

Definition of Healthcare Services under the HCS Bill

“healthcare service” means —

- a) assessment, diagnosis, treatment, prevention or alleviation of an ailment, a condition, disability, disease or disorder or an injury affecting any part of the human body or mind;*
- b) nursing or rehabilitative care of an individual suffering from such ailment, condition, disability, disease, disorder or injury;*
- c) provision of any medical procedure to change, or that is intended to change, the appearance or anatomy of an individual;*
- d) assessment of the health of an individual; or*
- e) provision of any service of a clinical nature related to the provision of any service referred to in paragraph (a), (b), (c) or (d),*
whether or not provided for a reward;

Proposed Healthcare Services to be Licensed under HCS Bill

S/N	Type of Service	Pre-requisite Licence¹
1.	Acute Hospital Service	None required
2.	Community Hospital Service	
3.	General Dental or Medical Clinic Service	
4.	Specialist Dental or Medical Clinic Service	
5.	Ambulatory Surgical Centre Service	
6.	Renal Dialysis Centre Service	
7.	Nursing Home Service	
8.	Chronic Sick Unit Service	
9.	Inpatient Palliative Care Service	
10.	Emergency Ambulance Service	
11.	Medical Transport Service	
12.	Tele-medicine Service	
13.	Mobile Medical Service	
14.	Clinical Laboratory Service	
15.	Tissue Banking Service	
16.	Blood Banking Service	
17.	Radiological Service	
18.	Health Screening Service	
19.	Assisted Reproduction Service	Acute Hospital Service or Specialist Medical/Dental Clinic Service
20.	Blood Transfusion Service	Acute Hospital Service or Community Hospital Service or Ambulatory Surgical Centre Service or Inpatient Palliative Care Service or Renal Dialysis Centre Service or Specialist Medical/Dental Clinic Service
21.	Haematopoietic Stem Cell Transplant Service	Acute Hospital Service
22.	Clinical Genetic and Genomic Service	Acute Hospital Service or Specialist Medical/Dental Clinic Service or Clinical Laboratory Service
23.	Cell, Tissue and Gene Therapy Service	Acute Hospital Service or Specialist Medical/Dental Clinic Service or General Medical/Dental Clinic Service

¹ Service providers that wish to provide services listed in the first column must hold at least one licence listed in the corresponding second column

24.	Hyperbaric Oxygen Therapy Service	Acute Hospital Service or Specialist Medical/Dental Clinic Service
25.	Neonatal Intensive Care Unit Service	Acute Hospital Service
26.	Collaborative Prescribing Service	Acute Hospital Service or Specialist Medical/Dental Clinic Service
27.	Organ Transplant Service	Acute Hospital Service
28.	Radiation Oncology Service	Acute Hospital Service or Specialist Medical/Dental Clinic Service
29.	Proton Beam Therapy Service	Acute Hospital Service or Specialist Medical Clinic Service
30.	Sterile Pharmaceutical Service	Acute Hospital Service or Community Hospital Service or Specialist Medical Clinic Service or Inpatient Palliative Care Service or General Medical/Dental Clinic Service
31.	Specialised Interventional Procedure Service	Acute Hospital Service or Specialist Medical/Dental Clinic Service or Ambulatory Surgical Centre Service or Radiological Service

Licensable Services Definitions

I. DEFINITIONS OF HCS BILL SERVICES (other than ‘Specified Services highlighted in Figure 2)

1. **“acute hospital service”** means a service providing –
 - (a) all of the following to any individual:
 - (i) the examination of the human body or mind, or any matter derived from the human body;
 - (ii) the assessment of health, diagnosis, treatment, intervention, care or rehabilitation;
 - (iii) reception or accommodation intended for a period exceeding 24 hours;
 - (b) medical procedures that is intended to change the appearance or anatomy of an individual; or
 - (c) the reception and care of pregnant women before, during and after they have given birth, including antenatal and postnatal care and child delivery service.

2. **“ambulatory surgical centre service”** means the provision of anaesthesia and surgical treatment to any individual without provision of accommodation to that individual for a period exceeding 24 hours, and in relation to that individual, includes —

