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**No. S 429**

# HEALTHCARE SERVICES ACT 2020

# HEALTHCARE SERVICES (ASSISTED REPRODUCTION SERVICE) REGULATIONS 2023

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*Division 1 — Provision of service to patients*

Regulation



In exercise of the powers conferred by section 57 of the Healthcare Services Act 2020, the Minister for Health makes the following Regulations:

## PART 1

## PRELIMINARY

### Citation and commencement

**1.** These Regulations are the Healthcare Services (Assisted Reproduction Service) Regulations 2023 and come into operation on 26 June 2023.

### Definitions

**2.** In these Regulations —

"assisted reproduction cycle", in relation to a patient, means the patient's menstrual cycle —

(*a*) that is a stimulated cycle; or

(*b*) any menstrual cycle other than a stimulated cycle, in which any oocyte was collected or attempted to be collected from, or any oocyte or embryo was transferred into, the body of the patient;

"assisted reproduction procedure" means any of the following:

(*a*) the collection of oocytes from a woman, other than by way of surgical excision of the woman's ovarian tissue;

(*b*) the fertilisation of an oocyte for the subsequent distribution (including transfer into the body of a woman) of the embryo;

(*c*) the transfer of any oocyte or embryo into the body of a woman;

(*d*) any removal of cells from an embryo for the purpose of testing the embryo;

"assisted reproduction service", "embryo", "oocyte" and "reproductive cell" have the meanings given by paragraph 2 of the First Schedule to the Act;

"calendar day" includes Saturday, Sunday and every public holiday;

"donor", in relation to any reproductive cell or embryo, means the individual from whose body the reproductive cell is collected, or from whose reproductive cells the embryo is created, but excludes a patient or a patient's husband;

"elective oocyte storage", in relation to a patient, means —

(*a*) the administration of gonadotropins to the patient for the collection of oocytes from the patient;

(*b*) the collection of oocytes from the patient; and

(*c*) the storage of the oocytes collected from the patient,

where none of the collected oocytes are fertilised before the storage of the oocytes;

"embryology laboratory" means any place equipped to carry out any of the following:

(*a*) culture medium preparation and quality control testing in relation to preparation of reproductive

cells or embryos for cryopreservation, maturation, fertilisation, treatment or distribution;

(*b*) examination of follicular aspirates with oocyte identification;

(*c*) oocyte quality and maturing grading;

(*d*) sperm analysis in relation to sperm selection for IVF or ICSI and sperm washing and capacitation;

(*e*) insemination of oocytes via IVF or ICSI;

(*f*) determination of fertilisation;

(*g*) embryo culture and embryo quality and maturation grading;

(*h*) preparation of embryos for embryo transfer (either uterine or tubal);

(*i*) reproductive cell or embryo cryopreservation or storage;

(*j*) micromanipulation of reproductive cells or embryos;

"embryology procedure" means any of the following procedures:

(*a*) the examination of follicular aspirates;

(*b*) oocyte classification;

(*c*) sperm preparation for subsequent use in an assisted reproduction procedure or distribution;

(*d*) oocyte insemination (whether by IVF or ICSI);

(*e*) documentation of fertilisation;

(*f*) preparation of embryos for transfer;

"essential life-saving measure" means any basic emergency procedure that may be carried out on a person for the purpose of resuscitating the person;

"General Regulations" means the Healthcare Services (General) Regulations 2021 (G.N. No. S 1035/2021);

"ICSI" means intracytoplasmic sperm injection;

"IVF" means in vitro fertilisation;

"licensee" means a person who holds a licence to provide an assisted reproduction service;

"patient", in relation to a licensee, means any woman who receives an assisted reproduction service from the licensee;

"pre-implantation genetic testing" means the biopsy of any cell from a blastocyst created by IVF or ICSI;

"qualified assisted reproduction practitioner" means a medical practitioner who fulfils the criteria mentioned in regulation 11(1);

"qualified embryologist" means a person who fulfils the criteria mentioned in regulation 11(2);

"recipient", in relation to a reproductive cell or an embryo that is transferred, means the woman into whose body the reproductive cell or embryo is transferred;

"relevant assisted reproduction service" means an assisted reproduction service —

(*a*) licensed under the Act; or

(*b*) in a medical clinic or an acute hospital that is licensed under the Private Hospitals and Medical Clinics Act 1980 and approved to provide assisted reproduction services;

"restricted procedure", in relation to a patient, means any of the following assisted reproduction procedures:

(*a*) the fertilisation of the oocytes collected from the patient with the sperm of any man by IVF or ICSI;

(*b*) the transfer of any oocyte or embryo into the body of the patient;

"sperm" means live human sperm and includes the cells of the male germ line at any stage of maturity;

"stimulated cycle", in relation to a patient, means the patient's menstrual cycle in which —

(*a*) gonadotropins have been administered to the patient during the menstrual cycle; and

(*b*) one or more oocytes are collected or attempted to be collected from the patient,

whether or not any oocyte or embryo is transferred into the body of the patient.

**Application of Regulations**

**3.** Unless otherwise expressly provided in these Regulations, the provisions of these Regulations —

(*a*) apply in addition to the provisions of the General Regulations; and

(*b*) prevail if, and to the extent that, there is any inconsistency between these Regulations and the General Regulations insofar as the matter relates to a licensee.

**Specified services**

**4.** For the purposes of section 9A(1) of the Act, the services set out in the Schedule are specified services for an assisted reproduction service.

**Prohibited service delivery modes**

**5.** A licensee must not provide an assisted reproduction service using any of the following service delivery modes:

(*a*) at any premises other than permanent premises;

(*b*) using a conveyance.

**Mandatory services**

**6.** A licensee must —

(*a*) in the provision of the assisted reproduction service to any patient, provide clinical care incidental to the collection of

oocytes from the patient or the screening of donors of reproductive cells or embryos; and

(*b*) be equipped and capable of providing the service of transferring an oocyte or embryo into the body of a patient.

## PART 2

## GOVERNANCE OF SERVICE, CERTIFICATION AND PROCESSES

### Qualifications, skills and competencies for Clinical Governance Officer

**7.**—(1) For the purposes of section 24(3)(*b*) of the Act, an individual is suitably qualified to be appointed a Clinical Governance Officer for an assisted reproduction service if the individual —

(*a*) is registered under section 20(1) or (2) of the Medical Registration Act 1997 as a fully registered medical practitioner;

(*b*) holds a valid practising certificate under the Medical Registration Act 1997;

(*c*) is registered under section 22 of the Medical Registration Act 1997 as a specialist in obstetrics and gynaecology;

(*d*) has work experience in the provision of a relevant assisted reproduction service, which includes performing oocyte collections or oocyte or embryo transfers for a period of 3 years within a period of 5 years, of which one year must be immediately before the individual's appointment; and

(*e*) whose work experience in performing oocyte collections or oocyte or embryo transfers mentioned in sub-paragraph (*d*) includes independently performing —

(i) at least 250 oocyte collections or oocyte or embryo transfers within a period of 3 years; or

(ii) at least 350 oocyte collections or oocyte or embryo transfers within a period of 5 years.

(2) For the purposes of paragraph (1)(*e*), an individual independently performs a procedure where there is no other medical practitioner supervising the individual's performance of the procedure.

**Additional duties and responsibilities of Clinical Governance Officer**

**8.** In addition to regulation 15 of the General Regulations, a Clinical Governance Officer of a licensee must ensure that proper arrangements are in place for the storage and disposal of all reproductive cells and embryos handled in the provision of the assisted reproduction service by the licensee.

**Licensee must be certified**

**9.** A licensee must, for the duration of the licensee's licence, have a valid certification of conformity to the Code of Practice for Assisted Reproductive Technology Units issued by a certifying body recognised by the Reproductive Technology Accreditation Committee established by the Fertility Society of Australia and New Zealand.

**Quality management system**

**10.**—(1) A licensee must establish and implement a quality management system in accordance with this regulation to ensure —

(*a*) the safety and welfare of patients, husbands of patients and donors;

(*b*) the safety, quality and viability of any reproductive cell and embryo collected, tested, processed, stored and distributed by the licensee;

(*c*) the proper collection, testing, processing, storage and distribution of reproductive cells and embryos; and

(*d*) the objective and systematic monitoring, evaluation, identification of problems in laboratory, clinical and counselling practices and actions to improve the level and appropriateness of care.

