

**LICENCE CONDITIONS FOR
ACUTE HOSPITAL SERVICE LICENSEES PROVIDING OR
INTENDING TO PROVIDE SPECIALISED AND INTENSIVE
CARE SERVICES TO NEONATES**

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

1 Application

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

- (a) who have been licensed under the HCSA to provide an acute hospital service; and
 - (b) who provide an obstetric service,
- (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:

- (a) suspension or revocation of the Licensee’s licence(s) to provide acute hospital service;
- (b) shortening the term of the Licensee’s licence(s) to provide acute hospital service;
- (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.

1.3 For avoidance of doubt:

- (a) 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;
- (b) these LCs do not override a healthcare professional’s duty to make clinical decisions that are in the best interests of each patient; and
- (c) 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 and Scope

2.1 The following definitions shall apply to these LCs:

- (a) **“HCSA”** refers to the Healthcare Services Act 2020.
- (b) **“Level 1 neonatal care”** refers to the provision of a basic level of care to a Neonate who is well or who is born with mild medical conditions. Level 1 neonatal care requires the Licensee(s) to have the capability to perform resuscitation on a Neonate and to evaluate and provide routine post-natal care for a healthy Neonate and a stable Neonate born at 35 to 37 weeks. See **Annex A** for examples of a Neonate that may require Level 1 neonatal care.
- (c) **“Level 2 neonatal care”** refers to the provision of care to a Neonate who is physiologically immature or is moderately ill. See **Annex A** for examples of a Neonate that may require Level 2 neonatal care.
- (d) **“Level 3 neonatal care”** refers to an intensive care service that provides care to a Neonate who (i) is critically ill or requires mechanical ventilation; and (ii) requires continuous monitoring of respiration or heart rate. See **Annex A** for examples of a Neonate that may require Level 3 neonatal care.
- (e) **“Neonate”** refers to a person from birth to 28 days old (inclusive).
- (f) **“Neonatal Intensive Care Unit”** or **“NICU”** refers to a clinical area that is designated for the provision of Level 3 neonatal care.
- (g) **“Neonatologist”** refers to a medical practitioner who is registered under section 22 of the Medical Registration Act 1997 as a specialist in the branch of paediatric medicine with a sub specialisation in neonatology.
- (h) **“Paediatrician”** refers to a medical practitioner who is registered under section 22 of the Medical Registration Act 1997 as a specialist in the branch of paediatric medicine.
- (i) **“Special care nursery”** or **“SCN”** refers to a clinical area that is designated for the provision of Level 2 neonatal care.

3 Requirements Relating to Personnel

Neonatologist or Advisory Committee in charge of Level 2 Neonatal Care and Level 3 Neonatal Care

3.1 The Licensee shall either:

- (a) appoint a Neonatologist, for the purpose of charging him or her with the responsibility of supervising the provision of Level 2 neonatal care and Level 3 neonatal care to a Neonate; or
- (b) establish a neonatal specialised and intensive care unit advisory committee that: -
 - (i) is chaired by a medical practitioner; and
 - (ii) includes at least one member who is a Paediatrician credentialed by the Licensee to provide Level 2 neonatal care and Level 3 neonatal care to Neonates.

Medical Practitioners Attending to Inpatient Neonates

- 3.2 The Licensee shall designate an admitting Paediatrician or Neonatologist to oversee the care given to each Neonate admitted as an inpatient who requires Level 2 neonatal care or Level 3 neonatal care. Where the admitting Paediatrician or Neonatologist is unable to oversee the care given to each Neonate for any period of time, the Licensee shall ensure that a covering-Neonatologist is designated to cover the duties of that Paediatrician or Neonatologist in the interim.
- 3.3 In addition to Paragraph 3.2 above, the Licensee shall ensure that each Neonate admitted as an inpatient who requires Level 3 neonatal care, is co-managed by a Neonatologist. The Licensee shall ensure that the Neonatologist oversees the daily management plans for that Neonate.
- 3.4 The Licensee shall ensure that there is at least one medical practitioner physically present at the approved permanent premises at all times to attend immediately to any emergencies that may arise in the SCN and the NICU.
- 3.5 The Licensee shall ensure that the medical practitioner referred to in Paragraph 3.4 above, is adequately trained in neonatal specialised and intensive care, including resuscitation of Neonates.

Nurses

- 3.6 The Licensee shall ensure that nursing care at the approved permanent premises is supervised at all times by a registered nurse with the relevant training and competencies in caring for Neonates.

- 3.7 The Licensee shall ensure that the following requirements for nursing staff are met at all times:
- (a) at least 80% of the total nursing staff providing Level 2 neonatal care and Level 3 neonatal care shall be registered nurses;
 - (b) in relation to Level 3 neonatal care, at least 20% of the registered nurses on duty at each shift shall have the relevant training and competencies in caring for Neonates; and
 - (c) in relation to Level 2 neonatal care, at least one registered nurse on duty at each shift shall have the relevant training and competencies in caring for Neonates.
- 3.8 The Licensee shall ensure that the relevant training and competencies referred to in Paragraphs 3.6, 3.7(b) and 3.7(c), include: -
- (a) a certified course in neonatal nursing, paediatric nursing, critical care nursing or an equivalent field, by a body recognised by the Director-General, including but not limited to the Singapore Nursing Board; or
 - (b) an in-house training programme endorsed by the registered nurse supervising nursing services at the approved permanent premises, including but not limited to the chief nurse appointed by the Licensee or the director of nursing appointed by the Licensee.