- (a) examination of his or her body, conducting of any point-of-care test on him or her, assessment of his or her health, observation, diagnosis, intervention and treatment of his or her condition, and provision of care for him or her; and
 - (b) any medical procedure that changes, or is intended to change, his or her appearance or anatomy;
3. **“blood banking service”** means a service relating to blood and blood products for therapeutic transfusion, comprising the following:
- (a) collection of blood and blood products;
 - (b) testing, processing and storage of blood and blood products;
4. **“chronic sick unit service”** means a service that provides long term residential care for individuals with long term complications,
- a) Which may include but not limited to the care of chronic wounds, artificial airways such as tracheostomies, tube feedings; and
 - b) requiring intensive, complex and skilled nursing and medical care.
5. **“clinical laboratory service”** means the examination or testing of any matter derived from the body of any individual for the purpose of —
- (a) assessing the health, condition or genetic disposition of that individual or any other individual;
 - (b) predicting or providing a prognosis of the health or medical condition of that individual or any other individual;
 - (c) diagnosing a disease, disability, condition or an injury of the body or mind of that individual or any other individual; or
 - (d) ascertaining the cause of death of that individual or any other individual, or the result of a medical or surgical treatment given to that individual or any other individual;
6. **“community hospital service”** means a service that provides non-acute clinical, convalescent or rehabilitative care over a limited time period to any individual involving all of the following:
- (a) the examination of the human body or mind, or any matter derived from the human body;
 - (b) the assessment of health, diagnosis, treatment, intervention, care or rehabilitation;
 - (c) the provision of reception or accommodation intended for a period exceeding 24 hours.
7. **“emergency ambulance service”** means a service to transport, by land, air or sea, any individual suffering, or believed to be suffering, from an injury or condition of acute or sudden onset of an emergency nature, who is being

provided with clinical monitoring and may include the diagnosis and provision of clinical treatment or intervention en-route.

8. “general dental or medical clinic service” the provision of any of the following at fixed premises to any individual without provision of accommodation to that individual for a period exceeding 24 hours:

(a) examination of his or her body, conducting of any point-of-care test on him or her, assessment of his or her health, observation, diagnosis, intervention and treatment of his or her condition, and provision of care for him or her;

(b) any medical procedure that changes, or is intended to change, his or her appearance or anatomy,

but does not include the provision of any procedure that involves the use of general anaesthesia.

9. “health screening service” means a service involving the examination or testing of an individual for the purposes of detecting health risks, diseases, injury, disability or condition of the body or mind

10. “inpatient palliative care service” means a service involving all of the following -

(a) the assessment of health, diagnosis, treatment, care or rehabilitation;

(b) assistance with the activities of daily living;

(c) reception or accommodation for a period exceeding 24 hours, to any individual with diagnosed with –

(i) a terminal condition or illness; or

(ii) any condition or illness that is expected to reduce the life expectancy that individual to 12 months or less.

11. “medical transport service” means a service to transport, by land, air or sea, any individual suffering, or believed to be suffering, from an injury or condition and who is being provided with non-emergency clinical care or clinical monitoring en-route.

12. “mobile medical service” means providing to an individual in person other than from a fixed premises:

(a) a service comprising all of the following:

(i) the examination of the human body, or any matter derived from the human body of that individual;

(ii) the assessment of health, diagnosis, treatment, intervention or care;

(b) medical procedures that is intended to change the appearance or anatomy of an individual,

- 13. “nursing home service”** means a service that provides elderly, disabled or chronically ill individuals all of the following:
- (a) the assessment of health, diagnosis, treatment, care or rehabilitation;
 - (b) the assistance with the activities of daily living;
 - (c) the reception or accommodation for a period exceeding 24 hours.
- 14. “radiological service”** means the use of ionising or non-ionising radiation and radioactive substances for any of the following purposes:
- (a) examination of the body, or any matter derived from the body, of an individual;
 - (b) assessment of the health of an individual;
 - (c) observation, diagnosis, intervention and treatment of a disease, disability, condition or an injury of the body or mind of an individual;
 - (d) provision of care for an individual;
- 15. “renal dialysis service”** means the provision of renal dialysis treatment to any individual, without the provision of any accommodation to the individual, for a period exceeding 24 hours, and includes any service incidental to the provision of renal dialysis treatment and the conduct of any point-of-care test on him or her;
- 16. “specialist dental or medical clinic service”** means the provision to any individual, without provision of accommodation to that individual for a period exceeding 24 hours, of treatment or care in any specialty in medicine or dentistry as defined or recognised by —
- (a) the Specialists Accreditation Board established under the Medical Registration Act (Cap. 174); or
 - (b) the Dental Specialists Accreditation Board under the Dental Registration Act (Cap. 76),
- but does not include the provision of any procedure that involves the use of general anaesthesia;
- 17. “telemedicine service”** means a service involving the assessment of health, diagnosis, treatment, intervention or care of any individual where the service is provided through the use of info-communications technology and not in person.
- 18. “tissue banking service”** means the procurement and storage of biological material, excluding a gamete or embryo, derived or obtained from the body of an

individual, which is distributed for subsequent use in the body of another individual, and includes the screening of any donor.

