

Transitioning from PHMCA to HCSA

Presented by the Health Regulation Group (HRG)
Ministry of Health
Feb 2023

Agenda

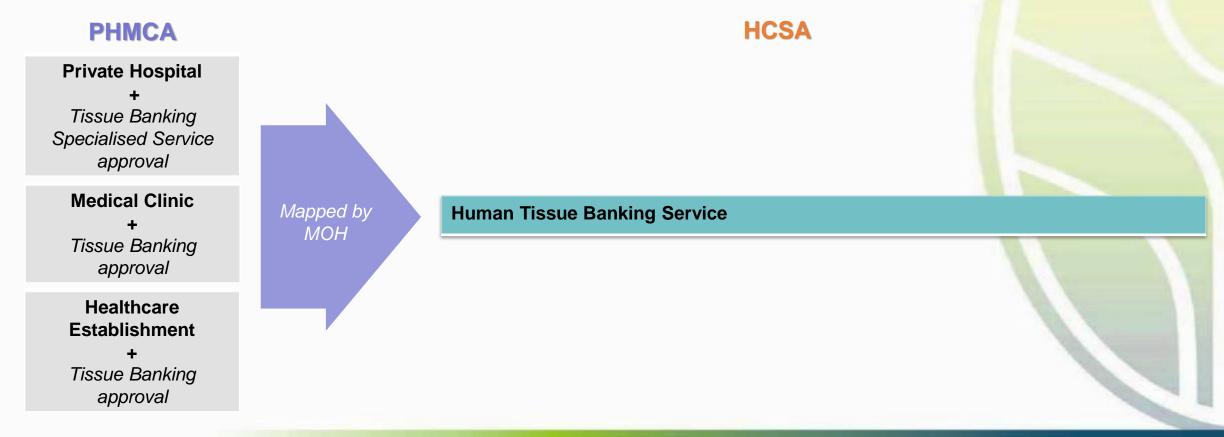
S/N	Items	Slide No.			
1	Transition plan for licensees from PHMCA to HCSA	Slide 3			
2	Mapping of PHMCA licensees with Tissue Banking Approval				
	A) Mapping of Licensable Healthcare Services (LHSes)	<u>Slides 4 – 6</u>			
	B) Mapping of Specified Services (SSes)	Slide 7			
	C) Mapping of Key Governance Personnel	Slide 8			
3	Transition plan for licensees from PHMCA to HCSA (2022/23)	Slide 9			
4	Quick Overview: Applying for a New Licence (HCSA)	Slide 10			
5	Key Takeaways	Slide 11			
6	Licensing Matters	Slide 12			
7	Licensing Fees under HCSA	Slide 13			
8	Annex	Slide 19			

Transition plan for licensees from PHMCA to HCSA (2022/23)

- HCSA Phase 2 will be implemented in mid 2023 and will involve the following licensees providing tissue banking under the PHMCA:
 - Private Hospital;
 - Medical Clinic; and
 - Healthcare Establishment.
- Unlike Phase 1 licensees, HCSA Phase 2 licensees are NOT required to perform any service mapping and data verification steps prior to the transition.
- Instead, MOH will be mapping existing PHMCA to HCSA licences seamlessly.
- The next few slides will explain how we will be mapping your current PHMCA licences to HCSA licences and what action would be required from existing PHMCA licensees.

2A) Mapping of Licensable Healthcare Service: Human Tissue Banking Service

- All existing PHMCA licensees that are approved to provide tissue banking services will be issued with the HCSA Human Tissue Banking Service licenses.
- HCSA licences will be issued with the remaining licence tenure from the PHMCA licences that were mapped
 over to the HCSA licences.



2A) Mapping of Licensable Healthcare Service: Human Tissue Banking Service

- No further action would be required from an existing PHMCA licensee with regard to the transition of their PHMCA to HCSA licence.
- However, if your current PHMCA licences are expiring before September 2023, we strongly encourage
 that you submit your renewal applications in eLIS before 1 April 2023.



• This will help facilitate our processing of your renewals before the transition and help us identify licensees that would continue with their tissue banking service after mid 2023 and those that intend to cease their service before the transition to HCSA.

before licence expiry

Refer to next slide for illustration on how your PHMCA licences should be renewed and how we will process
your licences.

