

MH 78:44/1

MOH Circular No. 39/2023

26 June 2023

All Private Hospitals and Medical Clinics Act (PHMCA) and Healthcare Services Act (HCSA) licensees

Telemedicine and Home Medical Care Providers

IMPLEMENTATION OF REGULATIONS AND ISSUANCE OF LICENCE CONDITIONS UNDER PHASE 2 OF THE HEALTHCARE SERVICES ACT (HCSA)

This circular informs all Licensees under the Private Hospitals and Medical Clinics Act (PHMCA), Licensees under the Healthcare Services Act (HCSA), and Telemedicine and Home Medical Care Providers on the implementation of Phase 2 HCSA Regulations and the applicable licence conditions that licensees will need to comply with in the provision of the healthcare services.

The HCSA was enacted in January 2020 to replace the current PHMCA to better safeguard patient safety and well-being and strengthen the governance of healthcare service providers in the evolving healthcare environment, while enabling the rollout of new and innovative healthcare services. The Act is being rolled out in three phases. Phase 1 commenced on 3 January 2022, implementing the Healthcare Services (General Regulations) 2021, the Healthcare Services (Fees) Regulations 2021, the Healthcare Services (Advertisement) Regulations 2021, and the relevant service regulations for Phase 1 services.

Implementation of HCSA amendments and Phase 2 Regulations

- Following feedback from various stakeholders, MOH has reviewed and made amendments to the HCSA and its Regulations previously promulgated under Phase 1, to better support the delivery of healthcare services under a robust regulatory regime. These amendments will be implemented together with the commencement of Phase 2.
- 4 The amended Act and list of applicable Regulations are found in **Annex A**.











Licence conditions ("LCs")

- Phase 2 Licensees may also be issued one or more sets of LCs together with their service licences imposed under Section 13(1) of the Healthcare Services Act 2020¹. The type of LCs issued will depend on the type of licensable healthcare services that the Licensee provides or intends to provide. Please refer to **Annex B** for the LCs applicable to the Phase 2 licensable healthcare services you are providing and ensure that you and your personnel are familiar and comply with these LCs when providing the healthcare services. The full list of LCs can be found in **Annex C**. Any 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.

For avoidance of doubt, these LCs do not override a healthcare professional's duty to make clinical decisions that are in the best interests of each patient.

- Following further feedback from Phase 1 Licensees, MOH has also reviewed the LCs issued to Phase 1 Licensees and modified the LCs accordingly to take into account the amendments made to the Act and the regulations. Phase 1 Licensees whose LCs will be modified will be separately notified of the amendments.
- 7 In addition, all HCSA Licensees will be subject to the Code of Practice for Key Officeholders. A copy of the amended Act, its Regulations, the Code of Practice, and the various Licence Conditions applicable to each licensee can be found at www.HCSA.sg from 26 June 2023.
- Please refer to www.HCSA.sg for the latest information on the transition from PHMCA to HCSA, the various HCSA regulations, and other latest updates and resources. A set of Frequently Asked Questions for each licensable healthcare service will also be uploaded in due course. Should you require further clarification, please email us at HCSA enquiries@moh.gov.sg.



PROFESSOR KENNETH MAK DIRECTOR-GENERAL OF HEALTH MINISTRY OF HEALTH

¹ Section 13(1) of the Healthcare Services Act 2020:

^{13.—(1)} In granting a licence to any person or renewing any licence, the Director-General may impose any conditions that the Director-General considers requisite or expedient having regard to the purposes of this Act.

ANNEX A: AMENDED HEALTHCARE SERVICES ACT AND LIST OF APPLICABLE REGULATIONS

a) Applicable to all HCSA Licensees

- I. Healthcare Services Act²
- II. Healthcare Services (Advertisement) Regulations 2021
- III. Healthcare Services (Fees) Regulations 2021
- IV. <u>Healthcare Services (General) Regulations 2021</u>

b) Applicable to HCSA Phase 1 Licensees

Amendments have been made to these regulations as a result of the amendments to the HCSA and the regulations set out in (a).

