STANDARDS

Assisted Reproductive Technology

STATUS:	**UNDER REVIEW**
Approved by Council:	September 2012
Amended:	November 2015
To be reviewed:	November 2020

PREAMBLE

The College of Physicians and Surgeons of Saskatchewan (CPSS) acknowledges the work of the Alberta College of Physicians and Surgeons in developing standards for facilities which provide In Vitro Fertilization Services. This document is adapted from the Alberta document.

Physicians may only provide Assisted Reproductive Technology (ART) procedures and services in a non-hospital facility in Saskatchewan that is approved by the College of Physicians and Surgeons of Saskatchewan pursuant to bylaw 26.1.

This document, and bylaw 26.1, do not apply to the standards or procedures for the management of pregnancies arising from ART.

This document addresses the standards expected of facilities which provide Assisted Reproductive Technology (ART) Procedures in Saskatchewan as defined in College bylaw 26.1

In this document:

- "shall" is used when a section is a requirement for accreditation;
- "should" is used when a section is recommended; and
- "may" is used when a section is discretionary.

All accredited medical facilities shall have a Medical Director (i.e. a practitioner who is registered with the College of Physicians & Surgeons of Saskatchewan) who is accountable for the practice of medicine within the facility.

Facilities which provide laboratory services will likely require a licence under **The Medical Laboratory Licensing Act** in addition to meeting other requirements.

DEFINITION OF CURRENT AND FUTURE SERVICES:

Assisted Reproductive Technology (ART) encompasses a variety of clinical treatments and laboratory procedures, which include the handling of human oocytes, sperm, or embryos, with the intent of establishing a pregnancy. This includes but is not limited to, oocyte retrieval, in vitro fertilization (IVF) and embryo transfer, blastocyst culture, gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), intracytoplasmic sperm injection (ICSI), ovulation induction (OI), controlled ovarian hyperstimulation (COH), intrauterine insemination (IUI), therapeutic donor insemination (TDI), embryo biopsy, preimplantation genetic diagnosis (PGD), preimplantation genetic screening (PGS), embryo cryopreservation, sperm and oocyte cryopreservation, sperm, oocyte or embryo donation, and gestational surrogacy.

Laboratory procedures include, but are not limited to, basic and advanced diagnostic semen testing, semen preparation for intrauterine insemination, therapeutic donor insemination and gamete cryopreservation.

Other services include:

- Infertility consultation and investigation
- Ultrasound imaging for:
    - infertility investigation (insured service)
    - treatment monitoring (insured and uninsured services)
    - sonohysterography (insured)
    - early pregnancy evaluation (insured)
- Dispensing of fertility-related medications
- Therapeutic percutaneous testicular sperm aspiration and epididymal aspiration (TESA/PESA)
- Fertility preservation / oncofertility
- Recurrent pregnancy loss investigation and treatment

GUIDING PRINCIPLES AND VALUES:

- To provide high quality care in assisted reproduction by qualified medical, nursing and laboratory professionals
- To provide safe patient care in the outpatient setting
- To maintain high ethical standards, putting the well-being of the patient and potential offspring above all else

1.0 MEDICAL STAFF – QUALIFICATIONS

1.1 Medical Director:

1.1.1 The Medical Director of an Assisted Reproductive Technology facility shall:

a. Have a current licence to practise in Saskatchewan and be recognized by the CPSS as a specialist in Obstetrics and Gynecology,

-and-

b. Have sub-specialty recognition by the Royal College of Physicians and Surgeons of Canada in Reproductive Endocrinology and Infertility,

-or-

c. Have international training and recognition in Reproductive Endocrinology and Infertility equivalent to that required for certification by the Royal College of Physicians and Surgeons of Canada.

-or-

d. Have approval from the CPSS to act as Medical Director.

1.2 PHYSICIANS PROVIDING FULL ASSISTED REPRODUCTIVE TECHNOLOGY SERVICES:

1.2.1 Physicians providing full services shall:

a. Have a current practice licence to practice in Saskatchewan and be recognized as a specialist in Obstetrics and Gynecology,

-and-

b. Have sub-specialty recognition by the Royal College of Physicians and Surgeons of Canada in Reproductive Endocrinology and Infertility,

-or-

c. Have international training and recognition in Reproductive Endocrinology and Infertility equivalent to that required for certification by the Royal College of Physicians and Surgeons of Canada,

-or-

d. Have 5 or more years of experience acceptable to the College that commenced before the REI fellowship was available,

-and-

e. Be recommended by the medical director of the facility.