2A) Mapping of Licensable Healthcare Service: Human Tissue Banking Service

Details on how licences should be renewed and how your licences will be issued

Licence expiry	Renew at which licensing system	Renew by when	Licence issued and tenure				
			PHMCA	HCSA			
Before 15 Jun 2023**	eLis	By 1 April 2023	From renewal to 14 Jun 2023	*15 June 2023 to remaining licence tenure (ported over from PHMCA).			
15 June – 31 August 2023**	eLis	By 1 April 2023	-	*15 June 2023 to remaining existing PHMCA licence tenure + renewed 2 year licence tenure.			
After 1 September 2023	HALP	From *15 June 2023 onwards	-	*15 June 2023 to end of licence tenure of existing PHMCA licence. Upon the end of licensing tenure, licensee will be renewed as new 2-year HCSA licence upon successful renewal in HALP.			
HCSA P2 Implementation PHMCA licence expiry date: Dec 22 Jan 23 Feb 23 Mar 23 Apr 23 May 23 Jun 23 Jul 23 Aug 23 Sep 23 Oct 23 Nov 23							

To renew licence(s) in eLis by 1 Apr 2023 To renew licence(s) in HALP from *15 Jun 2023 Take note of need to renew 2 months before Take note of need to renew 2 months before licence expiry. licence expiry.

Licences to be issued

PHMCA

HCSA

^{*} HCSA P2 Implementation date

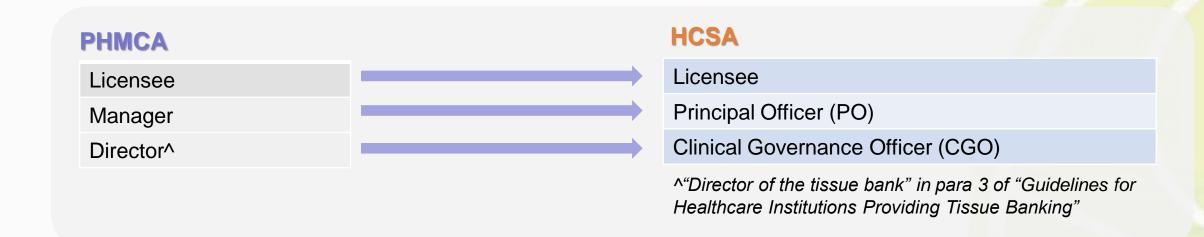
^{**}We will communicate separately to these licensees on what to do for their expiring licences

2B) Mapping of Specified Services under Human Tissue Banking Service

- "Specialised procedures or services" listed in the Second Schedule of PHCMR (details in Annex A) will be repealed once HCSA Phase 2 is implemented.
- MOH has reviewed and streamlined the licensing framework for Human Tissue Banking licensees.
- Licensees that currently bank tissue types (listed in the table) will be mapped accordingly as Specified Services ("SSes") under their Human Tissue Banking Service licences.

LHS	Specified Services
Human Tissue Banking	Ocular tissue
	Cardiac tissue
	Skin tissue
	Bone (excluding bone marrow)
	Vascular tissue
	Parathyroid tissue
	Haematopoietic Stem Cells (including bone marrow)
	Others

2C) Mapping of Key Personnel: Human Tissue Banking Service



Important Note:

- The above mapping would be based on information that is available in eLIS as of April 2023
- Licensees can make the necessary changes before the transition or in HALP after the transition
- All other licensing information (e.g. personnel information) will be migrated from eLis to HALP

Transition plan for licensees from PHMCA to HCSA (2022/23)

The transition plan is detailed below. Please take note of the actions required

Prior to implementation of each phase











After implementation





Oct – Nov 2022 Consultations

- Health Regulation Group (MOH) will be engaging licensees prior to each phase of HCSA implementation
- Details on these consultation sessions will be made available on hcsa.sg

Renewals for Existing PHMC Licences by 1 Apr 2023

- MOH will be engaging Phase 2 licensees with PHMCA licences expiring before Sep 2023 to submit renewal in eLIS preferably Apr 2023
- Only PHMCA licences with valid licence tenure will be transitioned to HCSA

Licensing Matters for transition to HCSA

- Beyond submitting their renewal applications early, no further action is required from licensees with regards to their HCSA licences.
- Licensees will
 however be asked
 to confirm the SSes
 that they would want
 to take under their
 Licensable
 Healthcare Service
 licences

Apr – May 2023 Training sessions

 MOH will also be engaging the licensees to sign up for training sessions to help licensees familiarise themselves with the new system, Healthcare Applications and Licensing Portal (HALP)

May 2023 (~2 weeks) Administrative Blackout Period

- An administrative blackout period will be announced nearer to Phase 2 implementation.
- Licensees may only view their licences in the licensing systems, i.e. eLis or HALP, during this blackout period
- This blackout period is to facilitate the data migration of existing information from eLis into HALP

~Mid 2023 Implementation of HCSA Phase 2

 Once HCSA Phase 2 is implemented, Licensees can logon to the new system, Healthcare Applications and Licensing Portal (HALP), to view and manage their HCSA licence(s)

Assistance from MOH

 Dedicated helpdesk will be setup to assist licensees who may face issues using the new system

Quick Overview: Applying for a New Licence (HSCA)

- Login to HALP (https://halp.moh.gov.sg) using SingPass.
- Select the Human Tissue Banking LHS, SSes provided
- Key in licensing details and other service related information
- Attach supporting documents.
- Submit application and pay licence fees as stated.