- I. Healthcare Services (Blood Banking Service) Regulations 2021
- II. <u>Healthcare Services (Clinical Laboratory Service and</u> Radiological Service) Regulations 2021
- III. <u>Healthcare Services (Cord Blood Banking Service) Regulations</u>
 2021
- IV. <u>Healthcare Services (Emergency Ambulance Service and</u>
 Medical Transport Service) Regulations 2022

Note: The Healthcare Services (Nuclear Medicine Assay Service and Nuclear Medicine Imaging Service) Regulations 2021 have been repealed under Phase 2 of HCSA. Nuclear Medicine Assay and Nuclear Medicine Imaging Service licensees will be licensed and regulated under the Regulations in (b)(II) and (c)(VII) respectively.

c) Applicable to HCSA Phase 2 Licensees

- I. Healthcare Services (Acute Hospital Service) Regulations 2023
- II. <u>Healthcare Services (Ambulatory Surgical Centre Service)</u>
 Regulations 2023
- III. <u>Healthcare Services (Assisted Reproduction Service)</u>
 Regulations 2023
- IV. <u>Healthcare Services (Community Hospital Service) Regulations</u>
 2023
- V. <u>Healthcare Services (Contingency Care Service) Regulations</u> 2023
- VI. <u>Healthcare Services (Human Tissue Banking Service)</u>
 Regulations 2023

² Most of the amendments stated within the Healthcare Services (Amendment) Act will be implemented by the 26 June 2023. Amendments related to employment restrictions will be implemented during HCSA Phase 3.

- VII. <u>Healthcare Services (Nuclear Medicine Service) Regulations</u>
 2023
- VIII. <u>Healthcare Services (Outpatient Dental Service) Regulations</u> 2023
- IX. <u>Healthcare Services (Outpatient Medical Service) Regulations</u> 2023
- X. <u>Healthcare Services (Outpatient Renal Dialysis Service)</u>
 Regulations 2023