(2) Without limiting paragraph (1), the quality management system mentioned in that paragraph must provide for all of the following:

(*a*) a system for regular review of the performance and complications (if any) of every assisted reproduction cycle carried out with the aim to improve the quality of care and ensure the safety of patients;

(*b*) the investigation of any occurrence or complaint that discloses or may disclose any weakness or inadequacy affecting the quality of the assisted reproduction service;

(*c*) the identification and implementation of appropriate and effective actions to address any weakness or inadequacy mentioned in sub-paragraph (*b*) and prevent a recurrence;

(*d*) the maintenance of adequate and appropriate documentation on the clinical outcomes of any assisted reproduction procedure performed or clinical use of any reproductive cells or embryos by the licensee, including any event that affects or may affect any patient that relates to or is the result of an assisted reproduction procedure;

(*e*) quality control measures for equipment used in the provision of the assisted reproduction service, including quality control tests and regular monitoring of equipment performance;

(*f*) a system to ensure the appropriate and adequate documentation of the licensee's policies and processes, including —

(i) creating, reviewing and updating documentation for the applicable licensee's quality assurance measures and the compliance of the licensee's personnel with those measures; and

(ii) ensuring proper document control of all documentation mentioned in sub-paragraph (i);

(*g*) the availability of all policies and procedures on laboratory safety to all personnel who work in the licensee's embryology laboratory, and measures to ensure that all

such personnel take appropriate infection control measures within the embryology laboratory;

(*h*) the documentation of the quality control programme for the embryology laboratory, which must include the goals of the programme, the applicable policies and procedures to meet those goals, and the corrective actions taken where the goals are not met;

(*i*) the establishment of written procedures for —

(i) the risk management of potential cross-contamination of reproductive cells or embryos stored by the licensee; and

(ii) where the suitability of any reproductive cell or embryo for its intended use is, or is believed to have been, adversely affected for any reason —

(A) where the oocyte or embryo has been transferred into the body of an individual — the notification of any person who receives or has received the oocyte or embryo; and

(B) in any other case — the recall of the reproductive cell or embryo;

(*j*) the implementation of quality control measures for all activities relating to the storage of reproductive cells and embryos, including measures pertaining to the safety, quality and viability of the reproductive cells and embryos in relation to —

(i) the recruitment of donors;

(ii) the collection and transport of the reproductive cells and embryos;

(iii) the processing and testing of the reproductive cells and embryos;

(iv) the quarantine of the reproductive cells and embryos; and

(v) the storage and distribution of the reproductive cells and embryos;

(*k*) a system for appropriate accountability, roles, responsibilities and continuing educational programmes for quality management;

(*l*) documentation of the organisational reporting relationships, responsibilities and accountability of each personnel;

(*m*) the identification of key performance indicators for assessing performance outcomes of the storage of reproductive cells and embryos, including mechanisms for periodic monitoring and evaluation of these indicators.

(3) A licensee must —

(*a*) conduct regular reviews of the quality management system mentioned in paragraph (1);

(*b*) make and maintain accurate reports of all reviews conducted under sub-paragraph (*a*); and

(*c*) update the quality management system as may be necessary, including in response to the findings of any review conducted under sub-paragraph (*a*).

(4) A second or subsequent review of the quality management system mentioned in paragraph (1) must be conducted during the twelfth month after the month in which the licensee conducted the immediately preceding review.

(5) In addition, a licensee must —

(*a*) participate in and perform satisfactorily for the relevant external quality assessment programme for every test provided by the licensee; and

(*b*) ensure that a Clinical Governance Officer or another suitably qualified personnel designated by a Clinical Governance Officer reviews the results of every quality assessment programme mentioned in sub-paragraph (*a*) and implements appropriate and effective actions to

address any weakness or inadequacy in the provision of the assisted reproduction service.

## PART 3

## REQUIREMENTS RELATING TO PERSONNEL

### No employment or engagement of unqualified persons

**11.**—(1) Subject to paragraph (3), a licensee must not permit or deploy any personnel to practise medicine or do any act as a medical practitioner in the provision of the assisted reproduction service unless the personnel —

(*a*) is a medical practitioner registered under section 20(1) or (2) of the Medical Registration Act 1997 as a fully registered medical practitioner and holds a valid practising certificate under that Act;

(*b*) is a medical practitioner registered under section 22 of the Medical Registration Act 1997 as a specialist in obstetrics and gynaecology;

(*c*) has at least 18 months of training in the provision of a relevant assisted reproduction service, during which the medical practitioner is trained in all of the following:

(i) reproductive endocrinology, particularly in the use of ovulation-inducing agents and hormonal control of the menstrual cycle;

(ii) ultrasound-guided oocyte collection techniques;

(iii) gynaecological endoscopy;

(iv) oocyte and embryo transfer;

(*d*) has at least 6 months of practical hands-on experience under the supervision of an experienced assisted reproduction practitioner, in the provision of a relevant assisted reproduction service;

(*e*) has satisfactorily performed at least 20 oocyte collection procedures and 20 embryo transfers under the supervision of an experienced assisted reproduction practitioner;

(*f*) has attended at least one course or seminar on assisted reproduction; and

(*g*) has been assessed by the Clinical Governance Officer to possess the competencies required to practise medicine or do any act as a medical practitioner without the supervision of an experienced assisted reproduction practitioner.

(2) Subject to paragraph (4), a licensee must not permit or deploy any personnel to carry out any embryology procedure unless the personnel —

(*a*) holds a Bachelor of Science degree or an equivalent qualification;

(*b*) has at least 6 months of practical hands-on experience in carrying out the embryology procedures under the supervision of an experienced embryologist;

(*c*) has satisfactorily performed at least 50 each of every embryology procedure under the supervision of an experienced embryologist;

(*d*) has attended at least one course or seminar on assisted reproduction; and

(*e*) has been assessed by the Clinical Governance Officer to possess the competencies required to carry out embryology procedures without the supervision of an experienced embryologist.

(3) Despite paragraph (1), a licensee may permit or deploy a medical practitioner to practise medicine or do any act as a medical practitioner in the provision of the assisted reproduction service if the medical practitioner does so under the supervision of an experienced assisted reproduction practitioner.

(4) Despite paragraph (2), a licensee may permit or deploy a personnel who holds a Bachelor of Science degree or an equivalent qualification to carry out an embryology procedure if the personnel does so under the supervision of an experienced embryologist.

(5) In this regulation —

"experienced assisted reproduction practitioner" means a qualified assisted reproduction practitioner who —

(*a*) has at least 6 months of independent practical hands-on experience in the provision of a relevant assisted reproduction service after completing the period of practical hands-on experience under the supervision of an experienced assisted reproduction practitioner mentioned in paragraph (1)(*d*); and

(*b*) has been assessed by a Clinical Governance Officer to possess the competencies required to practise medicine, perform any assisted reproduction procedure or do any act as an assisted reproduction practitioner in the provision of the assisted reproduction service independently;

"experienced embryologist" means a qualified embryologist who —

(*a*) has at least 3 years of practical hands-on experience in carrying out the embryology procedures with a relevant assisted reproduction service; and

(*b*) has been assessed by a Clinical Governance Officer to possess the competencies required to carry out embryology procedures independently.

**Appointment of chief embryologist**

**12.**—(1) A licensee must appoint an experienced embryologist who fulfils the following criteria as the chief embryologist of the assisted reproduction service:

(*a*) work experience as an experienced embryologist for a period of at least 2 years immediately before the date of appointment;

(*b*) independent performance of at least 300 assisted reproduction cycles in the course of providing a relevant assisted reproduction service.

(2) For the purposes of paragraph (1)(*a*), a person has not obtained work experience as an experienced embryologist for a period of at least 2 years immediately before a date, if the person had ceased working as an experienced embryologist for any consecutive period of at least 6 months within the period of 2 years immediately before that date.

(3) A licensee must ensure that the person appointed as the chief embryologist of an assisted reproduction service —

(*a*) assists the Clinical Governance Officer in the day-to-day technical management of the embryology laboratory;

(*b*) supervises, trains and guides each personnel under the charge of the chief embryologist in conducting tests or procedures in the embryology laboratory;

(*c*) assesses and ensures the competency of each personnel deployed to perform tasks in the embryology laboratory;

(*d*) evaluates any test or equipment before it is used in the provision of the assisted reproduction service;

(*e*) monitors the performance of all tests or procedures carried out in the embryology laboratory, including ensuring the implementation of quality control measures;

(*f*) establishes and reviews policies and procedures for the safe and effective performance of all tests or procedures carried out in the embryology laboratory;

(*g*) resolves any technical issue that arises from the performance of a test or procedure carried out in the embryology laboratory; and

(*h*) reviews all service records in relation to the tests or procedures carried out in the embryology laboratory.

(4) In this regulation, "experienced embryologist" has the meaning given by regulation 11(5).

**Minimum staffing requirements**

**13.** For the purposes of providing an assisted reproduction service, a licensee must employ or engage —

(*a*) at least one qualified assisted reproduction practitioner; and

(*b*) at least 2 persons to carry out embryology procedures, one of whom must be the chief embryologist.

**General requirements relating to personnel**

**14.**—(1) A licensee must ensure all of the following in relation to each personnel:

(*a*) that records of any assessment of each personnel's competencies and work performance are kept;

(*b*) each of the following personnel (other than a qualified assisted reproduction practitioner or a person performing embryology procedures) is supervised by an experienced person when performing any task or providing any service in relation to the assisted reproduction service:

(i) any personnel with less than 2 years of work experience in providing an assisted reproduction service;

(ii) any personnel who has not been assessed by the Clinical Governance Officer to be able to perform the task or provide the service competently without supervision.

(2) A licensee must ensure that —

(*a*) a person other than the assessor audits records of the assessment mentioned in paragraph (1)(*a*); and

(*b*) records of every audit mentioned in sub-paragraph (*a*) are kept.

