

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**

**IMPOSED UNDER SECTION 13(1) OF
THE HEALTHCARE SERVICES ACT 2020**

1 Application

1.1 These licence conditions (“**LCs**”) apply to:

- (1) all persons which have been licensed under the Healthcare Services Act 2020 (the “**HCSA**”) to provide:
 - (a) an outpatient medical service (“**OMS**”);
 - (b) an outpatient dental service (“**ODS**”);
 - (c) an outpatient renal dialysis service (“**ORDS**”);
 - (d) an acute hospital service (“**AHS**”);
 - (e) a community hospital service (“**CHS**”); or
 - (f) a contingency care service (“**CCS**”);
- (2) that provide or intend to provide, as part of the aforementioned service or services, COVID-19 Vaccination (as defined in paragraph 2.1).

(such persons referred to as “**Licensees**”).

1.2 A breach of these LCs may result in regulatory action being taken against Licensees under section 20 of the HCSA, including but not limited to:

- (1) suspension or revocation of the Licensee’s AHS, CCS, CHS, ODS, OMS, and/or ORDS licence;
- (2) shortening the term of the Licensee’s AHS, CCS, CHS, ODS, OMS, and/or ORDS licence;
- (3) a direction requiring the Licensee to rectify the contravention, or prevent a recurrence of the contravention; and/or
- (4) a direction requiring the Licensee to pay a financial penalty.

1.3 For avoidance of doubt:

- (1) the defined terms as used in these LCs shall have the meanings ascribed to them in the HCSA and any Regulations made thereunder, unless otherwise stated;
- (2) these LCs do not override a healthcare professional's duty to make clinical decisions that are in the best interests of each patient; and
- (3) 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 In these Licensing Conditions, unless the context otherwise requires:

- (1) **"COVID-19"** means the infectious disease known as the Coronavirus Disease 2019 (COVID-19);
- (2) **"COVID-19 Vaccination"** means an intramuscular injection to introduce a vaccine into the body of an individual for the purpose of providing the individual protection against COVID-19;
- (3) **"HSA"** means the Health Sciences Authority;
- (4) **"MOH"** means the Ministry of Health or its authorised representative(s);
- (5) **"SAE"** means a serious reportable event;
- (6) **"Registered Nurse"** means a nurse who is registered under the Nurses and Midwives Act 1999 and holds a valid practising certificate under that Act; and
- (7) **"Vaccine Recipient"** means an individual who is receiving a COVID-19 vaccine.
- (8) **"WHO"** means the World Health Organisation.

3 Policies and Protocols

3.1 Licensees shall establish and implement policies and procedures relating to all aspects of their provision of COVID-19 Vaccination ("**Policies**"), which shall include (but are not limited to) the following:

- (1) the screening of Vaccine Recipients for their suitability to receive a COVID-19 vaccine;
- (2) the handling of COVID-19 vaccines, including (A) their preparation; (B) their administration (whether for single-dose or multi-dose vial vaccines); (C) infection control; and (D) waste management;

- (3) the management of SAEs;
- (4) a reporting and escalation workflow to MOH for Reportable Incidents (as defined in paragraph 6.1 below); and
- (5) governance and oversight of the COVID-19 Vaccination operations.

3.2 Licensees shall regularly review and update their Policies.

3.3 Licensees shall ensure that their Policies are in accordance with (i) the prevailing guidelines that may be issued from time to time by MOH, HSA or WHO in relation to a COVID-19 vaccine, as well as (ii) any requirements that may be imposed by law on the reporting of SAEs to any government authority or statutory board.

4 Post-Vaccination Monitoring

4.1 Licensees shall ensure that all Vaccine Recipients who have received a COVID-19 Vaccination are (i) monitored post-vaccination; and (ii) discharged only after he or she has been assessed to be fit to leave the approved premises, approved temporary premises or approved conveyance (as the case may be) where the COVID-19 Vaccination is being provided ("**Vaccination Site**"), in accordance with the prevailing guidelines that may be issued from time to time by MOH, HSA and WHO in relation to a COVID-19 vaccine.

4.2 Licensees shall ensure that a (i) medical practitioner; or (ii) a Registered Nurse ("**Monitoring Healthcare Professional**") is physically present and available at the Vaccination Site to:

- (1) supervise the post-vaccination monitoring of Vaccine Recipients who have received a COVID-19 Vaccination; and
- (2) provide assistance to those Vaccine Recipients in a timely manner if so required or requested.

4.3 Licensees shall ensure that, if a Vaccine Recipient who has received a COVID-19 Vaccination:

- (1) refuses to undergo post-vaccination monitoring; or
- (2) after being assessed by the Monitoring Healthcare Professional to require further treatment at a hospital, declines to be conveyed by ambulance to a hospital for such treatment,

that Vaccine Recipient endorses an At-Own-Risk (AOR) form before leaving the Vaccination Site.

5 Record-Keeping and Reporting

5.1 Licensees shall adopt and use an MOH-approved IT system, which is linked to the National Electronic Health Record, to maintain records of the COVID-19 Vaccinations provided.

5.2 Licensees shall provide such information on the COVID-19 Vaccinations that is has provided as the Director-General of Health may require from time to time.

6 Incident Reporting

6.1 Licensees shall report any incident which may affect or disrupt the provision of vaccinations ("**Reportable Incidents**") to MOH as soon as possible, and no later than three hours after the start of the Reportable Incident. Reportable Incidents include, but are not limited to the following:

- (1) **Medical emergencies following vaccination**, which may or may not be related to the vaccine (e.g. syncope, cardiac arrest);
- (2) **Vaccine administration errors**, such as wrong dose and use of expired vaccines;
- (3) **Supply chain problems**, such as late or wrong supply shipments, power outage leading to vaccines being stored in improper temperatures;
- (4) **IT issues**, such as system downtime, suspected cyber-attacks, or data breaches; and
- (5) **Service delivery issues**, such as recording or broadcasting of vaccination operations on social media without consent, unmanageable queues or protests against the vaccinations.

6.2 Licensees shall ensure that an appropriate assessment or review is conducted for each Reportable Incident and shall put in place measures to mitigate the risks of and to prevent any future occurrence of such Reportable Incidents.

6.3 Licensees shall also provide MOH with any information or documentation in relation to any (i) assessment or review; or (ii) any measures implemented, in furtherance of paragraph 6.2 above, which MOH may require from time to time.