ANNEX B: LIST OF LICENCE CONDITIONS APPLICABLE FOR THE PHASE 2 LICENSABLE HEALTHCARE SERVICES

S/N	Licensable Healthcare Services	Applicable Licence Conditions
		Licence Conditions for All Licensees Relating to Immunity
		against Measles and Diphtheria for Personnel in
		Healthcare Institutions
		Licence Conditions for Licensees Providing or Intending
		to Provide Simple in Vitro Diagnostic Tests
	All Phase 2 Licensees	Licence Conditions for Mortality and Morbidity Review
		Licence Conditions for Serious Reportable Events
		Licence Conditions on Case Reviews by Clinical Ethics
		Committees
		Licence Conditions on Licensees Providing or Intending
1		to Provide Restricted Services
		Licence Conditions on Peer Review Learning
		Licence Conditions on the Provision of Luxturna
		(Voretigene Neparvovec) As a Treatment Option for Patients
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		Licence Conditions on the Retention Periods of Patient
		Health Records
		Licence Conditions on Vaccine Cold Chain for Licensees
		Involved in the Handling, Storage and/or Transport of
		Vaccines
		Licence Conditions for Acute Hospital and Outpatient
		Medical Service Licensees Providing or Intending to
		Provide Artificial Insemination Procedures
		Licence Conditions for Acute Hospital Service and
		Ambulatory Surgical Centre Service Licensees Providing
		Cataract Surgery
		Licence Conditions for Acute Hospital Service and
		Outpatient Medical Service Licensees Providing or
	Acute Hospital Service	Intending to Provide Organ Transplant Service
		Licence Conditions for Acute Hospital Service Licensees
		Providing or Intending to Provide Specialised and
		Intensive Care Services to Neonates
		Licence Conditions for Acute Hospital Service,
2		Ambulatory Surgical Centre Service and Outpatient
		Medical Service Licensees Providing or Intending to
		Provide Proton Beam Therapy
		Licence Conditions for Acute Hospital Service,
		Ambulatory Surgical Centre Service and Outpatient
		Medical Service Licensees Providing or Intending to
		Provide Radiation Oncology and Radiation Therapy
		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
		Licence Conditions for All Acute Hospital Service,
		Outpatient Dental Service and Outpatient Medical
		Service Licensees Administering or Intending to
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		Administer Cell, Tissue and Gene Therapy Products
		Manufactured in-House by Healthcare Institutions
		Licence Conditions for Licensees Providing or Intending to Provide Blood Transfusion Service
		Licence Conditions for Licensees Providing or Intending
		to Provide Treatments to Terminate Pregnancy
		Licence Conditions for Outpatient Medical Service,
		Outpatient Dental Service, Outpatient Renal Dialysis
		Service, Acute Hospital Service, Community Hospital
		Service, Contingency Care Service Licensees Providing or
		Intending to Provide COVID-19 Vaccination
		Licence Conditions for Providing or Intending to Provide
		Emergency Life Saving Measures
		Licence Conditions for Acute Hospital Service and
		Ambulatory Surgical Centre Service Licensees Providing
		Cataract Surgery
		Licence Conditions for Acute Hospital Service,
		Ambulatory Surgical Centre Service and Outpatient
		Medical Service Licensees Providing or Intending to
		Provide Proton Beam Therapy
		Licence Conditions for Acute Hospital Service,
		Ambulatory Surgical Centre Service and Outpatient
		Medical Service Licensees Providing or Intending to
		Provide Radiation Oncology and Radiation Therapy
		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
3	Ambulatory Surgical Centre	Licence Conditions for Assisted Reproduction Service,
3	Service	Radiological Service, Outpatient Medical Service,
		Outpatient Dental Service, Nuclear Medical Service,
		Ambulatory Surgical Centre Service, Community Hospital
		Service and Contingency Care Service Licensees
		Providing or Intending to Provide (1) Sedation; or (2)
		General Anaesthesia
		Licence Conditions for Licensees Providing or Intending
		to Provide Blood Transfusion Service
		Licence Conditions for Licensees Providing or Intending
		to Provide Treatments to Terminate Pregnancy
		Licence Conditions for Outpatient Medical Service and
		Ambulatory Surgical Centre Service Licensees Providing
		or Intending to Provide Liposuction
		Licence Conditions for Providing or Intending to Provide
		Emergency Life Saving Measures
	Assisted Reproduction Service	Licence Conditions for Assisted Reproduction Service
		Licensees Providing or Intending to Provide Pre-
4		Implantation Genetic Testing for (a) Monogenic or Single
		Gene Defects or (b) Chromosomal Structural
		Rearrangements
		Licence Conditions for Assisted Reproduction Service,
		Radiological Service, Outpatient Medical Service,
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		Outpatient Dental Service, Nuclear Medical Service, Ambulatory Surgical Centre Service, Community Hospital Service and Contingency Care Service Licensees Providing or Intending to Provide (1) Sedation; or (2) General Anaesthesia Licence Conditions for Licensees Providing Assisted Reproduction Services
		Licence Conditions for Providing or Intending to Provide
		Emergency Life Saving Measures
		Licence Conditions for Assisted Reproduction Service,
		Radiological Service, Outpatient Medical Service, Outpatient Dental Service, Nuclear Medical Service, Ambulatory Surgical Centre Service, Community Hospital Service and Contingency Care Service Licensees Providing or Intending to Provide (1) Sedation; or (2) General Anaesthesia
_		Licence Conditions for Licensees Providing or Intending
5	Community Hospital Service	to Provide Blood Transfusion Service
		Licence Conditions for Outpatient Medical Service, Outpatient Dental Service, Outpatient Renal Dialysis Service, Acute Hospital Service, Community Hospital Service, Contingency Care Service Licensees Providing or Intending to Provide COVID-19 Vaccination Licence Conditions for Providing or Intending to Provide Emergency Life Saving Measures
6	Contingency Care Service	Licence Conditions for Assisted Reproduction Service, Radiological Service, Outpatient Medical Service, Outpatient Dental Service, Nuclear Medical Service, Ambulatory Surgical Centre Service, Community Hospital Service and Contingency Care Service Licensees Providing or Intending to Provide (1) Sedation; or (2) General Anaesthesia Licence Conditions for Outpatient Medical Service, Outpatient Dental Service, Outpatient Renal Dialysis Service, Acute Hospital Service, Community Hospital
		Service, Contingency Care Service Licensees Providing or Intending to Provide COVID-19 Vaccination Licence Conditions for Providing or Intending to Provide Emergency Life Saving Measures
7	Human Tissue Banking Service	Licence Conditions for Human Tissue Banking Service Licence Conditions for Human Tissue Banking Service Licensees Providing or Intending to Provide Banking of Cardiac and Vascular Tissue Licence Conditions for Human Tissue Banking Service Licensees Providing or Intending to Provide Banking of Haematopoietic Stem Cell (Including Bone Marrow)
		Licence Conditions for Human Tissue Banking Service Licensees Providing or Intending to Provide Banking of Ocular Tissue

