LICENCE CONDITIONS FOR
OUTPATIENT RENAL DIALYSIS 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 who have been licensed under the Healthcare Services Act 2020 (the "**HCSA**") to provide an Outpatient Renal Dialysis Service ("**ORDS**") (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:

(a) suspension or revocation of the Licensee's ORDS licence;

(b) shortening the term of the Licensee's ORDS licence;

(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.

1.4 These LCs do not override a healthcare professional's 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, codes of practice made thereunder.

2 Definitions

2.1 The following definitions shall apply to these LCs:

(1) "**renal medicine specialist**" means a medical practitioner who is registered under section 22 of the Medical Registration Act 1997 as a specialist in the branch of renal medicine.

(2) "**high-dependency haemodialysis**" has the meaning given under the Schedule to the Healthcare Services (Outpatient Renal Dialysis Service) Regulations 2023.

(3) "**registered nurse**" shall have the same meaning as its definition under regulation 2 of the Healthcare Services (Outpatient Renal Dialysis Service) Regulations 2023.

(4) "**nursing personnel**" shall have the same meaning as its definition under regulation 2 of the Healthcare Services (Outpatient Renal Dialysis Service) Regulations 2023.

(5) "**enrolled nurse**" shall have the same meaning as its definition under regulation 2 of the Healthcare Services (Outpatient Renal Dialysis Service) Regulations 2023.

(6) "**specified infectious disease**" shall have the same meaning as its definition under regulation 2 of the Healthcare Services (Outpatient Renal Dialysis Service) Regulations 2023.

3 Medical Services

3.1 The Licensee shall ensure that a patient is reviewed regularly by a renal medicine specialist at the following frequencies:

(a) At least once every two months for a patient on haemodialysis.

(b) At least once a month for a patient on high-dependency haemodialysis.

3.2 The Licensee shall ensure that each patient receiving an ORDS undergoes routine biochemical tests in accordance with the minimum testing frequencies set out in **Table 1**.

3.3 For haemodialysis patients, in the event that the applicable biochemical tests listed in **Table 1** are scheduled to be conducted on the same day as an intended haemodialysis treatment, the Licensee shall ensure that the tests are conducted prior to the start of the haemodialysis treatment.

Table 1: Minimum Biochemical Tests and Testing Frequencies

Type of Dialysis Patient	Biochemical Test	Minimum Testing Frequency
Haemodialysis and Peritoneal Dialysis patients	1) Serum Potassium 2) Serum Calcium 3) Serum Phosphate 4) Albumin 5) Haemoglobin 6) Transferrin Saturation 7) Ferritin 8) Simple in vitro diagnostic glucose test (if patient is diabetic) 9) Alanine transaminase	Every 4 months

	10) Parathyroid Hormone	Annually
Haemodialysis patients	11) Pre- and post- dialysis blood urea or dialysis adequacy test (i.e. Kt/V)	Every 2 months
Peritoneal Dialysis patients	12) Serum Creatinine 13) Serum Urea	Every 4 months

3.4 The Licensee shall ensure that the results of all biochemical blood tests are reviewed and acknowledged by a renal medicine specialist.

4 Nursing Services

4.1 The Licensee shall ensure that there is at least one registered nurse with at least 6 months experience in dialysis present at all times on the Licensee's approved permanent premises when the ORDS is being provided to patients.

4.2 The Licensee shall ensure that the skills and competencies of all nursing personnel are assessed and reviewed annually.

5 Life-saving Measures

5.1 The Licensee shall ensure that each haemodialysis station at the Licensee's approved permanent premises has sufficient space to ensure that resuscitation can be carried out on a patient in a safe and proper manner.

5.2 Without limiting paragraph 5.1, the Licensee shall ensure that, at each haemodialysis station:

(a) there is space that measures at least 5.8 square meters;

(b) there is space to accommodate the proper deployment of resuscitation equipment and at least one person standing on each side of the patient; and

(c) where a haemodialysis chair is present, there is space to adjust the haemodialysis chair to the Trendelenburg position.

6 Quality of Water and Dialysis Fluid

6.1 The Licensee shall ensure that water meant for haemodialysis treatment is treated by reverse osmosis ("**RO water**") and meets the following chemical and microbiological standards:

(a) with respect to the chemical standards for the RO water: –

i in addition to sub-paragraphs (a)(iv) and (v), the RO water shall be tested once every six months for the following chemical contaminants specified in **Table 2**;

ii the RO water tested pursuant to sub-paragraph (a)(i), the RO water sample 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;

Table 2: Chemical standards for 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 dialysis treatment day;

v the RO water shall be tested for Chloramines / Total chlorine using an appropriate test kit at the beginning of each dialysis session if Total chlorine of more than 1 mg/L is used to disinfect the RO water;

(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 sub-paragraph (b)(i) shall be obtained from the end of the distribution loop of the haemodialysis water distribution system;

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 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

6.2 The Licensee shall ensure that dialysis fluid used meets the following chemical and microbiological standards:

(a) with respect to the chemical standards for the dialysis fluid –

i the dialysis fluid shall be sampled –

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/ servicing of the corresponding haemodialysis machine;

for the electrolytes specified in **Table 4**;

ii. the dialysis fluid tested pursuant to sub-paragraph (a)(i) shall be sampled from the sampling port of a haemodialysis machine;

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; and

(2): Obtaining an assessment by the renal medicine specialist on whether the deviation is clinically significant and if a re-testing is required;

(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.

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 –

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;

B. after each major repair/ servicing of the corresponding haemodialysis machine;

for total viable microbial count and endotoxin level;

ii the dialysis fluid tested pursuant to sub-paragraph (b)(ii) shall be sampled from the sampling port of a haemodialysis machine;

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

6.3 The Licensee shall ensure that the tests for the RO water and dialysis fluid mentioned in sub-paragraphs 6.1 and 6.2 are carried out by a laboratory accredited by the Singapore Accreditation Council to perform these tests.

6.4 The Licensee shall ensure that the results of the tests conducted on the RO water and dialysis fluid pursuant to sub-paragraphs 6.1 and 6.2 are endorsed by a renal medicine specialist.

7 Prevention of Transmission of Blood Borne Viruses and Pathogenic Bacteria

7.1 The Licensee shall ensure that –

(a) Before a patient starts receiving haemodialysis, the patient is tested for 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, the patient is tested for the following in relation to specified 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.

(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, 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

7.2 The Licensee is not required to comply with –

(a) paragraph 7.1(a)(i), (b)(i), (b)(ii) and (b)(iv), if the patient had undergone these tests within 3 months prior to starting haemodialysis under the ORDS;

(b) paragraph 7.1(b)(iii), if the patient had a known Anti-HBc (total) result prior to starting haemodialysis under the ORDS, unless otherwise instructed by a Renal Medicine Specialist; and

(c) paragraph 7.1(b)(v), if the patient had undergone this test within 6 months prior to starting haemodialysis under the ORDS.

7.3 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.

8 Emergency Plan

8.1 The Licensee shall ensure that annual drills are carried out for emergency medical coverage and evacuation plans.

8.2 The Licensee shall ensure that emergency medical coverage and evacuation plans are reviewed regularly.