(3) In this regulation —

"experienced person" means —

(*a*) the Clinical Governance Officer; or

(*b*) another of the licensee's personnel with at least 2 years of relevant work experience and who is

designated by the Clinical Governance Officer to provide supervision;

"relevant work experience", in relation to any personnel designated by the Clinical Governance Officer to provide supervision, means work experience in any task performed or service provided which the personnel is designated to supervise.

## PART 4

## PREMISES, FACILITIES AND EQUIPMENT

### Requirements relating to premises

**15.** A licensee must ensure that every approved permanent premises —

(*a*) has adequate space and is appropriately equipped for the licensee to provide the assisted reproduction service in a proper and safe manner;

(*b*) is adequately secured to prevent unauthorised access to the approved permanent premises;

(*c*) includes a room or an area that enables the conduct of consultations and counselling for patients and their husbands or donors in a manner that ensures confidentiality and privacy; and

(*d*) includes an embryology laboratory.

### Requirements relating to facilities and equipment

**16.** A licensee must ensure that all of the following requirements are satisfied in relation to the facilities and equipment used in the provision of the assisted reproduction service (including those used in the licensee's embryology laboratory):

(*a*) each instrument and equipment is installed, commissioned and used or operated properly, in accordance with the instructions of the manufacturer of the instrument or equipment;

(*b*) each instrument and equipment is, and the supplies and reagents used or intended to be used are, effective to ensure the safety, and maintenance of the quality or viability, of every reproductive cell and embryo handled, processed or stored by the licensee;

(*c*) every instrument or equipment is used in a manner that —

(i) prevents the mix-up, or contamination or cross-contamination, of stored reproductive cells and embryos; and

(ii) ensures the safety, and maintenance of the quality or viability, of every reproductive cell and embryo handled, processed or stored by the licensee;

(*d*) every refrigerator or storage tank undergoes periodic maintenance to ensure that there is no degradation in the quality and usability of the reproductive cells and embryos and reagents kept in the refrigerator or storage tank;

(*e*) a procedure is put in place for monitoring, inspecting, sterilising and cleaning each piece of instrument or equipment used;

(*f*) appropriate tests and procedures are carried out periodically to ensure that any instrument, equipment or reagent used by the licensee complies with the tolerance limits determined by the manufacturer of the instrument, equipment or reagent;

(*g*) the following information about any supplies or reagent used in the collection, testing, processing and storage of any reproductive cell or embryo by the licensee is identified and recorded, where applicable:

(i) the name of the supply or reagent;

(ii) the name of the manufacturer;

(iii) the lot number;

(iv) the date received;

(v) the date opened;

(vi) the expiration date;

(*h*) where any instrument, equipment, reagent or other material is sterilised — the instrument, equipment, reagent or other material is clearly labelled to indicate the date on which sterilisation took place and the expiry date of the sterilisation;

(*i*) every laboratory chemical and reagent is labelled to indicate the date received, date opened, and shelf life, where applicable;

(*j*) procedures are put in place to monitor and maintain the conditions in which each reproductive cell or embryo is stored, including the immediate notification of and response to temperature deviations outside acceptable ranges;

(*k*) the carrying out of regular evaluation of suppliers of materials the use of which is likely to have a material impact on the safety, quality and viability of stored reproductive cells or embryos to ensure that the materials obtained from the suppliers are safe and effective;

(*l*) adequate and stable electricity supply is provided for all equipment used in the embryology laboratory, including an adequate number of grounded electrical outlets and an emergency power supply for each piece of equipment that is essential for maintaining the safety, quality, viability and potency of stored reproductive cells or embryos.

## PART 5

## ADMINISTRATION AND USE OF ANAESTHETICS

### Definitions of this Part

**17.** In this Part —

"deep sedation" means a drug-induced depression of a patient's consciousness —

(*a*) during which the patient cannot be easily aroused but will respond purposefully following repeated or painful stimulation;

(*b*) where the patient's ability to independently maintain ventilatory function may be impaired;

(*c*) where the patient may require assistance in maintaining a patent airway and spontaneous ventilation may be inadequate; and

(*d*) where the patient's cardiovascular function is usually maintained;

"general anaesthesia" has the meaning given by paragraph 2 of the First Schedule to the Act;

"neuraxial anaesthesia" means the anaesthesia that is caused in a patient by the administration of an anaesthetic around the nerves of the central nervous system of the patient;

"specified anaesthetic" means an anaesthetic used to cause deep sedation, general anaesthesia or neuraxial anaesthesia.

**Anaesthesia service**

**18.**—(1) Where any anaesthetic is administered to a patient for the purpose of conducting any procedure as part of the provision of an assisted reproduction service, a licensee must —

(*a*) ensure that the patient is regularly monitored throughout the procedure by the person who administered the anaesthetic, using the appropriate patient monitoring device; and

(*b*) establish, implement and regularly review processes and procedures to ensure the continued monitoring and care of the patient mentioned in sub-paragraph (*a*) after completion of the procedure mentioned in that sub-paragraph.

(2) A licensee must ensure that the administration of any specified anaesthetic to a patient is performed in the provision of an assisted reproduction service only by an anaesthesiologist.

(3) A licensee must —

(*a*) ensure that sufficient supplies of anaesthetics, anaesthetic delivery equipment and patient monitoring devices are kept and maintained at each approved permanent premises; or

(*b*) establish, implement and regularly review processes to ensure that the licensee is able to obtain the supplies mentioned in sub-paragraph (*a*) before the administration of any anaesthetic to a patient.

(4) A licensee must —

(*a*) before administering any type of anaesthetic to a patient, properly inform the patient of the risks and benefits of, and (if any) the alternatives to, that type of anaesthetic; and

(*b*) having satisfied the condition mentioned in sub-paragraph (*a*) in respect of a patient —

(i) obtain the written consent of the patient before any type of anaesthetic is administered to the patient; and

(ii) keep and maintain proper and accurate records of the patient's consent.

**Procedural room**

**19.** A licensee must ensure that every procedural room at every approved permanent premises is appropriately designed, built, furnished and equipped to enable the provision of anaesthetics in a proper, effective and safe manner.

**Specified anaesthetic must be suitable for patient**

**20.**—(1) A licensee must ensure that —

(*a*) a specified anaesthetic is not offered or administered to any patient at any approved permanent premises unless the approved permanent premises has the appropriate equipment and facilities to ensure that the specified anaesthetic may be administered safely and effectively;

(*b*) a specified anaesthetic is not offered or administered to any patient for whom that specified anaesthetic would be inappropriate; and

(*c*) every medical practitioner who offers a specified anaesthetic to a patient documents the reasons for doing so.

(2) A licensee must ensure that before a specified anaesthetic is administered to a patient, an anaesthesiologist assesses that the patient is a suitable candidate for the administration of specified anaesthetics.

(3) The licensee must ensure that the assessment mentioned in paragraph (2) includes —

(*a*) the taking of a comprehensive medical and surgical history (including previous use of anaesthetics) of the patient;

(*b*) physical examination of the patient; and

(*c*) the conduct of relevant tests and investigations.

(4) The licensee must keep proper and accurate records of the assessment mentioned in paragraph (2).

**Safe provision of specified anaesthetics**

**21.** A licensee must ensure that —

(*a*) any specified anaesthetic that is administered to a patient is administered in a proper, effective and safe manner;

(*b*) the patient or the patient's caregiver is informed of all relevant pre-procedure care instructions before the specified anaesthetic is administered; and

(*c*) appropriate post-procedure care instructions are given to the patient or the patient's caregiver, including the patient's care needs and the signs and symptoms of possible adverse reactions that the patient may experience after the administration of any type of anaesthetic.

**Post-procedure care**

**22.**—(1) A licensee must ensure that each patient who is administered any anaesthetic is monitored and given appropriate

post-procedure care for recovery and management of adverse effects from the administration of anaesthetics.

(2) Without limiting paragraph (1), the licensee must, in relation to each patient, ensure that during the post-procedure observation period —

(*a*) one or more of the licensee's personnel observe and monitor the patient at intervals and for the length of time appropriate to the anaesthetic administered and the assisted reproduction procedure performed;

(*b*) timely and appropriate post-procedure treatment is given to the patient where necessary;

(*c*) one or more of the licensee's personnel assist the patient with toileting needs where necessary; and

(*d*) adequate nutrition and hydration are given to or made available to the patient.

**Recovery and observation area**

**23.** A licensee must ensure that —

(*a*) there are adequate and proper facilities to accommodate patients in every approved permanent premises after they have undergone any assisted reproduction procedure involving the administration of anaesthetics;

(*b*) the patients mentioned in paragraph (*a*) are observed and monitored by the licensee's personnel;

(*c*) there is adequate space for the movement of personnel for the monitoring of patients and treatment of complications; and

(*d*) the area in which the patients are accommodated has —

(i) adequate furniture for patients to sit or lie down;

(ii) monitoring equipment; and

(iii) a resuscitation trolley.

