LICENCE CONDITIONS FOR

COMMUNITY 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 a community hospital service ("**CHS**") (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) "**CHS regulations**" means the Healthcare Services (Community 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) "**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 Patient Care (Regulation 11 of the CHS regulations)

3.1 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.

3.2 Without limiting paragraph 3.1, 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.

4 Specific Requirements Relating to Transport of Patients (Regulation 14 of the CHS Regulations)

4.1 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.

5 Specific Requirements Relating to Nursing Service (Regulation 16 of the CHS Regulations)

5.1 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.

6 Specific Requirements Relating to Nutrition Service (Regulation 17 of the CHS Regulations)

6.1 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”]

6.2 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.

7 Specific Requirements Relating to Dietetic Service (Regulation 21 of the CHS 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.

8 Specific Requirements Relating to Quality of Water and Dialysis Fluid (Regulation 26 of the CHS Regulations)

8.1 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 8.1(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 8.1(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 8.1(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

8.2 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 8.2(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*
Potassium	Within 5% of the expected concentration*
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 8.2(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

8.3 The Licensee shall ensure that the tests for the RO water and dialysis fluid mentioned in paragraphs 8.1 and 8.2 are carried out by a laboratory accredited by the Singapore Accreditation Council to perform these tests.

8.4 The Licensee shall ensure that the results of the tests conducted on the RO water and dialysis fluid pursuant to paragraphs 8.1 and 8.2 are endorsed by a renal medicine specialist.

9 Specific Requirements Relating to the Prevention of Transmission of Blood Borne Viruses and Pathogenic Bacteria (Regulation 27 of the CHS Regulations)

9.1 Subject to paragraph 9.2, 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:

(i) Alanine Transaminase; and

(ii) any other markers that the renal medicine specialist 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:

(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 renal medicine specialist.

(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

9.2 The Licensee is not required to comply with –

(a) paragraphs 9.1(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 9.1(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 Renal Medicine Specialist; and

(c) paragraph 9.1(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.

9.3 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.