4 Facilities

- 4.1 The Licensee shall provide adequate workspace for each cot in the SCN and the NICU.
- 4.2 The Licensee shall ensure that: -
- (a) for Level 2 neonatal care, there be at least 2 cots per 1000 live births per year born in the approved permanent premises; and
 - (b) for Level 3 neonatal care, there shall be at least 0.5 cots per 1000 live births per year born in the approved permanent premises.
- 4.3 Notwithstanding Paragraph 4.2 above, where the Licensee provides an acute hospital service to persons with high-risk pregnancies, persons with in-utero transfers and Neonates born outside of the Licensee's approved permanent premises, the Licensee shall ensure that: -
- (a) for Level 2 neonatal care, there shall be at least 3.5 cots per 1000 live births per year born in the approved permanent premises; and
 - (b) for Level 3 neonatal care, there shall be at least 1.5 cots per 1000 live births per year born in the approved permanent premises.

- 4.4 The Licensee shall ensure that its radiographers are familiar with x-ray techniques for a Neonate so as to minimise a Neonate's repetitive exposure to radiation.
- 4.5 The Licensee shall designate an area within the approved permanent premises to prepare feeds for Neonates and ensure that the area is suitably sited and adequately equipped for this purpose.
- 4.6 The Licensee shall ensure that all of the criteria set out below, are fulfilled before a Neonate admitted in the SCN or the NICU is transferred out of the Licensee's approved permanent premises to an approved permanent premises of another licensee licensed under the HCSA to provide an acute hospital service: -
- (a) the receiving Neonatologist has consulted with the referring Neonatologist, and the receiving Neonatologist has agreed to the transfer; and
 - (b) the management of the referring and the receiving Licensee have been informed of the transfer arrangements.
- 4.7 The Licensee shall ensure that the transfer arrangements referred to in Paragraph 4.6 above are adequate and safe for the Neonate, including but not limited to ensuring that:
- (a) the Neonate is transported using an emergency ambulance operated by an emergency ambulance service licensee licensed under the HCSA;
 - (b) there is adequate and appropriate medical equipment and facilities available to the Neonate during the transfer, including but not limited to:
 - (i) a transport incubator;
 - (ii) emergency resuscitation equipment;
 - (iii) oxygen supply;
 - (iv) ventilator;
 - (v) means of administration of drugs; and
 - (vi) equipment for the monitoring and maintenance of vital functions such as body temperature, heart rate, respiratory rate and blood pressure; and
 - (c) the referring Neonatologist is responsible for the Neonate being appropriately stabilised and adequately managed before and during the transfer.

5 Equipment

- 5.1 The Licensee shall ensure that the SCN and the NICU are each equipped with the relevant equipment set out in **Annex B**, which shall be regularly checked, re-stocked and maintained in accordance with the manufacturer's instructions.

- 5.2 The Licensee shall ensure that equipment used to monitor the Neonate's vital functions have alarm systems that are operative at all times.
- 5.3 The Licensee shall ensure that its approved permanent premises, including the area providing the 24-hour clinic service, is equipped to perform resuscitation for Neonates.

6 Quality Assurance

- 6.1 The Licensee shall ensure that there are documented indications on the criteria for admission of a Neonate to the SCN and the NICU.
- 6.2 The Licensee shall ensure that there is a documented quality assurance programme in relation to the care of Neonates ("**QA Programme**"). The Licensee shall ensure that regular reports on the QA Programmes are made available to the Director-General as and when required. The QA Programme shall include a review of the following:
- (a) documented regular audit on the indications on the criteria for admission of a Neonate to the SCN and the NICU;
 - (b) neonatal mortality;
 - (c) targeted major neonatal morbidities; and
 - (d) documented regular audit of hand hygiene practices and healthcare associated infections including but not limited to central venous line associated blood stream infection, ventilator associated pneumonia and methicillin-resistant *Staphylococcus aureus* colonisation or infection.
- 6.3 The Licensee shall ensure that there are documented policies and procedures in relation to the safe conduct of the care of Neonates, including but not limited to the management and referral of Neonates that may require admission to the SCN and the NICU.

Examples of a Neonate that may require Level 1 Neonatal Care

1. A well Neonate or a Neonate born with mild medical conditions that requires a basic level of care, including but not limited to: -
 - (a) a Neonate with G6PD deficiency;
 - (b) a Neonate whose mother is a Hepatitis B carrier;
 - (c) a Neonate with mild congenital malformations, including but not limited to polydactyly, pre-auricular tags, hydrocele;
 - (d) a Neonate receiving phototherapy, at the discretion of the specialist in charge;
 - (e) a Neonate whose mother had maternal complications like diabetes mellitus, pyrexia, prolonged rupture of membrane, mild meconium staining, but who is free from all clinical manifestations of illnesses; and
 - (f) a pre-term Neonate at 35 to 37 weeks' gestation who is physiologically stable.