-or-

f. Have approval from the CPSS.

1.3 GRANDFATHERING:

1.3.1 Medical Directors and physicians providing full services that are already practicing in Assisted Reproductive Technology facilities in Saskatchewan prior to the adoption of these standards will be grandfathered.

2.0 ASSISTING PERSONNEL – QUALIFICATIONS

Ideally, laboratory staff members will be qualified in accordance with the recommendations of the Canadian Fertility and Andrology Society (CFAS).
However, until such time as there are sufficient embryology training programs and graduates, the Medical Director is solely responsible for ensuring that all facility staff members are qualified and competent to perform their duties.
Ideally, counselors will meet the qualifications contained in the Assisted Human Reproduction Counselling Practice Guidelines published by the Canadian Fertility and Andrology Society Counselling Special Interest Group
Ideally, nursing staff members will be qualified in accordance with the recommendations of the Nurses Special Interest Group in association with the Canadian Fertility and Andrology Society (CFAS).

3.0 PATIENT SELECTION

Criteria for acceptable patients shall be written and shall include screening tests for hepatitis B & C, HIV, and syphilis on all patients within one year prior to providing gametes.

4.0 PROCEDURES

4.1 There shall be written procedures for all surgical procedures in the facility.
4.2 There shall be written procedures for all non-surgical procedures in the facility that are essential to the provision of an Assisted Reproductive Technology service (e.g. use of ultrasound, processing and storage of semen, oocytes and embryos.)

5.0 PATIENT RECORDS

In addition to the College's requirements for medical records in non-hospital surgical facilities, each patient record in an accredited Assisted Reproductive Technology facility shall include:

5.1 consent forms approved by Health Canada or the College and signed by each gamete provider,
5.2 the number of oocytes retrieved,
5.3 the number of embryos transferred,
5.4 the number of oocytes/embryos cryopreserved,
5.6 the number of oocytes/embryos discarded, and
5.7 discharge and follow-up instructions given after oocyte retrieval and embryo transfer.

6.0 QUALITY ASSURANCE PROGRAM

In addition to guidelines for quality assurance in non-hospital surgical facilities, an Assisted Reproductive Technology facility shall be a member of the Canadian Assisted Reproductive Technology Registry and make its data submissions to the registry available to the College for review.

7.0 CLINICAL PRACTICE GUIDELINES

7.1 The medical director shall be familiar with all clinical practice guidelines and other guidelines published by the Canadian Fertility and Andrology Society.

7.2 The medical director shall be familiar with all clinical practice guidelines and other guidelines published by the American Society of Reproductive Medicine.

7.3 The medical director shall be responsible to ensure that, where consistent with appropriate medical judgment, the practices of the facility shall be consistent with:

a) Clinical Practice Guidelines and other guidelines published by the Canadian Fertility and Andrology Society;
b) Clinical Practice Guidelines and other guidelines published by the American Society of Reproductive Medicine where there is not a relevant Clinical Practice Guideline or guideline published by the Canadian Fertility and Andrology Society.

7.4 The medical director shall ensure that there are policies and procedures in place within the facility to ensure that if the care provided to a patient departs from a Clinical Practice Guideline or other guideline referenced in paragraph 7.3:

a) the nature of the departure is documented;
b) the reason for the departure is documented; and,
c) the patient is advised of the departure and the reason for the departure.

7.5 Physicians providing Assisted Reproductive Technology services shall be familiar with all clinical practice guidelines and other guidelines published by the Canadian Fertility and Andrology Society.

7.6 Physicians providing Assisted Reproductive Technology services shall be familiar with all clinical practice guidelines and other guidelines published by the American Society of Reproductive Medicine

7.7 Physicians providing Assisted Reproductive Technology services shall ensure that if the care provided to a patient departs from a Clinical Practice Guideline or other guideline referenced in paragraph 7.3:

a) the nature of the departure is documented;
b) the reason for the departure is documented; and,
c) the patient is advised of the departure and the reason for the departure.