

LICENCE CONDITIONS FOR ACUTE HOSPITAL SERVICE LICENSEES

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

1 Application

- 1.1 These licence conditions (“**LCs**”) apply to all persons licensed under the Healthcare Services Act 2020 (the “**HCSA**”) to provide an acute hospital service (“**AHS**”) (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);
 - (b) shortening the term of the Licensee’s licence(s);
 - (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 HCSA and any Regulations made thereunder, unless otherwise stated;
 - (b) 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; and
 - (c) these LCs do not override a healthcare professional’s duty to make clinical decisions that are in the best interests of each patient.

2 Definitions

- 2.1 In these LCs, unless otherwise specified:
- (a) “**AHS regulations**” means the Healthcare Services (Acute Hospital Service) Regulations 2023.
 - (b) “**IDDSI Framework**” means the **prevailing** global standardised framework developed by the International Dysphagia Diet Standardisation Initiative to describe texture modified foods and thickened fluids used for people with swallowing problems.

- (c) **"Intensive Care Unit"** means a designated area in the Licensee's approved permanent premises to provide any intensive care service.
- (d) **"Intensivist"** means a medical practitioner who is registered under section 22 of the Medical Registration Act 1997 as a specialist in the branch of intensive care medicine.
- (e) **"Radiopharmaceutical"** means any radioactive material that is administered to a patient as a therapeutic agent.
- (f) **"Speech Therapist"** means an allied health professional who is registered and has a valid practising certificate under the Allied Health Professions Act 2011 for the prescribed allied health profession of Speech-Language Pathology (or Speech Language Pathology).

3 Specific Requirements Relating to Approved Permanent Premises, Equipment, etc. (Regulation 8 of the AHS regulations)

- 3.1 Where a Licensee provides accommodation to patients administered with radiopharmaceuticals, the Licensee shall ensure that the area where the patient is accommodated: -
 - (a) complies with the relevant requirements imposed under written law; and
 - (b) has adequate radiation protection measures in place to protect personnel, patients and visitors within the area.

4 Specific Requirements Relating to Recovery Area (Regulation 10 of the AHS regulations)

- 4.1 The Licensee shall ensure that the area that is designated for the use of patients recovering after an operation has sufficient resuscitative equipment, including but not limited to oxygen supply, suction apparatus, pulse oximetry and other monitoring facilities.

5 Specific Requirements Relating to Patient Care (Regulation 12 of the AHS regulations)

- 5.1 The Licensee shall ensure that a patient receiving care at the approved permanent premises is provided with appropriate care by different classes of healthcare professionals, in an integrated manner that addresses the healthcare, medical needs and dental needs of the patient in a holistic manner.

- 5.2 Without limiting paragraph 5.1, the Licensee shall establish, implement and regularly review processes and procedures in relation to the care of a patient, including processes and procedures for the referral of a patient to an appropriate healthcare professional based on the patient's health condition.

6 Specific Requirements Relating to Transport of Patients (Regulation 15 of the AHS Regulations)

- 6.1 The Licensee shall establish, implement and regularly review policies and processes to inform a patient or (if the patient is a minor or lacks mental capacity) a next-of-kin or carer of the patient, who the Licensee is aware has engaged or intends to engage an emergency ambulance service or a medical transport service for the transfer of the patient to or from the Licensee's approved permanent premises, that the patient or (if the patient is a minor or lacks mental capacity) a next-of-kin or carer of the patient should not engage such service from a person who does not hold a licence granted under the HCSA to provide such service.

7 Specific Requirements Relating to Dietetic Service and Nutrition Service (Regulation 19 of the AHS Regulations)

- 7.1 A Licensee shall establish, implement and regularly review processes and procedures to promptly assess the medical condition of every patient and determine whether a dietetic plan needs to be formulated for the patient.

7.2 Where a patient is screened or assessed to require a dysphagia diet, the Licensee shall take appropriate measures to ensure that all foods provided to that patient are prepared and served in a safe manner, which shall include ensuring that the food:

- (a) is prepared and served to that patient in accordance with the level in the IDDSI Framework that the patient is screened or assessed to require; or
- (b) if (a) cannot be done, is prepared and served to that patient in accordance with the alternative level(s) specified in Column 2 of **Table 1** corresponding to the level in the IDDSI Framework that the patient is screened or assessed to require as specified in Column 1 of **Table 1**.