II. DEFINITIONS OF 'SPECIFIED' HCS BILL SERVICES

(Arranged alphabetically)

1. **“assisted reproduction service”** means the provision of clinical treatment and laboratory procedure that brings about, or is intended to bring about, the conception of a child, and includes —
 - (a) storage of gametes and embryos;
 - (b) removal or attempted removal of oocytes from a woman; and
 - (c) handling of oocytes or embryos for the purpose of conception;

2. **“blood transfusion service”** means a service comprising any of the following relating to blood and blood products:
 - (a) Pre-transfusion testing;
 - (b) Storage and Transfusion;

3. **“haematopoietic stem cell transplant service”** means a service involving the transplantation of bone marrow or multipotent hematopoietic stem cells that are of either an autologous or allogeneic source into an individual, and includes the harvesting of bone marrow and/or multipotent hematopoietic stem cells.

4. **“clinical genetic and genomic service”** means a service involving diagnostic, management, risk assessment, education, counselling or genetic testing services to individuals or families with conditions, or at risk of developing conditions, that have a genetic basis.

5. **“cell, tissue and gene therapy”** means a service involving the processing of:
 - (a) autologous or allogeneic human cells or tissues;
 - (b) animal cells or tissues (xenogeneic);
 - (c) recombinant nucleic acids (i.e. modified DNA or RNA as carriers of a therapeutic gene)that are used for or administered to, or intended to be used for or administered to human beings for the diagnosis, treatment or prevention of human disease or conditions, or to change the appearance or anatomy of an individual, but excludes:
 - (a) transplantation of any human organ to replace a corresponding diseased organ;
 - (b) transfusion of whole blood and blood components for treating blood disorders; and
 - (c) use of any reproductive tissues or cells for assisted reproductive procedures;

6. **“collaborative prescribing service”** means a service in which medication is prescribed by registered nurses and pharmacists with recognised qualifications under the supervision and oversight of a registered medical practitioner.
7. **“hyperbaric oxygen therapy”** means a service involving the treatment of a disease or injury of an individual by exposing the individual to a higher concentration of oxygen than the ordinary oxygen level at sea level inside a treatment chamber.
8. **“neonatal intensive care unit”** means a service involving the provision of treatment or care for neonates with critical illnesses or conditions.
9. **“organ transplant”** means a service involving the removal of organs (part or whole), as defined under the Human Organ Transplant Act (Cap. 131A), from human bodies (living or dead) and the transplantation of the organs into the bodies of living individuals.
10. **“radiation oncology”** means a service which uses ionising radiation as part of treatment for cancer.
11. **“proton beam therapy service”** means the provision of proton beam therapy.
12. **“specialised interventional procedural service”** means a service consisting of interventional, catheterisation, or nuclear medicine, therapy or assay procedures, including the placement of devices, in any part of the human body affected by disease.
13. **“sterile pharmaceutical service”** means a service that involves the sterile compounding and reconstitution of pharmaceutical products.

Proposed Services requiring Clinical Governance Officer (CGO)

S/N	Type of Service
1.	Assisted Reproduction Service
2.	Blood Transfusion Service
3.	Cell, Tissue and Gene Therapy Service
4.	Clinical Genetic and Genomic Service
5.	Clinical Laboratory Service
6.	Collaborative Prescribing Service
7.	Haematopoietic Stem Cell Transplant Service
8.	Hyperbaric Oxygen Therapy Service
9.	Neonatal Intensive Care Unit Service
10.	Organ Transplant Service
11.	Proton Beam Therapy Service
12.	Radiation Oncology Service
13.	Radiological Service
14.	Sterile Pharmaceutical Service
15.	Specialised Interventional Procedure Service

SIXTH SCHEDULE OF THE PHMC REGULATIONS**SIXTH SCHEDULE**

Regulation 12A(1) and (4)

QUALITY ASSURANCE COMMITTEES

<i>First column</i>	<i>Second column</i>	<i>Third column</i>
<i>Prescribed healthcare institution</i>	<i>Quality assurance committee(s) required</i>	<i>Applicable directives</i>
1. Every licensed private hospital (excluding nursing homes)	(a) At least one Mortality and Morbidity Quality Assurance Committee (b) At least one Serious Reportable Event Quality Assurance Committee	(a) Directives for Review of Mortality and Morbidity (b) Directives for Review of Serious Reportable Events
2. Every licensed nursing home	At least one quality assurance committee	Directives for Quality Assurance Committees (Nursing Homes)
3. Every licensed medical clinic providing special care services listed under the Third Schedule	(a) At least one Mortality and Morbidity Quality Assurance Committee (b) At least one Serious Reportable Event Quality Assurance Committee	(a) Directives for Review of Mortality and Morbidity (b) Directives for Review of Serious Reportable Events
4. The following medical clinics: (a) every licensed medical clinic that is operated as a polyclinic (b) National Skin Centre (c) Student Health Centre	(a) At least one Mortality and Morbidity Quality Assurance Committee for each medical clinic (b) At least one Serious Reportable Event Quality Assurance Committee for each medical clinic	(a) Directives for Review of Mortality and Morbidity (b) Directives for Review of Serious Reportable Events
5. The following licensed private hospitals: (a) Alexandra Hospital (b) Changi General Hospital (c) Concord Cancer Hospital (d) Gleneagles Hospital	At least one Peer Review Learning Quality Assurance Committee	Directives for Peer Review Learning

