuction to patients participates in a quality assurance programme that consists minimally of a peer review that:
 - (1) is conducted once every 6 months in relation to the clinical performance and complications arising from any Liposuction provided by that medical practitioner:
 - (2) is conducted in a group that includes at least 4 medical practitioners who are accredited by MOH, of which at least 50% of them shall not be medical practitioner practising at the licensee's licensed service;
 - (3) presents and discusses all Liposuction that was provided by that medical practitioner with any form of complications; and
 - (4) documents the following in the minutes of meetings:
 - (a) the names of medical practitioners who participated in each peer review session; and

- (b) the discussion points of the peer reviews of all Liposuction cases provided by all the medical practitioners (regardless of where they were performed).
- 8.2 Licensees shall implement a framework for receiving, evaluating, investigating, and documenting all errors, adverse events, and accidents arising from or in connection with Liposuctions provided by the Licensee. Details of each error, adverse event, and accident must be documented.
- 8.3 Licensees shall submit a report to the Director-General of Health at such time and in such form as he shall require on any quality assurance programme that is conducted pursuant to paragraph 8.1.

9 Reporting of Major Liposuction Complications

- 9.1 Subject to paragraph 9.2, Licensees shall complete and submit **Form B** to the Ministry of Health's Health Regulation Group, if any patient suffers from any major complication arising from or in relation to any Liposuction provided to that patient, within 24 hours of onset of the earliest complication,
- 9.2 For the purposes of paragraph 9.1, "major complication" refers to any complication that requires the affected patient to:
 - (1) undergo remedial treatment; or
 - (2) be referred to another medical practitioner for remedial treatment; or
 - (3) be medically managed in an acute hospital.

ACCREDITATION FRAMEWORK MINISTRY OF HEALTH ACCREDITATION REQUIREMENTS FOR LIPOSUCTION

A. <u>Accreditation of Specialists</u>

- 1. All medical practitioners who are registered under the MRA by the SMC as a specialist in plastic surgery ("**Specialist(s)**") may be accredited by MOH to provide Liposuction.
- 2. The accreditation given by MOH under paragraph 1 shall be valid until such time the medical practitioner ceases to be a Specialist.
- Specialists accredited by MOH under paragraph 1 are accredited to perform Liposuction in relation to <u>all</u> Per Session Volumes (i.e., <100mLs and ≥100mLs) for the duration that their accreditation is valid.

B. <u>Accreditation of Non-Specialists</u>

- 4. All medical practitioners who are not Specialists ("**Non-Specialist(s)**") may be accredited by MOH to provide Liposuction if they satisfy the following:
 - (1) have not previously been accredited by the Accreditation Committee of Liposuction ("**ACL**") to provide Liposuction;
 - (2) in the last 2 years:
 - have received proper and accredited training in surgery, including having undergone at least 1 year of training post-housemanship in an acute hospital or equivalent in any of the following postings:
 - (i) General Surgery;
 - (ii) Orthopaedic Surgery;
 - (iii) Obstetrics & Gynaecology;
 - (iv) Paediatric Surgery;
 - (v) Cardiothoracic Surgery; and
 - (vi) Urology;
 - (b) observed at least 10 Liposuctions under preceptorship by a preceptor approved by the ACL; and

- (c) performed at least 1 Liposuction per month under the close supervision by a preceptor approved by the ACL.
- 5. Non-Specialists applying for accreditation under paragraph 4 must ensure that all Liposuctions observed and performed as part of preceptorship are properly documented and signed by both the medical practitioner and the preceptor; and include the following information:
 - (1) particulars of each patient/case;
 - (2) name and medical registration number (e.g., MCR) of the preceptor;
 - (3) name and medical registration number of the medical practitioner;
 - (4) site of training (e.g., name of Medical Clinic, ASC, acute hospital);
 - (5) type of Liposuction technique observed/performed and its description;
 - (6) adverse effects or events arising from the Liposuction, if any; and
 - (7) Evaluation and comments by the preceptor on the performance of the medical practitioner.
- 6. The accreditation given by MOH under paragraph 4 shall be valid for a period of 2 years.
- 7. Non-Specialists accredited by MOH under paragraph 4 are accredited to perform Liposuction in relation to <u>all</u> Per Session Volumes (i.e., <100mLs and \ge 100mLs) for the duration that their accreditation is valid.
- C. <u>Re-accreditation of Non-Specialists</u>
- 8. Non-Specialists may be accredited by MOH to provide Liposuction after the end of the validity of their previous accreditations under paragraph 4 or this paragraph (as the case may be), if they satisfy the following in the last 2 years:
 - performed at least 24 Liposuctions involving the Per Session Volume of <100mLs; or
 - (2) performed at least 24 Liposuctions involving the Per Session Volume of \ge 100mLs.

- 9. The accreditation given by MOH under paragraph 8 shall be valid for a period of 2 years.
- 10. Non-Specialists accredited by MOH under paragraph 8 are accredited to perform Liposuction:
 - (1) if they are accredited under paragraph 8(1), in relation to the Per Session Volume of <100mLs; or
 - (2) if they are accredited under paragraph 8(2), in relation to <u>all</u> Per Session Volumes (i.e., <100mLs and \ge 100mLs),

for the duration that their accreditation is valid.

11. To minimise disruption of care, Non-Specialists are reminded to apply for accreditation under paragraph 8 before the end of the validity of their previous accreditations under paragraph 4 or paragraph 8 (as the case may be).

Form A

(Clinic Letterhead)

PATIENT FEEDBACK FORM

Part 1 to 6 to be completed by the doctor								
1.								
Name and NRIC of								
patient								
2. Name of								
procedure/treatment								
3. Date(s) of								
procedure/treatment								
4. Indication(s) of								
procedure/treatment								
5. Name and MCR								
No. of doctor who								
performed the								
procedure								
6. Signature of								
doctor who								
performed the								
procedure								
Part 7 to 9 to be completed by the patient								
7. How satisfied are	Not						Highly	
you with the	satisfied						satisfied	
treatment received?								
	1	2	3	4	5	6	7	
8. Other comments /								
remarks								
Terridiks								
9. Signature of								
patient and date								

Form B

REPORTING OF MAJOR COMPLICATIONS ARISING FROM OR RELATED TO LIPOSUCTION

S/N	Code for patients ¹	Age and gender of patient	Date of procedure	Clinic where liposuction was performed	Name of doctor who performed procedure	Type of liposuction procedure	Description of major complication ² including site.

Name and MCR of reporting doctor: ______ Name and address of clinic/ASC: _____

Date: _____

¹ Patient's name or NRIC number is not required. However, please de-identify your patient by providing a code and use the code for submission. Retain the code for your patient so that the case can be identified in the instance an audit needs to be done.

² 'Major complication' refers to any complication that requires (a) the affected patient to undergo remedial treatment or to be referred to another doctor for remedial treatment; and/or (b) the affected patient to be medically managed in an acute hospital.