**Discharge of patients**

**24.**—(1) A licensee must ensure that a patient who has been administered any anaesthetic is discharged only after she has been assessed by a qualified assisted reproduction practitioner who is the licensee's personnel to be fit for discharge.

(2) Without limiting paragraph (1), the licensee must ensure that —

(*a*) the attending qualified assisted reproduction practitioner (who is the licensee's personnel) for a patient assesses whether the patient is fit for discharge;

(*b*) where the attending qualified assisted reproduction practitioner for a patient is not available to assess whether the patient is fit for discharge, another qualified assisted reproduction practitioner (who is the licensee's personnel) assesses the patient for that purpose instead;

(*c*) a patient is discharged from the licensee's care in accordance with the licensee's policy on when a patient can be discharged after anaesthesia or sedation; and

(*d*) a patient is not asked to leave the approved permanent premises before the patient is assessed to be fit for discharge.

## PART 6

## REQUIREMENTS RELATING TO CONSENT

**Written consent required for any procedure on patient**

**25.**—(1) A licensee must, before performing any assisted reproduction procedure on a patient, obtain written consent for the assisted reproduction procedure, in accordance with this regulation, from —

(*a*) the patient; and

(*b*) for an assisted reproduction procedure other than elective oocyte storage — the patient's husband.

(2) The licensee must, before obtaining the consent mentioned in paragraph (1), provide the following information to the patient and, if applicable, her husband:

(*a*) the applicable examination and treatment procedures required before or after the assisted reproduction procedure is performed;

(*b*) the estimated success rates, possible consequences and side effects of the assisted reproduction procedure;

(*c*) where the assisted reproduction procedure is the transfer of embryos — the number of embryos that will be transferred;

(*d*) whether and when any stored oocyte or embryo will be disposed of or donated;

(*e*) any additional information or increased risks (including risks to the child conceived through the assisted reproduction procedure) that is relevant based on the age of the patient, or the number of stimulated cycles the patient has already undergone.

(3) The licensee must not perform an assisted reproduction procedure on a patient if the patient has not given written consent for the assisted reproduction procedure within 3 months before the assisted reproduction procedure is performed.

(4) Where a licensee obtains written consent from a patient or the patient's husband for an assisted reproduction procedure, the licensee must keep records of the information explained and obtain a written acknowledgment from the patient or the patient's husband (as the case may be) that —

(*a*) the licensee's personnel has explained the information mentioned in paragraph (2); and

(*b*) the patient or the patient's husband (as the case may be) understands that information.

(5) Where the patient —

(*a*) is 45 years of age or older on the day of the assisted reproduction procedure; or

(*b*) intends to undergo elective oocyte storage and is not a patient mentioned in regulation 31(2)(*a*)(i), (ii) or (iii),

the licensee must not perform the assisted reproduction procedure unless the licensee has given the patient the information mentioned in paragraph (2) at least 7 calendar days before the day the patient or the patient's husband (as the case may be) gives written consent for the assisted reproduction procedure.

**Instructions regarding stored oocytes or embryos**

**26.**—(1) A licensee must not store any reproductive cell or embryo unless the relevant individual has given instructions on all of the following:

(*a*) in the case of the storage of an embryo — the disposal or donation of the embryo in the event the relevant individuals cease to be married, whether by death or divorce;

(*b*) where consent was obtained for the storage of the reproductive cell or embryo for a period and any relevant individual is uncontactable at the expiry of that period or any part of the payment for the storage of the reproductive cell or embryo is overdue — the disposal or donation of the reproductive cell or embryo in either event;

(*c*) where any relevant individual becomes incapable of giving consent for the transfer of the reproductive cell or embryo — the disposal or donation of the reproductive cell or embryo in that event.

(2) A licensee must document the instructions mentioned in paragraph (1).

(3) In this regulation, "relevant individual" means —

(*a*) in relation to a reproductive cell — the person from whom the reproductive cell is collected; and

(*b*) in relation to an embryo — the patient and the patient's husband.

**Written consent required from donors**

**27.**—(1) A licensee must, before collecting or transferring any reproductive cell or transferring an embryo, obtain written consent for the collection or transfer, in accordance with this regulation, from —

(*a*) the donor of the reproductive cell; or

(*b*) the donors of the embryo.

(2) Paragraph (1) does not apply where the donor or donors of the reproductive cell or embryo had given instructions for the donation of the reproductive cell or embryo in any of the events mentioned in regulation 26(1)(*a*), (*b*) or (*c*).

(3) To avoid doubt, paragraph (1) applies in relation to the transfer of a reproductive cell or an embryo —

(*a*) to another person, including another licensee; or

(*b*) into the body of an individual.

(4) The licensee must, at least 7 calendar days before obtaining the consent mentioned in paragraph (1), provide the following information to the donor or donors:

(*a*) each purpose for which the reproductive cell or embryo is to be used and any tests necessary to assess the suitability of the reproductive cell or embryo for the purpose;

(*b*) that the donor or donors will not be informed of any incidental finding unless the donor requests or donors request to be so informed;

(*c*) where the collection of the reproductive cell involves the licensee carrying out a procedure on the donor for the collection of oocytes —

(i) the applicable examination and treatment procedures required before or after the procedure is performed; and

(ii) the possible consequences and side effects of the procedure.

(5) Where a licensee knows or has reason to believe that the donor or donors (as the case may be) of any reproductive cell or embryo has or have specified a recipient for the reproductive cell or embryo and the licensee does not intend to use the reproductive cell or embryo for the recipient, the licensee must not receive the reproductive cell or embryo from another licensee or a person outside Singapore unless the licensee has obtained written consent from the donor or donors (as the case may be) of the reproductive cell or embryo for —

(*a*) the transfer of the reproductive cell or embryo to the licensee; and

(*b*) the storage and intended use of the reproductive cell or embryo by the licensee.

(6) In this regulation, "incidental finding", in relation to any examination or test of an individual, means any observation, result or other finding about the individual that is disclosed or discovered by or during the examination or test and has potential health or reproductive importance to the individual, but is not related to the purpose or objective of the examination or test.

**Additional requirements where donor reproductive cells or embryos used**

**28.**—(1) Before a licensee transfers any donor embryo into the body of a patient, or uses a donor reproductive cell for the purposes of creating an embryo that is intended to be transferred into the body of the patient, the licensee must inform the patient and the patient's husband of the prohibition under section 13 of the Human Cloning and Other Prohibited Practices Act 2004.

(2) Before a licensee transfers any reproductive cell or embryo from a person outside Singapore to be used for a patient, the licensee must inform the patient and the patient's husband on the risks of using a reproductive cell or an embryo from a person outside Singapore.

**Other requirements relating to obtaining consent**

**29.** A licensee must ensure that in relation to any written consent required in this Part —

(*a*) the written consent is signed by the person giving the consent;

(*b*) the signing of the written consent mentioned in paragraph (*a*) is witnessed by a person other than the person's spouse; and

(*c*) the consent is not obtained by means of harassment, coercion, intimidation, deception, misrepresentation, reward or remuneration by any officer, employee or agent of the licensee.

**Withdrawal of consent**

**30.**—(1) A licensee must not use any reproductive cell or embryo for a purpose if —

(*a*) at any time before the reproductive cell or embryo is used, a person withdraws consent in relation to the storage or use of any reproductive cell or embryo collected by, transferred to or stored by a licensee for that purpose; and

(*b*) the person informs the licensee of the withdrawal.

(2) Paragraph (1) does not apply where —

(*a*) the reproductive cell or embryo, in accordance with the consent of the donor or donors of the reproductive cell or embryo, has been stored anonymously; or

(*b*) the reproductive cell or embryo is no longer under the custody of the licensee.

(3) In this regulation, "use", in relation to any reproductive cell or embryo, means —

(*a*) to transfer the reproductive cell or embryo into the body of a woman; or

(*b*) to donate for research.

## PART 7

## REQUIREMENTS RELATING TO PROVISION OF SERVICE

*Division 1 — Provision of service to patients*

### When assisted reproduction service may be provided

**31.**—(1) A licensee must not perform any assisted reproduction procedure on a patient unless —

(*a*) a qualified assisted reproduction practitioner who is the licensee's personnel is of the view that the assisted reproduction procedure may be carried out safely on the patient; and

(*b*) any condition in paragraph (2) applies.

(2) The conditions mentioned in paragraph (1)(*b*) are the following:

(*a*) where the assisted reproduction procedure is elective oocyte storage — the patient —

(i) has any medical condition that significantly, permanently and adversely affects the patient's fertility;

(ii) is undergoing any medical treatment that will significantly, permanently and adversely affect the patient's fertility;

(iii) is a patient in respect of whom there is otherwise a medical indication for the storage of the oocyte, and is undergoing an assisted reproduction procedure (other than elective oocyte storage) for that medical indication; or

(iv) is at least 21 years of age but below 37 years of age;

(*b*) where the assisted reproduction procedure is not elective oocyte storage — the patient —

(i) is above 35 years of age; or

(ii) is 35 years of age or younger and there are medical indications for the performance of the assisted reproduction procedure on the patient.

(3) A licensee must not provide a restricted procedure to a patient unless —

(*a*) the patient is legally married to a man; and

(*b*) the patient's husband consents to the restricted procedure.