		License Conditions for House Times Dealth Cont
		Licence Conditions for Human Tissue Banking Service Licensees Providing or Intending to Provide Banking of Skin Tissue
8	Nuclear Medicine Service	Licence Conditions for Assisted Reproduction Service, Radiological Service, Outpatient Medical Service, Outpatient Dental Service, Nuclear Medical Service, Ambulatory Surgical Centre Service, Community Hospital Service and Contingency Care Service Licensees Providing or Intending to Provide (1) Sedation; or (2) General Anaesthesia Licence Conditions for Providing or Intending to Provide Emergency Life Saving Measures
		Licence Conditions for the Provision of Nuclear Medicine
		Services
		Licence Conditions for All Acute Hospital Service,
		Outpatient Dental Service and Outpatient Medical
		Service Licensees Administering or Intending to
		Administer Cell, Tissue and Gene Therapy Products
		Manufactured in-House by Healthcare Institutions
		Licence Conditions for Assisted Reproduction Service,
		Radiological Service, Outpatient Medical Service,
		Outpatient Dental Service, Nuclear Medical Service,
	Outrationt Bontal Comica	Ambulatory Surgical Centre Service, Community Hospital
9	Outpatient Dental Service	Service and Contingency Care Service Licensees
		Providing or Intending to Provide (1) Sedation; or (2) General Anaesthesia
		Licence Conditions for Outpatient Medical Service, Outpatient Dental Service, Outpatient Renal Dialysis
		Service, Acute Hospital Service, Community Hospital
		Service, Contingency Care Service Licensees Providing or
		Intending to Provide COVID-19 Vaccination
		Licence Conditions for Providing or Intending to Provide
		Emergency Life Saving Measures
		Licence Conditions for Acute Hospital and Outpatient
	Outpatient Medical Service	Medical Service Licensees Providing or Intending to
		Provide Artificial Insemination Procedures
		Licence Conditions for Acute Hospital Service and
		Outpatient Medical Service Licensees Providing or
		Intending to Provide Organ Transplant Service
		Licence Conditions for Acute Hospital Service,
		Ambulatory Surgical Centre Service and Outpatient
10		Medical Service Licensees Providing or Intending to
10		Provide Proton Beam Therapy
		Licence Conditions for Acute Hospital Service,
		Ambulatory Surgical Centre Service and Outpatient
		Medical Service Licensees Providing or Intending to
		Provide Radiation Oncology and Radiation Therapy
		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

		Licence Conditions for All Acute Hospital Service,
		Outpatient Dental Service and Outpatient Medical
		Service Licensees Administering or Intending to
		Administer Cell, Tissue and Gene Therapy Products
		Manufactured in-House by Healthcare Institutions
		Licence Conditions for Assisted Reproduction Service,
		Radiological Service, Outpatient Medical Service,
		Outpatient Dental Service, Nuclear Medical Service,
		Ambulatory Surgical Centre Service, Community Hospital
		Service and Contingency Care Service Licensees
		Providing or Intending to Provide (1) Sedation; or (2)
		General Anaesthesia
		Licence Conditions for Licensees Providing or Intending
		to Provide Blood Transfusion Service
		Licence Conditions for Licensees Providing or Intending
		to Provide Treatments to Terminate Pregnancy
		Licence Conditions for Outpatient Medical Service and
		Ambulatory Surgical Centre Service Licensees Providing
		or Intending to Provide Liposuction
		Licence Conditions for Outpatient Medical Service
		Licensees Prescribing and Supplying Benzodiazepines
		and Other Hypnotics
		Licence Conditions for Outpatient Medical Service
		Licensees Prescribing and Supplying Codeine Cough
		Preparations
		Licence Conditions for Outpatient Medical Service
		Licensees Providing or Intending to Provide
		Electrocardiography Stress Testing
		Licence Conditions for Outpatient Medical Service
		Licensees Providing or Intending to Provide Endoscopy
		Service
		Licence Conditions for Outpatient Medical Service,
		Outpatient Dental Service, Outpatient Renal Dialysis
		Service, Acute Hospital Service, Community Hospital
		Service, Contingency Care Service Licensees Providing or
		Intending to Provide COVID-19 Vaccination
		Licence Conditions for Providing or Intending to Provide
		Emergency Life Saving Measures Licence Conditions for Outpatient Medical Service,
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	Outpatient Renal Dialysis Service	Outpatient Dental Service, Outpatient Renal Dialysis Service, Acute Hospital Service, Community Hospital
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		Service, Contingency Care Service Licensees Providing or
11		Intending to Provide COVID-19 Vaccination
		Licence Conditions for Outpatient Renal Dialysis Service
		Licensees
		Licence Conditions for Providing or Intending to Provide
		Emergency Life Saving Measures

