Proposed new regulations under the Assisted Human Reproduction Act

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Health Canada is accepting and encouraging public comment on these proposed regulations until January 10, 2019.

On October 26, 2018, the Minister of Health announced the launch of consultations on three new sets of proposed regulations under the *Assisted Human Reproduction* Act (the Act). Health Canada is accepting and encouraging public comment on these proposed regulations until January 10, 2019.

The proposed regulations aim to protect and maintain the health and safety of donors, recipients and those born of assisted reproduction. This is especially important as more Canadians are relying on assisted reproduction to help build their families.

The proposed regulations would:

1. establish a health and safety framework for third-party donor sperm and ova;
2. identify the types of expenses that may be reimbursed to donors and surrogates;
3. establish necessary administration and enforcement procedures for the Act; and
4. update existing consent regulations.

Health-care providers who are involved in any aspect of assisted reproduction services should be aware of these proposed changes. Below we have outlined a high-level summary of the most significant changes.

Safety of Sperm and Ova

Currently, the safety of donor sperm is regulated by the *Processing and Distribution of Semen for Assisted Conception Regulations* under the *Food and Drugs Act*. Whereas, the donation of ova, also known as egg cells, are not subject to any safety requirements under federal laws. The proposed regulations provide for unified and modernized safety regulations for sperm and ova donation. This is essential to the health of those using assisted reproduction as both sperm and ova can transmit infectious and genetic diseases.

The proposed regulations introduce a number of requirements for establishments which process, import or distribute donor sperm and ova. These requirements include

measures related to traceability, quality control, testing, record keeping, and error, accident, or adverse reaction response. All establishments will be required to establish and maintain quality control systems and standard operating procedures, as well as suitable facilities and qualified personnel.

Primary establishments will be required to register with Health Canada. Primary establishments are defined as establishments which conduct, independently or through an agent, all of the processing activities in respect of donor sperm or ova for use in assisted human reproduction in Canada. The registration process will require the provision of certain information including the applicant's name, address and contact information, a list of the processing activities that are proposed to be conducted in each building, and an attestation signed by a senior executive officer.

Primary establishments will be required to assess donor suitability through a "regular process" with standard requirements, including screening and testing donors to reduce the risk of infection and genetic disease transmission. Primary establishments must also comply with a directive setting out exclusion criteria, which Health Canada maintains the authority to amend these criteria to respond to novel health and safety risks as they arise. Health Canada has released a proposed directive entitled *Draft Health Canada Directive: Technical Requirements for Conducting the Suitability Assessment of Sperm and Ova Donors*.

Where donor sperm or ova do not meet the regular process test, exceptional access may still be granted, subject to a number of conditions. Exceptional access is available where:
(1) the intended recipient has been previously exposed to the requested donor's sperm that was retested at the same time as the requested sperm;
(2) the intended recipient has previously been exposed to the donor's ova collected the same day as the requested ova; or
(3) the requested sperm or ova will be used to create a genetic sibling to a child of the requesting individual or couple.

Additionally, where the intended recipient and donor know each other, a directed donation process can be initiated by a health professional on behalf of the recipient. Qualifying directed donations are permitted even if the material does not meet all of the regular process requirements.

Reimbursement Related to Assisted Human Reproduction

The proposed regulations clarify permissible expenses for donors in the course of donating ova or sperm, surrogate mothers, and individuals maintaining or transporting an *in vitro* embryo. Reimbursement will be subject to certain documentary and record keeping requirements.

Donors of ova or sperm and surrogate mothers may be reimbursed for the following types of expenses:

- Travel including transportation, parking, meals, and accommodation
- Care of dependants
- Counselling services
- Legal services and disbursements

- Drugs or devices defined in section 2 of the *Food and Drugs Act*
- Health, disability, or life insurance coverage
- Obtaining or confirming medical records
- *Specific to donors of ova and sperm*: products or services recommended or provided by a licensed medical practitioner
- *Specific to surrogate mothers*: products or services recommended or provided by a person licensed to assess, monitor, and provide health care to a woman during her pregnancy, delivery, or post-partum.

Surrogate mothers may also be reimbursed for the following:

- Maternity clothes
- Delivery expenses
- Loss of work-related income

Expenses incurred by any person for the maintenance and transport of *in vitro* embryos may be reimbursed, including storage, preparing the embryo for transport, the shipping container, and preparing the shipping container for transport.

A person can only reimburse an eligible expense once they have obtained certain documentation from the person requesting the reimbursement, including a declaration setting out the recipient's name, address, the nature of the expenditure, and the date it was incurred.

Consent for Use of Human Reproductive Material and *In Vitro* Embryos

The proposed regulations make minor amendments to the previously named *Assisted Human Reproduction (Section 8 Consent) Regulations*.

One such amendment allows for the use of donated sperm, ova or *in vitro* embryos when they were originally donated anonymously and the person making use of the donations is not the person who obtained direct consent from the donor. For these anonymous donations, the person making use of the material must have a written document from the person who originally obtained the donor's consent, attesting to, among other things, that proper consent was obtained and specifying the purposes for which the donations can be used.

The current consent regulations do not include a requirement for the retention of records. The proposed new regulations would require individuals who make use of or remove reproductive material to keep records relating to these activities for ten years following the day of the activity.

By

Anna Marrison, Victoria Cistrone, Elizabeth White

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BLG Offices

Calgary

Centennial Place, East Tower
520 3rd Avenue S.W.
Calgary, AB, Canada
T2P 0R3

T 403.232.9500
F 403.266.1395

Ottawa

World Exchange Plaza
100 Queen Street
Ottawa, ON, Canada
K1P 1J9

T 613.237.5160
F 613.230.8842

Vancouver

1200 Waterfront Centre
200 Burrard Street
Vancouver, BC, Canada
V7X 1T2

T 604.687.5744
F 604.687.1415

Montréal

1000 De La Gauchetière Street West
Suite 900
Montréal, QC, Canada
H3B 5H4

T 514.954.2555
F 514.879.9015

Toronto

Bay Adelaide Centre, East Tower
22 Adelaide Street West
Toronto, ON, Canada
M5H 4E3

T 416.367.6000
F 416.367.6749