Table 1 – Alternative dysphagia diet

| Column 1 | Column 2 |
|--|--|
| Level in the IDDSI Framework that the patient requires | Alternative level(s) in the IDDSI Framework which the Licensee |

| | |
|------------------------------|--|
| | may prepare and serve to the patient |
| Level 7: Regular | Level 7: Easy to Chew |
| Level 7: Easy to Chew | Level 6: Soft and Bite Sized; or Level 5: Minced and Moist |
| Level 6: Soft and Bite Sized | Level 5: Minced and Moist |
| Level 5: Minced and Moist | Level 4: Pureed; or Level 3: Liquidised |
| Level 4: Pureed | Level 3: Liquidised [This alternative level shall not be used if the patient has been assessed by Speech Therapist to strictly require a dysphagia diet at "Level 4: Pureed"] |
| Level 3: Liquidised | Level 4: Pureed [This alternative level shall not be used if the patient has been assessed by Speech Therapist to strictly require a dysphagia diet at "Level 3: Liquidised"] |

7.3 Where a patient is screened or assessed to require a diet comprising of thickened fluids, the Licensee shall take appropriate measures to ensure that all drinks provided to that patient are prepared and served in a safe manner, which shall include ensuring that the drink is prepared and served to that patient in accordance with the level in the IDDSI Framework that the patient is screened or assessed to require.

8 Specific Requirements Relating to Intensive Care Service (Regulation 20(1) of the AHS Regulations)

8.1 The Licensee shall either: -

- (a) appoint an Intensivist, for the purpose of charging him or her with the responsibility of supervising the provision of any intensive care service to a patient; or
- (b) establish an intensive care unit advisory committee that: -

- (i) is chaired by a medical practitioner;
 - (ii) includes at least one member who is an Intensivist credentialed by the Licensee to provide intensive care services; and
 - (iii) establishes, implements and regularly reviews the standards for the provision of any intensive care service and the competency of the personnel involved in the provision of any intensive care service.
- 8.2 Without limiting paragraph 8.1, the Licensee shall ensure that the Intensivist or the intensive care unit advisory committee establishes and implements a protocol to determine the profile and acuity of a patient in the Intensive Care Unit, who would require an Intensivist to be involved in his care.
- 8.3 The Licensee shall ensure that a patient in the Intensive Care Unit has access to an Intensivist at all times, in the event that the primary physician in charge of that patient is unavailable for any reason.
- 8.4 The Licensee shall ensure that there is at least one medical practitioner physically present at the Licensee's approved permanent premises at all times to attend immediately to any emergencies that may arise in the Intensive Care Unit.
- 8.5 The Licensee shall ensure that the medical practitioner referred to in paragraph 8.4 above, is adequately trained in the provision of intensive care services.
- 8.6 The Licensee shall ensure that the area for the provision of any intensive care service is appropriately and sufficiently equipped to cater to the total number of patients in the Intensive Care Unit, including but not limited to: -
 - (a) equipment for the delivery of oxygen and negative pressure suction;
 - (b) equipment for the continuous respiratory and cardiac support of the patient;
 - (c) equipment for cardiac defibrillation with synchronisation;
 - (d) cardiac monitor;
 - (e) infusion pumps;
 - (f) syringe pumps;

- (g) equipment for monitoring of blood oxygen saturation levels;
- (h) immediate access to equipment for blood gas & biochemical analyses using micromethods¹; and
- (i) immediate access to renal replacement therapy for patients requiring Renal Dialysis.

8.7 The Licensee shall ensure that all of the criteria set out below, are fulfilled before a patient in the Intensive Care Unit is transferred out of the Licensee's approved permanent premises to an approved permanent premises of another licensee licensed under the HCSA to provide an acute hospital service: -

- (a) the receiving medical practitioner has consulted with the referring medical practitioner, and the receiving medical practitioner has agreed to the transfer;
- (b) the management of the referring and the receiving Licensee have been informed of the transfer arrangements; and
- (c) the patient will be transported using an emergency ambulance provided by a person that holds a licence under the HCSA to provide an emergency ambulance service.

8.8 The Licensee shall ensure that the referring medical practitioner is responsible for the patient being appropriately stabilised and adequately managed before and during the transfer.

8.9 National Healthcare Group Pte Ltd which is authorised by a licence under the HCSA to provide an acute hospital service at 10 Buangkok View, Singapore 539747 and known as the "Institute of Mental Health" is exempt from this paragraph 8.