<p>(e) Institute of Mental Health/Woodbridge Hospital</p> <p>(f) Johns Hopkins Singapore International Medical Centre</p> <p>(g) Khoo Teck Puat Hospital</p> <p>(h) KK Women's and Children's Hospital</p> <p>(i) Mount Alvernia Hospital</p> <p>(j) Mount Elizabeth Hospital</p> <p>(k) Mount Elizabeth Novena Hospital</p> <p>(l) National Heart Centre of Singapore</p> <p>(m) National University Hospital</p> <p>(n) Parkway East Hospital</p> <p>(o) Raffles Hospital</p> <p>(p) Singapore General Hospital</p> <p>(q) Tan Tock Seng Hospital</p> <p>(r) Thomson Medical Centre</p> <p>(s) Farrer Park Hospital</p> <p>(t) Ng Teng Fong General Hospital</p>		
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[S 430/2017 wef 01/08/2017]

[S 169/2016 wef 01/05/2016]

[S 450/2015 wef 01/08/2015]

[S 493/2014 wef 01/08/2014]

[S 831/2010 wef 02/01/2011]

[G.N.Nos.S 572/91; S 200/96; S 331/97; S 119/98; S 8/2000; S 145/2000; S 256/2000; S 90/2001; S 424/2001; S 223/2003; S 237/2003; S 411/2003; S 308/2008]

Functions of Service Review Committees (SRC)

S/N	Programmes/ Services for Review	Functions of SRC	Licensee
1	Proton Beam Therapy (PBT)	To ensure appropriate use for proven clinical indications in accordance with the service standards prescribed by MOH under the HCS Bill.	<ul style="list-style-type: none"> • Acute and community hospital services. • Specialist Medical Clinic Service.
2	Collaborative Prescribing (CP) Services ²	To ensure adequate supervisory oversight and patient safety in accordance to the collaborative prescribing regulatory framework.	<ul style="list-style-type: none"> • Acute and community hospital services (first phase) • Nursing homes and inpatient palliative care services (second phase).
3	Antimicrobial stewardship programmes (ASPs)	To ensure appropriate use of antibiotics and prevent development of multi-drug resistant organisms by monitoring the key performance indicators that hospitals have to report to the National Antimicrobial Resistance Control Committee.	<ul style="list-style-type: none"> • Acute and community hospital services.

² "Collaborative prescribing service" means a service in which medication is prescribed by registered nurses and pharmacists with recognised qualifications under the supervision and oversight of a registered medical practitioner.

Medical Treatments for Service Ethics Committee (SEC) Review

Medical Treatments	Prescribed Licensees required to conduct SEC review
1. Surgical separation of conjoint twins	Acute hospital services
2. Psychosurgery	Acute hospital services
3. Treatment for sexual sterilisation on an unmarried person with mental capacity and below the age of 21	Acute hospital services
4. Non-life-saving transplants (e.g. hand, face, penile and uterine transplants)	Acute hospital services
5. Gender reassignment surgery	Acute hospital services
6. Deep brain stimulation	Acute hospital services
7. Transcranial direct current stimulation	Acute hospital services Ambulatory surgical centre services
8. Foetal reduction of normal foetuses where the multiple pregnancy poses a danger to the mother's mental health	Acute hospital services
9. Preimplantation genetic diagnosis (PGD) for Human Leukocyte Antigen typing for the creation of saviour siblings (if / when PGD is mainstreamed)	Assisted reproduction services
10. Uterine transplantation	Acute hospital services
11. Testicular biopsy and testicular tissue freezing for fertility preservation in prepubertal age group going for gonadotoxic therapy and Klinefelter syndrome	Acute hospital services
12. Any form of innovative therapies (as defined in the 2016 Edition of the SMC Ethical Code and Ethical Guidelines) carried out within the institution	Acute hospital services Community hospital services Inpatient palliative care services Nursing home services Ambulatory surgical centre services Specialist medical/dental clinic services General medical/dental clinic services
13. Cases of non-genetically linked gamete donation within families for assisted reproduction procedures	Assisted reproduction services