**Assessment of patients above 45 years of age**

**32.** A licensee must establish and implement processes to ensure that —

(*a*) a qualified assisted reproduction practitioner who is the licensee's personnel assesses the fitness of each patient to carry a pregnancy, deliver and care for the child if the patient is or likely to be above 45 years of age at the start of the pregnancy; and

(*b*) appropriate clinical management and medical advice is given to a patient mentioned in paragraph (*a*) in the provision of the assisted reproduction service.

**Preventing ovarian hyperstimulation syndrome**

**33.**—(1) A licensee must establish and implement policies and procedures to minimise the incidence of the development of ovarian hyperstimulation syndrome in any woman in the provision of the assisted reproduction service.

(2) Without limiting paragraph (1), the policies and procedures mentioned in that paragraph must —

(*a*) identify and manage patients at risk of or experiencing ovarian hyperstimulation syndrome;

(*b*) monitor the incidence of ovarian hyperstimulation syndrome; and

(*c*) document the efforts taken to minimise the incidence of ovarian hyperstimulation syndrome.

**Transfer of multiple embryos**

**34.**—(1) Subject to paragraph (2), a licensee must not transfer more than 2 embryos into a patient's body in a single assisted reproduction cycle.

(2) Despite paragraph (1), a licensee may transfer no more than 3 embryos, each of which is not past the cleavage stage, into a patient's body in a single assisted reproduction cycle if the patient —

(*a*) is 37 years of age or older; and

(*b*) has undergone one or more stimulated cycles in which no oocytes were collected, or from which no oocyte collected resulted in a blastocyst.

(3) A licensee must, before transferring 2 or more embryos into a patient's body, inform the patient and the patient's husband that delivery for a multiple pregnancy is recommended to be carried out by an acute hospital licensee with the appropriate neonatal intensive care facilities for extremely premature infants.

**No combination of certain assisted reproduction procedures**

**35.** A licensee must not transfer any embryo into the body of a patient in the same assisted reproduction cycle that a gamete intrafallopian transfer was carried out for the same patient.

**Prohibited practices**

**36.** A licensee must not —

(*a*) transfer an embryo into the body of a woman who intends to give the child up for adoption;

(*b*) engage in any practice or carry out any procedure, including sperm sorting techniques, for the purpose of selecting or creating an embryo for transfer on the basis of the sex of the embryo, except where a qualified assisted reproduction practitioner assesses that there is a clinical need to do so; or

(*c*) perform mitochondrial replacement therapy.

*Division 2 — Donors*

**When donor reproductive cells or embryos may be used**

**37.**—(1) A licensee must not transfer into the body of a patient any embryo that —

(*a*) was not created from an oocyte collected from the patient, unless the patient is unable to produce any viable oocytes for collection, or has had one or more unsuccessful attempts at the collection of viable oocytes;

(*b*) was not created from sperm collected from the patient's husband, unless the patient's husband is unable to produce viable sperm for fertilisation of an oocyte; or

(*c*) is a consanguineous embryo.

(2) Where a donor reproductive cell or donor embryo is used in the provision of an assisted reproduction service by a licensee to a patient, the licensee must ensure the following:

(*a*) there is a clear set of criteria for the selection and acceptance of donors, which is documented;

(*b*) donor sperm is accepted only from a man who is at least 21 years of age but below 41 years of age;

(*c*) a donor oocyte is accepted only from a woman who is at least 21 years of age but below 38 years of age;

(*d*) a donor embryo is accepted only where the embryo is created from an oocyte from a woman mentioned in sub-paragraph (*c*).

(3) In this regulation —

"consanguineous embryo" means an embryo created from —

(*a*) an oocyte from a woman and sperm collected from a man who is the woman's biological grandfather, father, uncle, brother, half-brother, son, nephew or grandson; or

(*b*) sperm collected from a man and an oocyte collected from a woman who is the man's biological

grandmother, mother, aunt, sister, half-sister, daughter, niece or granddaughter;

"donor embryo", in relation to a patient, means an embryo created from reproductive cells that do not belong to either the patient or the patient's husband.

**Restriction on the use of certain embryos**

**38.**—(1) A licensee must, before carrying out any procedure that will result in the fertilisation of an intergenerational embryo —

(*a*) obtain approval for the procedure from a clinical ethics committee appointed by a section 25 licensee; and

(*b*) obtain signed written consent for the procedure and the intended use of the intergenerational embryo from each person from whom the reproductive cells for the fertilisation of the intergenerational embryo were collected.

(2) Except with the Clinical Governance Officer's written approval, a licensee must not transfer into the body of a patient any embryo that is created from a reproductive cell collected from a donor whose donated reproductive cells had previously resulted in at least 5 live birth events.

(3) The Clinical Governance Officer must not approve the transfer of an embryo mentioned in paragraph (2) to a patient unless —

(*a*) another embryo created from reproductive cells collected from the donor had previously been transferred to the patient, and resulted in a live birth event; and

(*b*) the patient has requested the transfer.

(4) In this regulation, "intergenerational embryo" means an embryo created from —

(*a*) an oocyte from a woman and sperm collected from the biological father of the woman's husband; or

(*b*) sperm collected from a man and an oocyte collected from the biological mother of the man's wife.

**Evaluation of donors**

**39.**—(1) A licensee must establish and implement a system to evaluate the medical fitness and suitability of every donor of a reproductive cell or an embryo before the reproductive cell or embryo is accepted for use in the provision of the assisted reproduction service.

(2) Without limiting paragraph (1), the system mentioned in that paragraph must include the following:

(*a*) the conduct of a clinical evaluation and the review of the medical history of the donor, carried out by a qualified assisted reproduction practitioner;

(*b*) the signing of a written declaration by each donor, to the best of the donor's knowledge, of the following matters:

(i) information relating to the donor's medical history;

(ii) whether the donor has engaged in behaviour that exposes the donor to a high risk of contracting or developing communicable diseases, including drug use and unprotected sex with multiple partners.

**Confidentiality of donor's identity**

**40.** A licensee must not disclose to any person the identity of a donor of a reproductive cell or an embryo, except —

(*a*) as required by or under any written law;

(*b*) as authorised or required by an order of court; or

(*c*) with the consent of the donor or the donor's legal representative.

**Directed donations**

**41.** Where a donor donates any reproductive cell or embryo to a specified person, the licensee must not —

(*a*) use the reproductive cell or embryo for a purpose other than for the provision of an assisted reproduction service to the specified person unless the donor has given written

consent for the use of the reproductive cell or embryo for that other purpose; and

(*b*) use the reproductive cell or embryo for the provision of an assisted reproduction service to the specified person unless the donor has consented to disclose the donor's identity to the specified person.

*Division 3 — Storage and disposal requirements*

**Storage and disposal in accordance with terms of consent**

**42.**—(1) A licensee must ensure that the storage, distribution for transfer, donation or disposal of any reproductive cell or embryo is carried out in accordance with the terms of the written consent given by all relevant donors.

(2) Where, in relation to a reproductive cell or an embryo in the custody of a licensee, the licensee is for any reason unable to obtain instructions from all relevant donors on the storage, distribution for transfer, donation or disposal of the reproductive cell or embryo, the licensee must —

(*a*) obtain guidance from a clinical ethics committee appointed by a section 25 licensee on how the reproductive cell or embryo should be handled; and

(*b*) inform the Director-General of every action or measure taken by the licensee in relation to the reproductive cell or embryo.

(3) Where all relevant donors have consented to the storage of the reproductive cell or embryo for a specified period, the licensee must request each relevant donor to confirm the continued storage of the reproductive cell or embryo before the expiry of the specified period.

(4) In this regulation, "relevant donor" means —

(*a*) in relation to a reproductive cell — the person from whom the reproductive cell is collected; and

(*b*) in relation to an embryo — each person from whose reproductive cells the embryo is created.

**Reproductive cells and embryos that may be stored**

**43.** A licensee must not store any reproductive cell or embryo except the following:

(*a*) any reproductive cell (except an oocyte) or embryo for the purpose of providing an assisted reproductive service to a patient;

(*b*) any sperm or human tissue containing any human gamete or germ cells at any stage of maturity for the purpose of preventing infertility, where the individual from whom the sperm or human tissue is collected —

(i) has any medical condition that significantly, permanently and adversely affects the individual's fertility; or

(ii) is undergoing any medical treatment that will significantly, permanently and adversely affect the individual's fertility;

(*c*) an oocyte collected from a patient —

(i) to whom the licensee intends to provide a restricted procedure; and

(ii) who has, together with the patient's husband, given signed written consent for the restricted procedure,

if the licensee is unable to, for any reason, provide the restricted procedure in the same assisted reproduction cycle that the oocyte is collected;

(*d*) any oocyte collected from a patient mentioned in regulation 31(2)(*a*).

**Storage of reproductive cells and embryos**

**44.**—(1) A licensee must store each reproductive cell and embryo in the licensee's custody in a manner that ensures that —

(*a*) the biological and functional properties of each reproductive cell and embryo are preserved; and

(*b*) the risk of contamination of each reproductive cell and embryo is minimised.