ANNEX C: FULL LIST OF LICENCE CONDITIONS

No	Title of Licence Conditions	Appendix
1.	Licence Conditions for Acute Hospital and Outpatient Medical Service Licensees Providing or Intending to Provide Artificial Insemination Procedures	C.1
2.	Licence Conditions for Acute Hospital Service and Ambulatory Surgical Centre Service Licensees Providing Cataract Surgery	C.2
3.	Licence Conditions for Acute Hospital Service and Outpatient Medical Service Licensees Providing or Intending to Provide Organ Transplant Service	C.3
4.	Licence Conditions for Acute Hospital Service Licensees Providing or Intending to Provide Specialised and Intensive Care Services to Neonates	C.4
5.	Licence Conditions for Acute Hospital Service, Ambulatory Surgical Centre Service and Outpatient Medical Service Licensees Providing or Intending to Provide Proton Beam Therapy	C.5
6.	Licence Conditions for Acute Hospital Service, Ambulatory Surgical Centre Service and Outpatient Medical Service Licensees Providing or Intending to Provide Radiation Oncology and Radiation Therapy	C.6
7.	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	C.7
8.	Licence Conditions for All Acute Hospital Service, Outpatient Dental Service and Outpatient Medical Service Licensees Administering or Intending to Administer Cell, Tissue and Gene Therapy Products Manufactured in-House by Healthcare Institutions	C.8
9.	Licence Conditions for All Licensees Relating to Immunity against Measles and Diphtheria for Personnel in Healthcare Institutions	C.9
10.	Licence Conditions for Assisted Reproduction Service Licensees Providing or Intending to Provide Pre-Implantation Genetic Testing for (a) Monogenic or Single Gene Defects or (b) Chromosomal Structural Rearrangements	C.10
11.	Licence Conditions for Assisted Reproduction Service, Radiological Service, Outpatient Medical Service, Outpatient Dental Service, Nuclear Medical Service, Ambulatory Surgical Centre Service, Community Hospital Service and Contingency Care Service Licensees Providing or Intending to Provide (1) Sedation; or (2) General Anaesthesia	C.11
12.	Licence Conditions for Human Tissue Banking Service	C.12
13.	Licence Conditions for Human Tissue Banking Service Licensees Providing or Intending to Provide Banking of Cardiac and Vascular Tissue	C.13
14.	Licence Conditions for Human Tissue Banking Service Licensees Providing or Intending to Provide Banking of Haematopoietic Stem Cell (Including Bone Marrow)	C.14
15.	Licence Conditions for Human Tissue Banking Service Licensees Providing or Intending to Provide Banking of Ocular Tissue	C.15
16.	Licence Conditions for Human Tissue Banking Service Licensees Providing or Intending to Provide Banking of Skin Tissue	C.16
17.	Licence Conditions for Licensees Providing Assisted Reproduction Services	C.17
18.	Licence Conditions for Licensees Providing or Intending to Provide Blood Transfusion Service	C.18

19.	Licence Conditions for Licensees Providing or Intending to Provide Simple in Vitro Diagnostic Tests	C.19
20.	Licence Conditions for Licensees Providing or Intending to Provide	C.20
20.	Treatments to Terminate Pregnancy	C.20
21.	Licence Conditions for Mortality and Morbidity Review	C.21
22.	Licence Conditions for Outpatient Medical Service and Ambulatory	C.22
	Surgical Centre Service Licensees Providing or Intending to Provide	
	Liposuction	
23.	Licence Conditions for Outpatient Medical Service Licensees Prescribing	C.23
	and Supplying Benzodiazepines and Other Hypnotics	
24.	Licence Conditions for Outpatient Medical Service Licensees Prescribing	C.24
	and Supplying Codeine Cough Preparations	
25.	Licence Conditions for Outpatient Medical Service Licensees Providing or	C.25
	Intending to Provide Electrocardiography Stress Testing	
26.	Licence Conditions for Outpatient Medical Service Licensees Providing or	C.26
	Intending to Provide Endoscopy Service	
27.	Licence Conditions for Outpatient Medical Service, Outpatient Dental	C.27
	Service, Outpatient Renal Dialysis Service, Acute Hospital Service,	
	Community Hospital Service, Contingency Care Service Licensees	
	Providing or Intending to Provide COVID-19 Vaccination	
28.	Licence Conditions for Outpatient Renal Dialysis Service Licensees	C.28
29.	Licence Conditions for Providing or Intending to Provide Emergency Life	C.29
	Saving Measures	
30.	Licence Conditions for Serious Reportable Events	C.30
31.	Licence Conditions for the Provision of Nuclear Medicine Services	C.31
32.	Licence Conditions on Case Reviews by Clinical Ethics Committees	C.32
33.	Licence Conditions on Licensees Providing or Intending to Provide	C.33
	Restricted Services	
34.	Licence Conditions on Peer Review Learning	C.34
35.	Licence Conditions on the Provision of Luxturna (Voretigene Neparvovec)	C.35
	As a Treatment Option for Patients	
36.	Licence Conditions on the Retention Periods of Patient Health Records	C.36
37.	Licence Conditions on Vaccine Cold Chain for Licensees Involved in the	C.37
	Handling, Storage and/or Transport of Vaccines	