1. Application

Submit application
at least 2 MONTHS
before
commencement
date

2. Inspection

- Fill in Selfassessment Checklist
- Receive confirmation on inspection date.
- Ensure documents are ready for inspection (e.g. MOM's Registration for Pressure Vessels, NEA's Licence for Irradiating Equipment etc.)
- Inspectors may contact you for further clarifications after inspection

- Receive email notification on application status when all licensing requirements are met.
- •View e-licence on HALP upon approval.

3. Outcome

4. Post-Approval

- Update on HALP if there are any changes to your licence.
- •Renew licence (on HALP) no later than 2 month from the expiry date.
- •For Enquires: email us at <u>HCSA_Enquiries@moh.</u> <u>gov.sq</u>

- Previous slides detail transition plans for existing licences that will be ported over to HCSA
- Should you intend to <u>start</u> a
 Human Tissue Banking LHS
 after the transition period,
 you will need to apply for
 these in HALP
- MOH will announce when HALP can start accepting applications for a new LHS

For more details, refer to our website at https://www.moh.gov.sg/hcsa/home.

KEY TAKEAWAYS

- There will be an Administrative Blackout period prior to implementation of HCSA Phase 2
 - During this blackout period, existing licensees can view their HCSA and PHMCA licences in HALP and eList respectively
- MOH will be providing the following assistance on using HALP:
 - > Training [1 ~ 2 months before HCSA P2 implementation]
 - Training sessions will also be organised nearer HCSA implementation to help licensees (and users) familiarise themselves with the new licensing application system
 - > FAQs, , E-guides and instructional videos
 - FAQs, E-guides and instructional videos will also be uploaded on the website as self-help tools for licensees
 - > Helpdesk Support
 - Helpdesk (via phone @ 67689796 will be available from Monday to Friday 8am to 8pm, excluding Saturdays and Public Holidays or email @halp_helpdesk@moh.gov.sg) will be available to the licensees during the transition
 - o For any other enquiries, licensees can approach MOH via HCSA enquiries @ HCSA_Enquiries@moh.gov.sg
- Once HCSA Phase 2 is implemented, licensees can view and manage their HCSA licences in HALP

Licensing Matters

Timelines for application, amendment, cessation of licence and others

Requirements

Licence

or information)

Notification of Cessation

Notification of Death of Licensee

Application for new licence	To be made via MOH licensing portal <u>no later than 2 months</u> before intended commencement date
Renewal of existing licence	 Application to be made <u>no later than 2 months</u> before expiry of licence Up to 2 months from date of application to issue renewed licence Late renewal fee specified in First Schedule
Addition of Premises / Conveyances to Licence	Application to be made <u>no later than 2 months</u> before the service is provided at that additional premises / conveyance
Removal of Premises / Conveyances from Licence	• Application to be made <u>no later than 1 month</u> before stopping provision of service at that premises / conveyance

- Any Other Amendment (particulars Application to MOH for change of licensee name, to be made **no later than 1 month** prior to doing so For other changes, to notify MOH no later than 10 calendar days before the change
 - Notification of intention to cease must be made **not less than 1 month** prior to cessation
 - Licensees who are individuals or sole proprietors are to provide details of a nominee. *Nominee to be contacted when licensee is uncontactable

Director must be notified of the licensee's death within 1 month

Nominee Display of Licence No longer need to display licence (licences will be issued electronically) However, details of licence and licensed healthcare services to be provided to patients upon request

Fees will be retained or reduced for most PHMCA licence categories

- Through process reviews and streamlining, MOH is able to retain or reduce the HCSA licensing fees for most existing PHMCA licensees
- Over 90% of the existing licensees will see either the same or a reduction in fees under HCSA
- The licence categories that will see a **fee reduction** under HCSA includes:
 - > Community Hospitals A more accurate categorization of the services that they offer
 - > Ambulatory Surgical Centres and Renal Dialysis Centres These are currently specialised care services under PHMCA, which no longer require a base licence (i.e. medical service) under HCSA
 - > Clinics Removal of fee tiers by number of doctors practising at the clinic