(2) Without limiting paragraph (1), the licensee must —

(*a*) ensure that each reproductive cell and embryo is stored in a validated device that is appropriate for the reproductive cell or embryo and the intended use of the reproductive cell or embryo;

(*b*) ensure that each reproductive cell and embryo is appropriately packaged and stored;

(*c*) maintain an inventory system for each reproductive cell and embryo in the licensee's custody (including those under quarantine);

(*d*) ensure that an inventory check is performed at least once every 2 years, where the purpose and duration of storage for every reproductive cell and embryo is reviewed to ensure compliance with these Regulations;

(*e*) implement an appropriate labelling system to ensure that each reproductive cell and embryo is correctly identified and traceable from the time of its collection until the time it is distributed;

(*f*) ensure that each reproductive cell and embryo that has been tested and processed is stored at an appropriate temperature;

(*g*) ensure that the storage requirements (including storage conditions) for each reproductive cell and embryo are appropriate, having regard to —

(i) the type of reproductive cell and stage of embryo concerned;

(ii) the packaging and processing requirements for the reproductive cell and embryo; and

(iii) the intended use of the reproductive cell or embryo;

(*h*) for any reproductive cell or embryo which is determined to be unsuitable for clinical use — ensure that the container or

tank in which the reproductive cell or embryo is stored is clearly labelled with all of the following:

(i) that the reproductive cell or embryo is unsuitable for clinical use;

(ii) the purpose for which the reproductive cell or embryo may be distributed;

(*i*) ensure any reproductive cell or embryo that is under quarantine must be clearly labelled and segregated from any reproductive cell or embryo intended for distribution; and

(*j*) ensure that a reproductive cell or an embryo that is to be used for a purpose is not stored together with another reproductive cell or embryo that is not to be used for the same purpose.

*Division 4 — General requirements*

**Verification of identity when semen or seminal fluid submitted**

**45.** A licensee must establish and implement processes in relation to the submission of any semen or seminal fluid to the licensee for any purpose related to the provision of the assisted reproduction service that include the following:

(*a*) requiring a person (whether a patient's husband or a donor) to submit his semen or seminal fluid in person at any of the licensee's approved permanent premises;

(*b*) verification and counterchecking of the person's identity by the licensee's personnel, with reference to any photo identification document;

(*c*) the signing of a written declaration by the person that the semen or seminal fluid submitted belongs to the person;

(*d*) the keeping of a record of the date and time that the person submitted his semen or seminal fluid at the licensee's approved permanent premises.

**Counterchecking procedures**

**46.**—(1) A licensee must establish and implement processes to prevent the use of the wrong specimens in any laboratory or clinical procedure.

(2) Without limiting paragraph (1), a licensee must ensure the following:

(*a*) the implementation of a protocol where 2 personnel check that the specimen relating to the correct patient has been collected for use in the laboratory or clinical procedure;

(*b*) the assignment of personnel who has the appropriate training or competencies for the protocol mentioned in sub-paragraph (*a*);

(*c*) documentation of the personnel who performed each check mentioned in sub-paragraph (*a*).

**Tests for specified pathogens**

**47.**—(1) Subject to paragraph (2), a licensee must ensure that, before collecting or receiving any reproductive cell from a patient, patient's husband or donor (called in this regulation the relevant person) or storing any reproductive cell collected from a relevant person, the relevant person has been tested for each specified pathogen within 6 months before the collection of the reproductive cell.

(2) A licensee must ensure that a donor of a reproductive cell is tested for the Human Immunodeficiency Virus —

(*a*) immediately before the licensee collects the reproductive cell from the donor; and

(*b*) after a period of at least 3 months after the collection of the reproductive cell.

(3) Where a relevant person tests positive for a specified pathogen, the licensee must do the following:

(*a*) inform the following persons of the positive test:

(i) the proposed recipient of a reproductive cell collected from the relevant person and the proposed recipient's husband;

(ii) the proposed recipient of an embryo that is created from a reproductive cell collected from the relevant person and the proposed recipient's husband;

(*b*) explain to the persons mentioned in sub-paragraph (*a*)(i) or (ii) (as the case may be) the risk of either of the persons or the child contracting an infectious disease caused by the specified pathogen or developing any related condition;

(*c*) obtain from each of the persons mentioned in sub-paragraph (*a*)(i) or (ii), as the case may be —

(i) a signed written declaration that the licensee has explained, and the person is aware of, the risk mentioned in sub-paragraph (*b*); and

(ii) a signed written consent for the transfer of the reproductive cell or embryo.

(4) Where a relevant person tests positive for a specified pathogen, a licensee must ensure that any reproductive cell collected from the relevant person or embryo created from a reproductive cell collected from the relevant person is stored in a manner that minimises the risk of cross-contamination with reproductive cells or embryos from persons who have tested negative for the specified pathogen.

(5) Where a patient intends to use a reproductive cell collected from a donor at any time before the donor is tested for the Human Immunodeficiency Virus under paragraph (2)(*b*), then the donor is deemed to have tested positive for the Human Immunodeficiency Virus for the purposes of paragraphs (3) and (4).

(6) In this regulation, "specified pathogen" means any of the following viruses or bacteria:

(*a*) Human Immunodeficiency Virus;

(*b*) hepatitis B;

(*c*) hepatitis C;

(*d*) syphilis virus.

**Conduct of ultrasound imaging**

**48.**—(1) A licensee must not conduct any ultrasound imaging on a patient unless a qualified assisted reproduction practitioner orders the ultrasound imaging for the patient.

(2) A licensee must ensure that any ultrasound imaging conducted on a patient is conducted —

(*a*) only as a service incidental to the provision of an assisted reproduction service; and

(*b*) by or under the supervision of the licensee's personnel who is —

(i) a medical practitioner;

(ii) a radiographer who is a duly qualified allied health professional; or

(iii) a sonographer.

**Testing of specimen**

**49.**—(1) A licensee may test any specimen for a patient if —

(*a*) a medical practitioner who is the licensee's personnel orders the test for the patient;

(*b*) the testing of the specimen only involves the conduct of a simple in vitro diagnostic test; and

(*c*) the testing of the specimen is provided only as a service incidental to the provision of an assisted reproduction service.

(2) A licensee who is approved to provide an assisted reproduction service by remote provision must not, in the course of providing the service by that service delivery mode, direct a person to conduct a self-administered test on himself or herself if the testing material for the self-administered test is a "professional use only" medical device

within the meaning given by regulation 2 of the Health Products (Medical Devices) Regulations 2010 (G.N. No. S 436/2010).

**Conduct of simple in vitro diagnostic test**

**50.**—(1) A licensee must ensure that any simple in vitro diagnostic test on a specimen or patient must be conducted —

(*a*) using testing material, where —

(i) the expiry date of the testing material has not passed; and

(ii) the personnel who is administering the test does not suspect or have any reason to suspect that the testing material is no longer fit for use; and

(*b*) in accordance with the instructions specified by the manufacturer of the testing material.

(2) A licensee must ensure that any testing material that may be used to conduct any simple in vitro diagnostic testing is stored under the conditions, and handled in the manner, specified by the manufacturer of the testing material so as to lower the risk of unnecessary exposure of the testing material to the environment and early deterioration of the testing material.

(3) In paragraph (1), "expiry date" has the meaning given by regulation 2 of the General Regulations.

**Instructions for self-collection of specimens**

**51.** Where any specimen is to be collected from a person by the person himself or herself, for the purpose of conducting any test on it (whether or not the test is to be self-administered by the person), a licensee must provide the person with —

(*a*) instructions on how and when the specimen is to be collected; and

(*b*) the precautions that are to be taken to avoid contamination and degradation of the specimen.

**Provision of life-saving measures**

**52.**—(1) Without affecting Part 5, a licensee must —

(*a*) ensure that adequate and appropriate facilities, equipment and drugs for the provision of any essential life-saving measure to a patient are readily available at each approved permanent premises; and

(*b*) at all times, be capable of providing any essential life-saving measure to any patient who is at risk of death.

(2) Without limiting paragraph (1), a licensee must ensure the following:

(*a*) resuscitation equipment and drugs are effective, functional and readily available for use at any time in the approved permanent premises;

(*b*) every personnel who provides any essential life-saving measure to a patient is adequately trained —

(i) to provide the essential life-saving measure in a proper, effective and safe manner; and

(ii) in the use of the equipment that is needed to deliver the essential life-saving measure;

(*c*) there is a comprehensive and detailed response plan to resuscitate, treat and transfer unstable patients;

(*d*) the licensee's personnel promptly assesses a patient who shows any sign of being unwell at any time after an assisted reproduction procedure and delivers the necessary treatment to stabilise the patient;

(*e*) any patient who remains unwell despite the delivery of treatment to stabilise the patient is transferred to the care of an acute hospital service licensee who is equipped to deliver the appropriate treatment to the patient;

(*f*) any patient who requires conveyance by an emergency ambulance is conveyed by an emergency ambulance operated by an emergency ambulance service licensee.