Proposed NEHR Contributing Licensees

S/N	Licensees
1.	Clinical Laboratory Service
2.	Acute Hospital Service
3.	Community Hospital Service
4.	Haematopoietic Stem Cell Transplant Service
5.	Neonatal Intensive Care Unit Service
6.	Blood Banking Service
7.	Organ Transplant Service
8.	General Dental or Medical Clinic Service
9.	Specialist Dental or Medical Clinic Service
10.	Ambulatory Surgical Centre Service
11.	Renal Dialysis Centre Service
12.	Nursing Home Service
13.	Chronic Sick Unit Service
14.	Inpatient Palliative Care Service
15.	Emergency Ambulance Service
16.	Tele-medicine Service
17.	Mobile Medical Service
18.	Radiological Service
19.	Health Screening Service
20.	Assisted Reproduction Service
21.	Blood Transfusion Service
22.	Clinical Genetic and Genomic Service
23.	Cell, Tissue and Gene Therapy Service
24.	Hyperbaric Oxygen Therapy Service
25.	Collaborative Prescribing Service
26.	Radiation Oncology Service
27.	Specialised Interventional Procedure Service
28.	Proton Beam Therapy Service

Phased Enforcement of NEHR

Participation on NEHR to be enforced by	Licensees
Phase 1 (Dec 2019)	Clinical Laboratory Service
Phase 2 (Jun 2020)	Acute Hospital Service
	Community Hospital Service
	Haematopoietic Stem Cell Transplant Service
	Neonatal Intensive Care Unit Service
	Blood Banking Service
	Organ Transplant Service
Phase 3 (Dec 2020)	General Dental or Medical Clinic Service
	Specialist Dental or Medical Clinic Service
	Ambulatory Surgical Centre Service
	Renal Dialysis Centre Service
	Nursing Home Service
	Chronic Sick Unit Service
	Inpatient Palliative Care Service
	Emergency Ambulance Service
	Medical Transport Service♦
	Tele-medicine Service
	Mobile Medical Service
	Tissue Banking Service♦
	Radiological Service
	Health Screening Service
	Assisted Reproduction Service
	Blood Transfusion Service
	Clinical Genetic and Genomic Service
	Cell, Tissue and Gene Therapy Service
	Hyperbaric Oxygen Therapy Service
	Collaborative Prescribing Service
	Radiation Oncology Service
	Sterile Pharmaceutical Service♦
Specialised Interventional Procedure Service	
Proton Beam Therapy Service	

♦ - Licensees who can access but do not need to contribute to the NEHR

List of Core Data Set to Contribute to NEHR

1. Patient Profile
2. Events
3. Diagnosis
4. Operating Theatre Notes/Procedures/Treatments
5. Discharge Summary
6. Medications
7. Laboratory Reports
8. Radiology Reports
9. Immunisation
10. Allergies

Proposed List of Prohibited Unsafe Practices/Services

1.	Bio-identical Hormone Replacement Therapy with therapeutic claims
2.	Colonic Irrigation and Chelation therapy (Detox medicine)
<i>From List B of the 2008 Guidelines on Aesthetic Practices for Doctors (Singapore Medical Council):</i>	
3.	Mesotherapy
4.	Carboxytherapy
5.	Microneedling Dermaroller
6.	Skin Whitening Injections
7.	Stem Cell Activator Protein for Skin Rejuvenation
8.	Negative Pressure Procedures (e.g. Vacustyler)
9.	Mechanised Massage (e.g. 'Slidestyler', 'Endermologie' for cellulite treatment)

Summary of Penalties and Regulatory Sanctions under HCS Bill

Penalties in the HCS Bill

S/N	Section	Offence	Penalty under PHMCA	Penalty under HCS Bill
1	77	<p>Composition of offences</p> <p>The Director may compound any offence under the HCS Bill that is prescribed as a compoundable offence</p>	<p>Max composition sum: \$2,000</p>	<ul style="list-style-type: none"> • Composition sum: one half of the amount of the max fine that is prescribed for the offence OR up to a max of \$10,000
2	66(3)	<p>Failure to furnish information to the Director</p> <p>Failure of any person to furnish the Director with documents and information requested by the Director</p>	<ul style="list-style-type: none"> • Max fine: \$10,000 • Imprisonment term: 12 months 	<ul style="list-style-type: none"> • Max fine: \$10,000 • Imprisonment term: 12 months
3	65(3)	<p>Failure to keep records and give information on quality of service</p> <p>Failure of a licensee to keep records and provide the Director with information on the quality of the healthcare service provided</p>	<ul style="list-style-type: none"> • Max fine: \$2,000 • Imprisonment: 12 months 	<ul style="list-style-type: none"> • Max fine: \$10,000 • Imprisonment term: 12 months
4	81(4)	<p>Unauthorised, misleading or wrongful use of term or name</p> <p>A licensee who uses a term or name, or any derivative of that term or name in any language that incorrectly describes a licensable healthcare service; or unauthorised use of the term “Singapore” or “National” by a licensee; or a licensee who uses any term or</p>	<ul style="list-style-type: none"> • Max fine: \$2,000 • Imprisonment term: 12 months 	<ul style="list-style-type: none"> • Max fine: \$10,000 • Imprisonment term: 12 months • Continuing offence: \$1,000