9 Specific Requirements Relating to Nursing Service (Regulation 21 of the AHS Regulations)

9.1 The Licensee shall ensure that there is an adequate number of nursing personnel present at all times at the Licensee's approved permanent premises, taking into account the number and type of patients expected at the Licensee's approved permanent premises.

¹ "Micromethods" are testing methods which utilise small volumes of blood from peripheral blood vessels which aims to minimise blood loss. Such testing methods are deployed for rapid blood gas and biochemical analysis.

10 Specific Requirements Relating to Surgical Service (Regulation 24 of the AHS Regulations)

- 10.1 The Licensee shall establish, implement and regularly review perioperative procedures to minimise the risk of infection of the surgical site of the patient on which any surgical procedure is conducted.
- 10.2 The Licensee shall establish, implement and regularly review processes to ensure that only the appropriate surgical procedure is conducted on a patient, and the surgical procedure is conducted in a proper, effective and safe manner.
- 10.3 The Licensee shall ensure that: -
- (a) each operating theatre at the Licensee's approved permanent premises is large enough to accommodate all personnel, fittings and equipment required for surgical procedures that may be undertaken in that operating theatre, to enable the provision of any surgical service in a proper, effective and safe manner;
 - (b) the door to each operating theatre is wide enough to permit the movement of all necessary equipment, trolleys and wheelchairs in and out of the operating theatre;
 - (c) each operating theatre is equipped with the following:
 - (i) a table designed to enable the carrying out of surgical procedures;
 - (ii) operating theatre lights;
 - (iii) suction equipment;
 - (iv) diathermy equipment;
 - (v) anaesthesia equipment;
 - (vi) resuscitation and monitoring equipment;
 - (vii) functional and effective surgical instruments; and
 - (viii) any other equipment necessary for the safe and effective conduct of any surgical procedure carried out in the operating theatre;

- (e) each operating theatre complies with internationally acceptable standards of air quality for number of air exchanges per hour and air pressure differential;
- (f) there is a procedure for the movement of soiled and clean supplies and equipment within the operating theatre such that there is no contamination of the clean supplies and equipment;
- (g) there is an effective anaesthetic gas scavenging system where general anaesthesia is used;
- (h) terminal cleaning is performed immediately after the completion of each surgical procedure and at the end of each day after the operating theatre is used; and
- (i) compliance with paragraph 10.3 (h) is recorded in writing.

10.4 National Healthcare Group Pte Ltd which is authorised by a licence under the HCSA to provide an acute hospital service at 10 Buangkok View, Singapore 539747 and known as the “Institute of Mental Health” is exempt from this paragraph 10.

11 Specific Requirements Relating to Emergency Department Service (Regulations 28 and 30 of the AHS Regulations)

11.1 Licensees approved to provide emergency department service must establish, implement and regularly review policies and procedures: -

- (a) to ensure the prompt deployment of personnel with the necessary qualification, experience, competency and skills at the Licensee’s approved permanent premises to ensure the provision of the emergency department service to any patient in a proper, effective and safe manner;
- (b) for the physical segregation and management of any patient who has a highly infectious disease or is contaminated with a hazardous material; and
- (c) for the provision of prompt resuscitation service and management of a patient who has a time-sensitive condition.

12 Specific Requirements Relating to Quality of Water and Dialysis Fluid (Regulation 35 of the AHS Regulations)

12.1 A Licensee who provides haemodialysis must ensure that the water used for haemodialysis is treated by reverse osmosis (“**RO water**”), meets the following chemical and microbiological standards and is safe and appropriate for use: -

- (a) with respect to the chemical standards for the RO water: -
 - (i) in addition to paragraphs 12.1(a)(iv) and (v), the RO water shall be tested once every six months for the chemical contaminants specified in **Table 2**;
 - (ii) the RO water tested pursuant to paragraph 12.1(a)(i), shall be obtained from either the start or end of the distribution loop of the haemodialysis water distribution system;
 - (iii) the chemical contaminants shall either: -
 - A. not exceed the respective maximum allowable level specified in **Table 2**; or
 - B. where the maximum allowable level for any of the chemical contaminant is exceeded, be treated with prompt corrective measures such as disinfection of the haemodialysis water distribution system and re-testing of the RO water, such that the chemical contaminants fall below their respective maximum allowable level specified in **Table 2**.