Examples of a Neonate that may require Level 2 Neonatal Care

2. A Neonate who is physiologically immature or is moderately ill, including but not limited to: -
 - (a) a Neonate with a birth weight of 1500 grams to 2000 grams (both figures inclusive);
 - (b) a preterm Neonate at 35 weeks' gestation and below;
 - (c) a pre-term Neonate at 35 to 37 weeks' gestation who is not physiologically stable;
 - (d) a Neonate with an Apgar Score of 4 to 6 (both figures inclusive) at five minutes
 - (e) a Neonate who was resuscitated at birth;
 - (f) a Neonate requiring continuous monitoring of respiration or heart rate;
 - (g) a Neonate receiving additional oxygen;
 - (h) a Neonate receiving intravenous glucose, electrolyte solutions or antibiotics;
 - (i) a Neonate being tube fed;
 - (j) a Neonate being barrier-nursed;
 - (k) a Neonate receiving phototherapy at the discretion of the admitting Paediatrician or Neonatologist overseeing the care given to each Neonate admitted as an inpatient who requires Level 2 neonatal care or Level 3 neonatal care, or the covering Neonatologist;
 - (l) a Neonate with persistent hypothermia of 36°C and below;
 - (m) a Neonate with congenital malformations that require special care;
 - (n) a Neonate who had minor surgery in the previous 24 hours;
 - (o) a Neonate convalescing after Level 3 neonatal care; and
 - (p) a Neonate born before 32 weeks gestation or weighing less than 1500 grams waiting for transfer to a NICU providing Level 3 neonatal care.

Examples of a Neonate that may require Level 3 neonatal Care

3. A Neonate who: -
- (a) is critically ill or requires mechanical ventilation; and
 - (b) requires continuous monitoring of respiration or heart rate,
- including but not limited to: -
- (i) a critically ill Neonate receiving assisted ventilation, including but not limited to intermittent mandatory ventilation (IMV) and constant positive airway pressure (CPAP);
 - (ii) a Neonate that had received assisted ventilation and is in the first 24 hours following its withdrawal;
 - (iii) a critically ill Neonate, including but not limited to a Neonate with recurrent apnoea requiring constant attention;
 - (iv) a Neonate who had major surgery, including but not limited to patent ductus arteriosus (PDA) ligation or other surgery requested by the paediatric surgeon;
 - (v) a Neonate with severe perinatal asphyxia i.e., an Apgar Score of 3 or less at five minutes;
 - (vi) a Neonate with severe meconium aspiration syndrome;
 - (vii) a Neonate born before 32 weeks gestation or weighing less than 1500 grams;
 - (viii) a Neonate directed to Level 3 neonatal care by the specialist in charge;
 - (ix) a Neonate with convulsions;
 - (x) a Neonate receiving partial or total parenteral nutrition; and
 - (xi) a Neonate undergoing major medical procedures, including but not limited to arterial catheterisation, peritoneal dialysis or exchange transfusions.

Equipment Required for Different Levels of Neonatal Care

1. The Licensee shall ensure that the SCN providing Level 2 neonatal care is equipped with a sufficient number of each equipment set out below:
 - (a) ambient oxygen analyser
 - (b) glucometer (point of care testing) **[NEW]**
 - (c) heart rate monitor
 - (d) high flow nasal cannula **[NEW]**
 - (e) incubator or radiant warmer **[NEW]**
 - (f) infusion pump
 - (g) jaundice meter (for transcutaneous bilirubin measurement) **[NEW]**
 - (h) phototherapy unit
 - (i) pulse oximeter with alarm **[NEW]**
 - (j) access to frequent blood gas analysis using micro-methods
 - (k) access to biochemical analysis using micro-methods
 - (l) access to equipment for radiological examination
 - (m) access to direct ophthalmoscopy (for red reflex screening) **[NEW]**
2. The Licensee shall ensure that the NICU providing Level 3 neonatal care is equipped with a sufficient number of each equipment set out below:
 - (a) the equipment set out in paragraph 1, Annex B
 - (b) chest drain (for pneumothorax or pleural effusion) **[NEW]**
 - (c) continuous positive airway pressure device **[NEW]**
 - (d) continuous temperature monitor
 - (e) device for indirect non-invasive automated blood pressure (DINAMAP) **[NEW]**
 - (f) fibre-optic transilluminator **[NEW]**
 - (g) intravascular blood pressure transducer
 - (h) syringe pump
 - (i) ventilator
 - (j) access to ultrasound scanner for cranial ultrasonography
 - (k) access to binocular indirect ophthalmoscopy **[NEW]**

[NEW] refers to equipment that was not listed in the 2001 Guidelines for Hospitals with Neonatal Intensive Care Service issued under the Private Hospitals and Medical Clinics Act 1980.