Transition Fee Support for Licensees who experience a Fee Increase

- Some licensees will see a fee increase due to the provision of:
 - New licensable healthcare services (e.g. Emergency Ambulance (EAS), Medical Transport (MTS), Nuclear Medicine); or
 - Specified services that are newly regulated under HCSA (e.g. collaborative prescribing, dental CBCT)
 - These services have additional regulatory standards and inspecting licensees' compliance to these standards results in additional costs, which translates to additional fees being required
- There will be a gradual fee increase for affected licensees:
 - > To mitigate the impact of a fee increase on affected licensees, MOH will gradually increase their fees over three renewal cycles*.

Gradual fee increase will not apply to Acute and Community Hospitals, which will pay the full HCSA fee from their next renewal.

Introducing fee bundles for related services

- Licensees may naturally take licences for several related HCSA LHSes, SSes and Modes of Service Deliveries ("MOSDs")
- MOH will offer lower fees for such related services where there are potential cost synergies in inspecting
 the services together. The groups of services that will enjoy the fee bundles are as follows:

Licence Fee Bundles

Bundle 1 – Ambulance: Emergency Ambulance (EAS), Medical Transport (MTS)

Bundle 2 – Hospital: Acute Hospital, Medical Service, Clinical Laboratory, Radiological Service, Ambulatory Surgical Centre

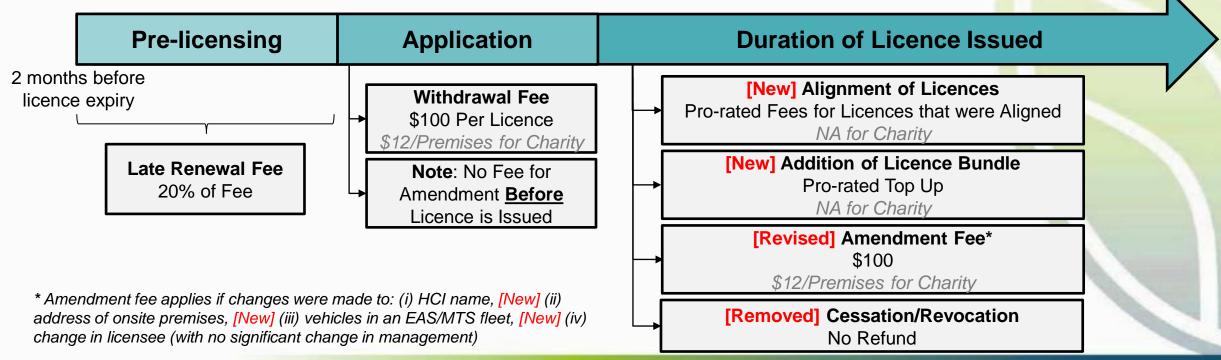
Bundle 3 – Specified Service: Licensees that provide two or more simple/complex specified services respectively

Bundle 4 – Modes of Service Delivery: Applicable to Medical Service and Dental Service only. No additional charge for licensees that provide remote delivery and/or temporary premises modes of service delivery, <u>in conjunction with permanent premises/conveyances</u>

Administrative Fees under HCSA remains largely similar

Admin fees under HCSA remain largely similar, **except**:

- No refund will be made for revocation or cessation, once the licence has been issued
- Fees may be pro-rated, if the licensee has chosen to align the licence tenures within the same premises
 or add on new LHSes, SSes and MOSDs to form a licence bundle
- \$100 amendment fee for changes to the address of onsite premises, changes to vehicles in an EAS/MTS fleet, or changes in licensee (with no significant change in management)



Stay connected with us

MOH will provide more information along the way



Visit **HCSA.SG** for more information



Write to us at HCSA_Enquiries@moh.gov.sg

The End Thank you





Annex A: List of Specialised Procedures and Services under Second Schedule of PHMCR

PHMCR Second Schedule

Blood and blood product collection, processing, storage, distribution and transfusion services (including autologous blood transfusion).

Assisted reproduction services, excluding pre-implantation genetic testing services.

The following testing services:

- (a) pre-implantation genetic testing for monogenic or single gene defects;
- (b) pre-implantation genetic testing for chromosomal structural rearrangements.

Neonatal intensive care unit

Nuclear medicine therapy and in vivo nuclear medicine assay services.

Renal dialysis.

Sperm banking.

Radiation oncology.

Tissue banking.

Proton beam therapy.

Organ transplant services, including transplant-related clinical services.