S/N	Section	Offence	Penalty under PHMCA	Penalty under HCS Bill
		name that causes confusion or is likely to deceive; or a non-licensee who uses a term or name that is similar to a healthcare service provider for a licensable healthcare service		
5	73	Furnishing false or misleading statement, information or document Any person who makes any statement, or furnishes any information or document	N/A (new offence)	<ul style="list-style-type: none"> • Max fine: \$20,000 • Imprisonment term: 12 months
6	72(1)(c)	Obstructing the Director or authorised officer in the exercise of powers Any person who refuses to give access to, or obstructs, hinders, impedes or delays the Director or authorised officer in the exercise of powers; any person who without reasonable excuse neglects or refuses to furnish any information or produce any book, document, record, electronic article or thing; or any person who neglects or refuses to attend before the Director or authorised officer	<ul style="list-style-type: none"> • Max fine: \$5,000 • Imprisonment term: 12 months 	<ul style="list-style-type: none"> • Max fine: \$20,000 • Imprisonment term: 12 months
7	66(4)	Intentional altering, suppression or destruction of document or information A person who intentionally alters, suppresses or destroys any document or information which is required by the Director OR a person who in furnishing any document or information required by the Director intentionally makes a false or misleading statement or recklessly makes a statement	<ul style="list-style-type: none"> • Max fine: \$10,000 • Imprisonment term: 12 months 	<ul style="list-style-type: none"> • Max fine: \$20,000 • Imprisonment term: 12 months

S/N	Section	Offence	Penalty under PHMCA	Penalty under HCS Bill
8	83(3)	<p>Unauthorised advertising of licensable healthcare services</p> <p>A non-licensee or any person who is not acting on the authority of a licensee who advertises on a licensable healthcare service</p>	N/A (new offence)	<ul style="list-style-type: none"> • Max fine: \$20,000 • Imprisonment term: 12 months • Continuing offence: \$1,000
9	90(3)(c)	<p>Contravention of any provision of the regulations</p>	Max fine: \$2,000	<ul style="list-style-type: none"> • Max fine: \$20,000 • Imprisonment term: 24 months • Continuing offence: \$1,000
10	71(5)	<p>Powers of entry, inspection and search, etc. (Interferes, tampers, removes documents, counterfeits labels or break lock or seal placed by authorised officer etc.)</p> <p>Any person who interferes, tampers with, removes or disposes of an article or document; alters, counterfeits, defaces, destroys, erases or removes any mark, seal or label or opens, breaks or otherwise tampers with the lock or seal placed by the Director or authorised officer on the whole or part of any premises</p>	N/A (new offence)	<ul style="list-style-type: none"> • Max fine: \$50,000 • Imprisonment term: 12 months
11	82(3)	<p>Use of licensed premises or licensed conveyance for other purpose</p> <p>A licensee or any other person who uses a licensed premises or licensed conveyance for purposes other than the provision of a licensable healthcare service; or the provision of any service or carrying out of any</p>	N/A (new offence)	<ul style="list-style-type: none"> • Max fine: \$50,000 • Imprisonment term: 12 months • Continuing offence: \$1,000

S/N	Section	Offence	Penalty under PHMCA	Penalty under HCS Bill
		activity, that is incidental to the provision of that licensable healthcare service		
12	70(2)	<p>Provision of designated healthcare service</p> <p>A licensee, in the course of providing a licensable healthcare service, may not provide treatment that is likely to cause harm to patient welfare or safety, and is not generally accepted treatment based on a balance of available evidence or in the opinion of a body of experts, or where that treatment is listed in a Schedule of the Bill</p>	N/A (new offence)	<ul style="list-style-type: none"> • Max fine: \$50,000 • Imprisonment term: 12 months • Continuing offence: \$1,000
13	69(9)	<p>Failure to comply with directions given by the Director</p> <p>Failure of a licensee to comply with any direction given by the Director if the director has reasonable grounds to believe that there are circumstances that may endanger, or are likely to endanger the health, safety or welfare of individuals or the general public affected by the provision of a licensable healthcare service of by the license</p>	<ul style="list-style-type: none"> • Max fine: \$10,000 • Imprisonment term: 12 months • Continuing offence: \$1,000 	<ul style="list-style-type: none"> • Max fine: \$50,000 • Imprisonment term: 12 months • Continuing offence: \$1,000
14	62(11)	<p>Failure to comply with directions given by the step-in operator</p> <p>Failure of a licensee to handover operations to the step-in operator; licensee obstructing step-in operator's access to property or the exercise of the</p>	N/A (new offence)	<ul style="list-style-type: none"> • Max fine: \$50,000 • Imprisonment term: 12 months • Continuing offence: \$1,000