Table 2: Maximum Allowable Level of Chemical Contaminants in the RO water

| Chemical Contaminant in the RO Water | Maximum Allowable Level (in mg/L) |
|--------------------------------------|-----------------------------------|
| Fluoride | 0.2 |
| Chloramines / Total chlorine | 0.1 |
| Copper | 0.1 |
| Aluminum | 0.01 |
| Lead | 0.005 |

- (iv) the RO water shall be tested for Chloramines / Total chlorine using an appropriate test kit at the beginning of each haemodialysis treatment day; and
- (v) if Total chlorine of more than 1 mg/L is used to disinfect the RO water, the RO water shall be tested for Chloramines / Total chlorine using an appropriate test kit at the beginning of each haemodialysis session;

- (b) with respect to the microbiological standards for the RO water: -
- (i) the RO water shall be tested once every two months for the total viable microbial count and endotoxin level;
 - (ii) the RO water tested pursuant to paragraph 12.1(b)(i), shall be obtained from the end of the distribution loop of the haemodialysis water distribution system; and
 - (iii) the total viable microbial count and endotoxin level of the RO water shall either: -
 - A. not exceed the action level specified in **Table 3**; or
 - B. where the action level of any of the contaminant is exceeded, be treated with prompt corrective measures such as disinfection of the haemodialysis water distribution system and re-testing of the RO water, such that the total viable microbial count and endotoxin level fall below their respective action level.

Table 3: Microbiological standards for the RO water

| Microbiological Contaminant in the RO Water | Action Level | Maximum Allowable Level |
|---|---|-------------------------------------|
| Total Viable Microbial Count | Total viable count ≥ 50 Colony Forming Unit (CFU) / mL | Total viable count < 100 CFU / mL |
| Endotoxin Level | Endotoxin level ≥ 0.125 Endotoxin Unit (EU) / ml | Endotoxin level < 0.25 EU / mL |

12.2 The Licensee shall ensure that dialysis fluid used for haemodialysis meets the following chemical and microbiological standards, and is safe and appropriate for use: -

- (a) with respect to the chemical standards for the dialysis fluid: -
- (i) the dialysis fluid shall be sampled for the electrolytes specified in **Table 4**: -
 - A. from haemodialysis machines for testing once every six months, such that dialysis fluid from each haemodialysis machine used to provide haemodialysis is tested for the electrolytes at least once a year; and

- B. after each major repair and/or servicing of the corresponding haemodialysis machine;
- (ii) the dialysis fluid sampled pursuant to paragraph 12.2(a)(i), shall be sampled from the sampling port of a haemodialysis machine; and
- (iii) the electrolytes shall either: -
 - A. fall within the allowable range specified in **Table 4**; or
 - B. where the respective electrolyte falls outside the allowable range specified in **Table 4**, the Licensee shall have policies and procedures to follow-up on the deviation which shall include but is not limited to the following:
 - (1): Obtaining an acknowledgement of the test results by the renal medicine specialist;
 - (2): Obtaining an assessment by the renal medicine specialist on whether the deviation is clinically significant and if a re-testing is required; and
 - (3): Implementing prompt corrective measures and re-testing of electrolytes, if this is assessed to be necessary by the renal medicine specialist, such that the respective electrolyte is within the allowable range specified in **Table 4**;

Table 4: Chemical standards for dialysis fluids

| Electrolyte | Allowable range |
|---|--|
| Sodium | Within 3% of the expected concentration* Within 5% of the expected concentration* |
| Potassium | |
| Calcium | |
| Magnesium | |
| Acetate or lactate expressed as bicarbonate equivalents | |
| Chloride | |

* Expected concentration of each electrolyte refers to the concentration of the electrolyte found on the label of the dialysis fluid.

- (b) with respect to the microbiological standards for the dialysis fluid: -
 - i the dialysis fluid shall be sampled for total viable microbial count and endotoxin level: -

- A. from haemodialysis machines for testing once every two months, such that the dialysis fluid from each haemodialysis machine used to provide haemodialysis is tested for total viable microbial count and endotoxin level at least once a year; and
 - B. after each major repair and/or servicing of the corresponding haemodialysis machine;
- ii the dialysis fluid sampled pursuant to paragraph 12.2(b)(i), shall be sampled from the sampling port of a haemodialysis machine; and
- iii the total viable microbial count and endotoxin level of the dialysis fluid shall either: -
 - A. not exceed the: (1) action level, in the case of standard dialysis fluid, or (2) maximum allowable level, in the case of ultrapure dialysis fluid, as specified in **Table 5**; or
 - B. where the action level (in the case of standard dialysis fluid,) or maximum allowable level (in the case of ultrapure dialysis fluid) is exceeded, prompt corrective measures (such as disinfection of the haemodialysis machine) and re-testing of the dialysis fluid for total viable microbial count and endotoxin level are done, such that the total viable microbial count and endotoxin level are maintained below the respective action or maximum allowable level.