**Transfer of reproductive cells and embryos to and from other licensees, etc.**

**53.**—(1) A licensee must not transfer any reproductive cell or embryo to or receive any reproductive cell or embryo from another person unless the person is —

(*a*) another licensee; or

(*b*) a person in a foreign jurisdiction that is licensed, registered, approved or otherwise allowed to provide an assisted reproduction service or to carry on the activities of a reproductive cell or embryo bank under the laws of the foreign jurisdiction.

(2) A licensee must not transfer a reproductive cell or an embryo to a person mentioned in paragraph (1)(*a*) or (*b*) unless the licensee has obtained written consent for the transfer from the person from whom the reproductive cell was collected, or the person from whose reproductive cell the embryo is created, as the case may be.

(3) A licensee must not receive a reproductive cell or an embryo from a person mentioned in paragraph (1)(*b*) unless the licensee is satisfied that the person is able to comply with regulation 54.

(4) In this regulation, "transfer", in relation to a reproductive cell or an embryo, does not include the transfer of the reproductive cell or embryo —

(*a*) into the body of an individual; or

(*b*) to a person conducting research on the reproductive cell or embryo.

**Requirements relating to transfer of reproductive cells and embryos**

**54.**—(1) A licensee must ensure that the transfer of any reproductive cell or embryo to or from the licensee is carried out in a manner that —

(*a*) preserves the biological and functional properties of the reproductive cell or embryo; and

(*b*) minimises the risk of contamination of the reproductive cell or embryo.

(2) Without limiting paragraph (1), a licensee must —

(*a*) ensure that the reproductive cell or embryo is at all times during the transfer packaged and transported in a validated device that is appropriate for the reproductive cell or embryo and the intended use of the reproductive cell or embryo;

(*b*) implement and maintain a system to prevent or control the spread of any communicable disease due to the contamination or infection of any reproductive cell or embryo in the licensee's custody, including the traceability of all equipment and materials used in the processing of the reproductive cell or embryo;

(*c*) ensure that the reproductive cell or embryo is transported and transferred in appropriate environmental conditions;

(*d*) ensure that an instruction sheet accompanies each transfer from the licensee of any reproductive cell or embryo stating all of the following information:

(i) the results of all tests performed on the person from whom the reproductive cell is collected or from whose reproductive cell the embryo is created;

(ii) the appropriate storage condition for the reproductive cell or embryo prior to its clinical use;

(iii) any special requirement or measure that the medical practitioner using the reproductive cell or embryo must take to ensure the safe and effective use of the reproductive cell or embryo;

(iv) the measures that must be taken if there is any evidence of damage to or mislabelling of the reproductive cell or embryo or its packaging; and

(*e*) in relation to each transfer from the licensee of any reproductive cell or embryo, ensure that the movement of the reproductive cell or embryo is tracked in a document,

and that every person who receives the reproductive cell or embryo signs the document upon receipt.

**Requirements for remote provision**

**55.**—(1) This regulation applies to a licensee who is approved to provide an assisted reproduction service by remote provision.

(2) The licensee must not provide an assisted reproduction service by remote provision unless it is for either of the following:

(*a*) the provision of clinical care incidental to the services mentioned in paragraph (*a*), (*b*), (*c*) or (*d*) of the definition of "assisted reproduction service" in paragraph 2 of the First Schedule to the Act;

(*b*) the administration of donor questionnaires in relation to donor screening.

(3) For the purposes of paragraph (2)(*a*), before the licensee provides an assisted reproduction service to a patient by remote provision, the licensee must ensure that —

(*a*) the licensee's personnel who is a healthcare professional first conducts a clinical assessment of the patient in person at any of the licensee's approved permanent premises to determine the suitability of the patient to be provided the assisted reproduction service by remote provision; and

(*b*) the assisted reproduction service can be provided by remote provision safely.

(4) For the purposes of paragraph (2)(*b*), before the licensee provides an assisted reproduction service to a patient by remote provision, the licensee must ensure that the assisted reproduction service can be so provided in a manner that ensures the confidentiality and security of any information relating to donor screening.

PART 8

EMBRYOLOGY LABORATORY

**Requirements relating to embryology laboratory**

**56.**—(1) A licensee must ensure that all of the following requirements are satisfied in relation to the embryology laboratory in each approved permanent premises:

(*a*) work in a wet laboratory is not performed in a manner that may adversely affect the handling, manipulation or quality of reproductive cells and embryos;

(*b*) every work area where procedures involving the manipulation of reproductive cells or embryos are performed has a controlled environment to ensure the quality and safety of the assisted reproduction procedures;

(*c*) entry to the embryology laboratory is restricted to persons authorised by the Clinical Governance Officer, to prevent tampering with any reproductive cell or embryo stored in the embryology laboratory;

(*d*) the embryology laboratory is situated at a location that has low human traffic, and with convenient access to the room in which the assisted reproduction procedures are performed;

(*e*) the maintenance manual for each laboratory equipment used in the embryology laboratory may be accessed by each personnel authorised to work in the embryology laboratory;

(*f*) every procedure in the embryology laboratory is carried out using such equipment or facility that is —

(i) designed for the purpose that it is used for; and

(ii) checked and maintained to ensure that the equipment or facility is in good working order at all times.

(2) A licensee must keep a record of all checks and maintenance work mentioned in paragraph (1)(*f*)(ii).

**Requirements relating to laboratory processes**

**57.**—(1) A licensee must —

(*a*) establish policies and processes for the processing, testing and quarantine of any reproductive cell or embryo in the licensee's custody in order to prevent the mix-up of reproductive cells and embryos, and ensure the safety, quality and viability of the reproductive cell or embryo for clinical use; and

(*b*) take measures to ensure that the policies and processes mentioned in sub-paragraph (*a*) are implemented.

(2) Without limiting paragraph (1), the licensee must do the following:

(*a*) ensure that the environment within which reproductive cells or embryos is processed, tested and quarantined is appropriate to ensure the safety, quality and viability of the reproductive cells and embryos, and the safety of the licensee's personnel handling the reproductive cells and embryos;

(*b*) ensure that —

(i) each reproductive cell is collected or cryopreserved; and

(ii) each embryo is cryopreserved,

within the appropriate time period for the reproductive cell or embryo to retain the biological functions compatible with the intended use of the reproductive cell or embryo;

(*c*) a reproductive cell collected from, or an embryo created using a reproductive cell collected from, an individual is not mixed with or placed together in the same straw, vitrification device or cryo vial as a reproductive cell collected from, or an embryo created using a reproductive cell collected from, another individual;

(*d*) take all reasonable steps to minimise the risk of contamination of each reproductive cell and embryo in the licensee's custody;

(*e*) use validated methods and appropriate protocols for the processing (including cryopreservation) and testing of each reproductive cell and embryo to maintain the safety, quality and viability of the reproductive cell and embryo and retain the clinical properties of the reproductive cell and embryo that are consistent with the intended use of the reproductive cell or embryo, as the case may be;

(*f*) maintain the traceability of all materials and equipment by keeping records of each material or equipment used to process each reproductive cell and embryo such that the specific material or equipment used to process the reproductive cell or embryo is known;

(*g*) ensure that every specimen is labelled with the full name of the patient to whom the specimen relates;

(*h*) implement a labelling system in the embryology laboratory to ensure identification and traceability of reproductive cells and embryos from their collection to storage, transfer, freezing, thawing and distribution or disposal;

(*i*) ensure that aseptic techniques are used for any laboratory procedure involving the handling of any reproductive cell or embryo;

(*j*) ensure that none of the following are used in the embryology laboratory:

(i) toxic chemicals or radioisotopes, including in cleaning materials;

(ii) aerosol or pest control substances;

(*k*) implement measures to minimise interruptions and distractions within the embryology laboratory when any laboratory procedure is being carried out;

(*l*) ensure each processing cabinet or workstation is, at any time, used only to process —

(i) except where sub-paragraph (ii) applies — reproductive cells collected from one person;

(ii) oocytes collected from one woman and sperm collected from one man, for the purpose of performing IVF or ICSI; or

(iii) embryos created using oocytes collected from one woman and sperm collected from one man.

(3) A licensee must ensure that —

(*a*) each procedure undertaken in the embryology laboratory for the provision of the assisted reproduction service is documented;

(*b*) each document mentioned in sub-paragraph (*a*) is available in the embryology laboratory; and

(*c*) the maintenance manual for each piece of laboratory equipment in the embryology laboratory is available in the embryology laboratory.

**Safety programme**

**58.**—(1) A licensee must develop and ensure the implementation of a safety programme for the embryology laboratory at each approved permanent premises setting out appropriate and effective safety measures to prevent the occurrence of any adverse incident and reduce any hazard at the embryology laboratory.

(2) Without limiting paragraph (1), a safety programme must contain appropriate and effective measures for —

(*a*) electrical safety and safety of water supply and outlets;

(*b*) the handling and disposal of sharp apparatus and objects that can readily puncture or cut human skin when encountered;

(*c*) the safety of all personnel and patients during the conduct of any test, examination or procedure;

(*d*) waste management;

(*e*) spills management;

(*f*) ensuring that there is adequate space, ventilation and lighting for every personnel to perform work safely;

(*g*) ensuring that all safety or emergency equipment is kept in good working order and there is an adequate stock of materials required for the handling of any medical emergency or adverse incident; and

(*h*) ensuring the cleanliness of the licensed premises or licensed conveyance.