S/N	Section	Offence	Penalty under PHMCA	Penalty under HCS Bill
		step-in operator's responsibilities; failure of licensee to comply with directions given by step-in operator		
15	49(4)	<p>Unauthorised access and use of anonymised health information</p> <p>Failure of a Government department or public authority or any other person to obtain prior approval from the Director to access and use anonymised health information</p>	N/A (new offence)	<ul style="list-style-type: none"> • Max fine: \$50,000 • Imprisonment term: 12 months • Continuing offence: \$1,000
16	48(12)	<p>Failure of a requestor to comply with conditions of access and use of health information for other purposes</p> <p>Failure of a requestor to obtain prior approval from the director to access and use individually identifiable or anonymised health information for other purposes</p>	N/A (new offence)	<ul style="list-style-type: none"> • Max fine: \$50,000 • Imprisonment term: 12 months • Continuing offence: \$1,000
17	47(7)	<p>Unauthorised disclosure of identifiable health information on the NIEP for research</p> <p>Failure of a requestor to obtain prior approval from the director to disclose individually identifiable health information for research</p>	N/A (new offence)	<ul style="list-style-type: none"> • Max fine: \$50,000 • Imprisonment term: 12 months
18	45(5)	<p>Failure to contribute health information to the NIEP</p> <p>Failure of a contributing licensee to contribute to the NIEP the required health information of all individuals who are receiving, or have received a healthcare service provided by the contributing licensee</p>	N/A (new offence)	<ul style="list-style-type: none"> • Max fine: \$50,000 • Imprisonment term: 12 months • Continuing offence: \$1,000

S/N	Section	Offence	Penalty under PHMCA	Penalty under HCS Bill
19	36(3)	<p>Provision of procedures requiring ethical reviews without approval from the Service Ethics Committee (SEC)</p> <p>Failure of SEC licensee to seek approval from the ethics review committee that the medical treatment is ethically appropriate prior to providing the treatment</p>	N/A (new offence)	<ul style="list-style-type: none"> • Max fine: \$50,000 • Imprisonment term: 12 months • Continuing offence: \$1,000
20	8(3)	<p>Provision of licensable healthcare services at an unlicensed premises or unlicensed conveyance</p> <p>A licensee who provides a licensed service at an unlicensed premise or conveyance</p>	N/A (new offence)	<ul style="list-style-type: none"> • Max fine: \$50,000 • Imprisonment term: 12 months • Continuing offence: \$1,000
21	51(7)	<p>Unauthorised access of health information from opted-out individuals on the NIEP</p> <p>Unauthorised access or use of an individual's health information from the NIEP by an accessing licensee or approved user, where the individual had imposed access restrictions to his or her data</p>	N/A (new offence)	<ul style="list-style-type: none"> • Max fine: \$100,000 • Imprisonment term: 24 months
22	46(3)	<p>Unauthorised access or use of health information on the NIEP without consent</p> <p>Unauthorised access or use of an individual's health information from the NIEP by an accessing licensee</p>	N/A (new offence)	<ul style="list-style-type: none"> • Max fine: \$100,000 • Imprisonment term: 24 months • Continuing offence: \$2,000
23	44(4)	<p>Unauthorised access of health information on the National Integrated Electronic Platform (NIEP)</p>	N/A (new offence)	<ul style="list-style-type: none"> • Max fine: \$100,000

S/N	Section	Offence	Penalty under PHMCA	Penalty under HCS Bill
		Unauthorised access or use of health information from the NIEP by an accessing licensee or approved user		<ul style="list-style-type: none"> • Imprisonment term: 24 months • Continuing offence: \$2,000
24	7(2)	<p>Unauthorised provision of licensable healthcare services</p> <p>A person who provides a licensable healthcare service but is not authorised to do so by a licence or is not exempt from this section by or under this Act in relation to that licensable healthcare service</p>	<ul style="list-style-type: none"> • Max fine: \$20,000 • Imprisonment term: 24 months 	<ul style="list-style-type: none"> • Max fine: \$100,000 • Imprisonment term: 24 months • Continuing offence: \$2,000