Table 5: Microbiological standards for dialysis fluids

| Type of dialysis fluid | Contaminant | Action level | Maximum allowable level |
|--------------------------|------------------------------|----------------|-------------------------|
| Standard dialysis fluid | Total Viable Microbial Count | ≥50 CFU / ml | <100 CFU/ mL |
| | Endotoxin Level | ≥0.25 EU / ml | <0.5 EU / mL |
| Ultrapure dialysis fluid | Total Viable Microbial Count | Not applicable | <0.1 CFU / mL |
| | Endotoxin Level | Not applicable | <0.03 EU / mL |

- 12.3 The Licensee shall ensure that the tests for the RO water and dialysis fluid mentioned in paragraphs 12.1 and 12.2 are carried out by a laboratory accredited by the Singapore Accreditation Council to perform these tests.

- 12.4 The Licensee shall ensure that the results of the tests conducted on the RO water and dialysis fluid pursuant to paragraphs 12.1 and 12.2 are endorsed by a renal medicine specialist.

13 Specific Requirements Relating to the Prevention of Transmission of Blood Borne Viruses and Pathogenic Bacteria (Regulation 36 of the AHS Regulations)

- 13.1 Subject to paragraph 13.2, a Licensee who provides haemodialysis shall ensure that: -

- (a) before a patient starts receiving haemodialysis at the Licensee's approved permanent premises, the patient must be tested to determine the level of each of the following liver markers, unless the patient is assessed by a medical practitioner to be in a critical condition and requires haemodialysis without delay:
 - (i) Alanine Transaminase; and
 - (ii) any other markers that the medical practitioner opines should be tested;
- (b) before a patient starts receiving haemodialysis at the Licensee's approved permanent premises, the patient must be tested for the following infectious diseases, unless the patient is assessed by a medical practitioner to be in a critical condition and requires haemodialysis without delay:
 - (i) Hepatitis B surface antigen ("**HbsAg**");
 - (ii) Hepatitis B surface antibody ("**Anti-HBs**");
 - (iii) Total hepatitis B core antibody ("**Anti-HBc (total)**");
 - (iv) Hepatitis C Virus antibody ("**Anti-HCV**"); and
 - (v) Human Immunodeficiency Virus antigen/antibody; and
- (c) a patient who has tested positive for Anti-HBc (total) is tested for Hepatitis B Virus ("**HBV**") DNA to rule out occult HBV infection as clinically indicated by a medical practitioner.

- (d) After a patient starts receiving haemodialysis at the Licensee's approved permanent premises, a patient who has been tested negative for a specified infectious disease is subject to routine testing at the frequency specified in **Table 6** to determine the presence of that specified infectious disease.

Table 6: Tests and Testing Frequencies for Blood Borne Viruses

| Test | | | Testing Frequency |
|---|--|--|-------------------|
| HbsAg | | | Every 4 months |
| Anti-HBs | | | |
| Anti-HCV | | | |
| Human Immunodeficiency Virus antigen/antibody | | | Every 6 months |

13.2 The Licensee is not required to comply with –

- (a) paragraphs 13.1(a)(i), (b)(i), (b)(ii) and (b)(iv), if the patient had been tested for Alanine Transaminase, HbsAg, Anti-HBs and Anti-HCV, respectively, within three months prior to starting haemodialysis at the Licensee's approved permanent premises;
- (b) paragraph 13.1(b)(iii), if the patient had been tested for Anti-HBc (total) prior to starting haemodialysis at the Licensee's approved permanent premises, unless otherwise instructed by a medical practitioner; and
- (c) paragraph 13.1(b)(v), if the patient had been tested for the Human Immunodeficiency Virus antigen/antibody within six months prior to starting haemodialysis at the Licensee's approved permanent premises.

13.3 The Licensee shall ensure that a patient who is not immune to Hepatitis B infection (i.e., HBsAg negative and Anti-HBs less than 10mIU/mL) is referred for immunisation against Hepatitis B infection.