(3) A licensee must keep up-to-date documentation of the policies and processes of the safety programme mentioned in paragraph (1) and make the documentation available to every personnel.

## PART 9

## MISCELLANEOUS

### Tests on persons must be conducted by licensed persons or accredited laboratories

**59.** Where a licensee requires a person to undergo any test (other than a simple in vitro diagnostic test) in the course of the licensee's provision of the assisted reproduction service, the licensee must —

(*a*) ensure that the test is conducted by —

(i) a person who holds a licence under the Act authorising the person to provide a clinical laboratory service; or

(ii) a person who operates a clinical laboratory outside Singapore that is accredited by an accreditation body approved by the Director-General; and

(*b*) retain a copy of any clinical laboratory report issued by the person mentioned in paragraph (*a*)(i) or (ii) for the test.

### Register of children conceived using assisted reproduction service

**60.**—(1) A licensee must keep a register of each live birth by a patient in Singapore known to the licensee, of a child resulting from an assisted reproduction service provided by the licensee to the patient.

(2) The register mentioned in paragraph (1) must include the birth certificate number and date of birth of the child.

(3) A licensee must, after a clinical pregnancy is confirmed for a patient, inform the patient that the licensee is required under these Regulations to keep the register mentioned in paragraph (1).

**Notification of incidental findings**

**61.**—(1) A licensee must inform a donor of an incidental finding relating to the donor if —

(*a*) the donor has requested to be informed of any incidental finding pertaining to the donor; and

(*b*) the licensee is aware of the incidental finding.

(2) A licensee must implement the necessary processes to ensure that paragraph (1) is complied with.

**Keeping of records**

**62.**—(1) A licensee must —

(*a*) maintain proper, complete and accurate records of every programme, policy, system, measure, protocol or process that the licensee is required to implement under these Regulations, and every activity undertaken under or change made to that programme, policy, system, measure, protocol or process;

(*b*) maintain records of every approval given by a Clinical Governance Officer under these Regulations; and

(*c*) maintain records of every policy and procedure established by a Clinical Governance Officer under these Regulations.

(2) Without limiting paragraph (1), the licensee must —

(*a*) establish and implement a process to ensure there is proper document control of all documents relating to the assisted reproduction service;

(*b*) ensure that a Clinical Governance Officer approves, signs and dates each record mentioned in paragraph (1)(*a*); and

(*c*) ensure that at least one personnel is responsible for the document control of all documents relating to the assisted reproduction service.

(3) The licensee must ensure that each record mentioned in paragraph (1)(*a*) is available for reference at all times to each personnel.

**Donor records**

**63.**—(1) A licensee must keep and maintain an accurate, complete and up-to-date record of the following information in relation to each donor whose reproductive cell or embryo is used in the licensee's provision of an assisted reproduction service to a patient:

(*a*) the donor's gender;

(*b*) the donor's date of birth;

(*c*) every investigation report and laboratory test result for an investigation or a test required under these Regulations;

(*d*) the number of live birth events that have resulted from the use of the donor's reproductive cells (including when used in the creation of an embryo) —

(i) in the course of the licensee's provision of the assisted reproductive service; and

(ii) by any other person who provides an assisted reproduction service, if the information is known to the licensee;

(*e*) where the donor is known to the patient, or donates reproductive cells directly at any of the licensee's approved permanent premises —

(i) the donor's name; and

(ii) the donor's national registration identification number or passport number;

(*f*) where the licensee receives an anonymous sample from a foreign assisted reproduction service provider or another licensee — the unique identifier assigned to the

anonymous sample by the foreign assisted reproduction service provider or other licensee, as the case may be.

(2) A licensee must take all reasonable steps to ensure the confidentiality and security of the records mentioned in paragraph (1).

(3) In this regulation —

"anonymous sample" means any reproductive cell or embryo in respect of which the identity of the donor of the reproductive cell or the reproductive cells from which the embryo is created, is not known;

"foreign assisted reproduction service provider" means a person in a foreign jurisdiction that is licensed, registered, approved or otherwise allowed to provide an assisted reproduction service or to carry on the activities of a reproductive cell or embryo bank under the laws of the foreign jurisdiction.

**Continuity of operations**

**64.**—(1) A licensee must establish a contingency plan to ensure the following in the event of any disruption to the licensee's operations:

(*a*) the continuity of care for each of the licensee's patients;

(*b*) the preservation of safety and quality of any reproductive cell or embryo in the licensee's custody.

(2) Without limiting paragraph (1), the contingency plan mentioned in that paragraph must include the following matters:

(*a*) contracts or other arrangements for or in relation to the prompt restoration of the licensee's operations or the transfer of the licensee's patients or reproductive cells or embryos in the licensee's custody to another licensee;

(*b*) processes to obtain the written consent of a patient for the proposed transfer of the patient's care to another licensee;

(*c*) processes to obtain the written consent of a patient or donor for the proposed transfer of the patient's or donor's reproductive cells or embryos to another licensee.

**Price transparency**

**65.**—(1) A licensee must, upon request by a patient or any person who intends to receive an assisted reproduction service from the licensee, inform the patient or person (as the case may be) of the applicable charges (including any administrative fee) for the assisted reproduction service.

(2) The licensee may inform a patient of the charges under paragraph (1) in the form of a range of charges.

**Disclosure of approved institution status**

**66.**—(1) A licensee who is an approved institution must display or otherwise make available at every approved permanent premises the fact that the licensee is an approved institution;

(2) A licensee who is not an approved institution must not —

(*a*) represent to any person or give any person the impression that the licensee is an approved institution; or

(*b*) otherwise mislead any person as to whether the licensee is an approved institution.

(3) In this regulation, "approved institution" means any of the following:

(*a*) an approved medical institution within the meaning of regulation 2(1) of the Central Provident Fund (Medisave Account Withdrawals) Regulations (Rg 17);

(*b*) an approved medical institution approved by the Minister under the MediShield Life Scheme Act 2015;

(*c*) an accredited clinic under the scheme established by the Government known as the Community Health Assist Scheme or any other similar public scheme providing financial assistance established by the Government.

**Financial counselling**

**67.**—(1) A licensee must, before providing any care or treatment to, or conducting a procedure on a patient, provide information on the fees charged by the licensee for the care, treatment or procedure, to

the patient or (if the patient is a minor or lacks mental capacity) a next-of-kin or carer of the patient.

(2) For the purposes of paragraph (1), the information on the fees for the care, treatment or procedure must include —

(*a*) the estimated range of the fees for the care, treatment or procedure;

(*b*) the fee benchmark for the same or similar care, treatment or procedure that is published on the website of the Ministry of Health at https://www.moh.gov.sg (if available);

(*c*) whether any part of the fees mentioned in sub-paragraph (*a*) may be —

(i) deducted from any medisave account;

(ii) reimbursed under the MediShield Life Scheme; or

(iii) reduced by any subsidy or grant under a public scheme; and

(*d*) any other benefit that the MediShield Life Scheme provides to the patient in respect of the care, treatment or procedure, if any.

(3) The licensee must, after providing the information mentioned in paragraph (2) to the patient or the next-of-kin or carer of the patient, obtain an acknowledgment from the patient, next-of-kin or carer (as the case may be) and keep the acknowledgment as part of the patient's patient health record.

(4) In this regulation, "medisave account" means a medisave account maintained under section 13 of the Central Provident Fund Act 1953.

**Offences**

**68.**—(1) A person who contravenes regulation 11(1) or (2), 15(*a*) or (*b*), 16(*a*), (*b*), (*c*), (*d*), (*e*), (*f*), (*j*), (*k*) or (*l*), 18(1), (2), (3) or (4), 19, 20(1), (2), (3) or (4), 21, 22(1), 23, 24(1), 25(1), (2), (3), (4) or (5), 27(1), (4) or (5), 29, 30(1), 31(1) or (3), 34(1) or (3), 35, 38(1), 40, 41, 42(1), (2) or (3), 44(1), 46(1), 47(1), (2), (3) or (4), 52(1), 53(1), (2) or

(3), 54(1), 56(1), 57(1), 58(1), 59 or 63(2) shall be guilty of an offence.

(2) A person who is guilty of an offence under paragraph (1) shall be liable on conviction —

(*a*) to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both; and

(*b*) in the case of a continuing offence, to a further fine not exceeding $1,000 for every day or part of a day during which the offence continues after conviction.

## THE SCHEDULE

Regulation 4

### SPECIFIED SERVICES

1. Pre-implantation genetic testing of an embryo to determine whether the embryo has any monogenic defect, single gene defect or chromosomal structural rearrangements, including the performance of embryo biopsy for such testing

Made on 21 June 2023.

CHAN YENG KIT
*Permanent Secretary,*
*Ministry of Health,*
*Singapore.*

[MH 78:44/1; AG/LEGIS/SL/122E/2020/28 Vol. 1]