Regulatory sanctions in the HCS Bill

S/N	Section	Regulatory sanction
1	17(1)	<p>Revocation of licence in part</p> <p>The Director may revoke a licence in part if the Director is satisfied that the licence has been obtained by fraud or the licensee has made a statement or furnished any information or document which is false, misleading or inaccurate during licence application or renewal; or the licensee has contravened any license condition, any provision of the Act, code of practice, direction issued by the Director or the licensee is unsuitable to be granted a licence etc.</p>
2	17(2)(a)	<p>Censuring of licensee</p> <p>The Director may, in lieu of 17(1), censure the licensee in writing, which may be published in such manner and made accessible to such persons as the Director thinks fit</p>
3	17(2)(b)	<p>Modification of licence</p>

S/N	Section	Regulatory sanction
		The Director may, in lieu of 17(1), modify any condition of the licence
4	17(2)(c)	<p data-bbox="427 276 1435 308">Furnishing performance bond, guarantee or other form of security</p> <p data-bbox="427 347 1980 491">The Director may, in lieu of 17(1), require the furnishing of any performance bond, guarantee or other form of security, or an additional performance bond, guarantee or other form of security, to secure compliance by the licensee or for the purpose of meeting any financial penalty arising out of any proceedings with a view to regulatory action started or likely to start against the licensee, or both</p>
5	17(2)(d)	<p data-bbox="427 499 1458 531">Forfeiture of performance bond, guarantee or other form of security</p> <p data-bbox="427 571 1980 643">The Director may, in lieu of 17(1), forfeit the whole or part of any performance bond, guarantee or other form of security</p>
6	17(2)(e)	<p data-bbox="427 651 1608 683">Directing licensee to do or refrain from doing things specified in the direction</p> <p data-bbox="427 722 1980 794">The Director may, in lieu of 17(1), direct the licensee to do, or refrain from doing, such things as specified in the direction, to rectify a contravention or non-compliance</p>
7	17(2)(f)	<p data-bbox="427 802 835 834">Shortening term of licence</p> <p data-bbox="427 874 1980 978">The Director may, in lieu of 17(1), shorten (for not longer than such period for a licence of such term as may be prescribed) the term of the licence without compensation and without refund or any licence fee or renewal fee</p>
8	17(2)(g)	<p data-bbox="427 986 880 1018">Suspension of licence in part</p> <p data-bbox="427 1058 1980 1161">The Director may, in lieu of 17(1), suspend the licence in part for such period as the Director thinks fit, in respect of all or any of the licensed premises or licensed conveyances (as the case may be)</p>
9	17(2)(h)	<p data-bbox="427 1169 864 1201">Payment of financial penalty</p> <p data-bbox="427 1241 1980 1347">The Director may, in lieu of 17(1), direct the licensee to pay, within a period specified in a direction, a financial penalty of not more than \$10,000 for each contravention or non-compliance; or in any other case, not more than \$10,000</p>

Proposed Licensable Healthcare Services to be brought into HCS Act by Phases

S/N	Licensable Healthcare Services
	<u>Phase 1 (From Dec 2019) – Medical and Dental Clinics and Clinical Laboratories licensed under PHMCA</u>
1.	Ambulatory Surgical Centre Service
2.	Assisted Reproduction Service
3.	Blood Banking Service
4.	Blood Transfusion Service
5.	Clinical Laboratory Service
6.	Tissue Banking Service
7.	General Medical or Dental Clinic Service
8.	Proton Beam Therapy Service
9.	Radiological Service
10.	Renal Dialysis Centre Service
11.	Specialist Medical or Dental Clinic Service
	<u>Phase 2 (From June 2020) – Hospitals licensed under PHMCA</u>
12.	Acute Hospital Service
13.	Haematopoietic Stem Cell Transplant Service
14.	Chronic Sick Unit Service
15.	Community Hospital Service
16.	Emergency Ambulance Service
17.	Inpatient Palliative Care Service
18.	Medical Transport Service
19.	Neonatal Intensive Care Unit Service
20.	Nursing Home Service
21.	Organ Transplant Service
22.	Radiation Oncology Service
23.	Specialised Interventional Procedure Service
	<u>Phase 3 (From Dec 2020) – New services currently unlicensed under PHMCA</u>
24.	Cell, Tissue and Gene Therapy Service
25.	Clinical Genetic and Genomic Service
26.	Collaborative Prescribing Service
27.	Health Screening Service
28.	Mobile Medical Service
29.	Sterile Pharmaceutical Service
30.	Telemedicine Service

31.	Hyperbaric Oxygen Therapy Service
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