Health Canada Santé Canada

Reimbursement of Expenditures Under the *Assisted Human Reproduction Act*

Public Consultation Document

Prepared by Health Canada

Canada

Table of Contents

Reimbursement of Expenditures

1. Introduction

The *Assisted Human Reproduction Act* (AHR Act), adopted by Parliament on March 29, 2004, governs the area of assisted human reproduction (AHR) and related research. It prohibits unacceptable AHR practices and provides for the regulation of controlled activities and the licensing of persons authorized to undertake these activities. The AHR Act also provides for the establishment of Assisted Human Reproduction Canada (the Agency), which will be responsible for issuing licences and compliance and enforcement of the provisions of the AHR Act and regulations.

Under the AHR Act, one of the prohibitions relates to the purchase of sperm or ova (eggs) from a donor. Another prohibition relates to paying for surrogacy. This is based on the principle that human reproductive capacity should not be commercialized. During the consultations that led to the creation of the AHR Act, this principle was strongly emphasized by Canadians. However, the reimbursement of receipted expenditures incurred in the course of donating sperm or ova may be permitted as a controlled activity pursuant to section 12 of the AHR Act provided that the reimbursement is made in accordance with the applicable regulations and a licence.

Purpose of the Document

The purpose of this consultation document is to seek input from Canadians on possible options for the regulation and licensing of the reimbursement of expenditures relating to:

- the donation of sperm or ova,
- maintaining or transporting *in vitro* embryos, and
- surrogacy.

The document provides relevant information and context so that feedback may be obtained. Comments will serve to inform the next steps of the regulatory development process.

Public consultation is a requirement of the Government of Canada's Cabinet Directive on Streamlining Regulations. Based on comments received, Health Canada will draft proposed regulations. These proposed regulations will then be published for public comment in the *Canada Gazette*, Part I and posted on Health Canada's web site. Following these consultations, there will be a Parliamentary review and ministerial approval. Once the regulations are published in Part II of the *Canada Gazette*, they will become law at a time as set out in the regulations.

For more information regarding the Regulatory Development Process, please visit: http://hc-sc.gc.ca/hl-vs/reprod/hc-sc/legislation/reg_e.html.

2. How can you provide input?

Public consultation provides an opportunity to hear what Canadians are thinking on a particular issue. Responses to consultations help form policies, programs, regulations and legislation that reflect the concerns of Canadians.

Please provide us with your input by answering the questions included in the document. We will carefully consider all comments received as the regulations are being developed. You may provide us with your comments online by answering the questions found in Parts A and B of the consultation workbook. You may also provide us with comments by e-mail at: ahr-pa@hc-sc.gc.ca , by fax at (819) 934-1828 or by mail at:

Assisted Human Reproduction Implementation Office
Health Canada
350-200 Promenade du Portage
Gatineau, QC
Address Locator: 7002A
K1A 0K9

If you have any questions, please call: 819-934-1830.

The AHR Act can be found at: http://laws.justice.gc.ca/en/showtdm/cs/A-13.4.

3. Supporting Canadian Values

The AHR Act, which received Royal Assent on March 29, 2004, provides a legislative framework to protect the health and safety of Canadians undergoing AHR and their children, while serving the broadest interests of Canadians.

The commercialization of the human reproductive capacity is not in keeping with Canadian values. Canadians feel strongly that human life is a gift which should not be bought and sold, or treated like a consumer commodity. A guiding principle of the AHR Act is to prevent trade in the reproductive capabilities of women and men. To this end, paragraph 2(f) of the AHR Act states:

> **2.** The Parliament of Canada recognizes and declares that
> **(f)** trade in the reproductive capabilities of women and men and the exploitation of children, women and men for commercial ends raise health and ethical concerns that justify their prohibition;

Building on this principle, section 6 of the AHR Act, which came into force on April 22, 2004, prohibits payment for surrogacy and establishes the minimum age of a surrogate mother. Section 6 states:

> **6. (1)** No person shall pay consideration to a female person to be a surrogate mother, offer to pay such consideration or advertise that it will be paid.
>
> **(2)** No person shall accept consideration for arranging for the services of a surrogate mother, offer to make such an arrangement for consideration or advertise the arranging of such services.
>
> **(3)** No person shall pay consideration to another person to arrange for the services of a surrogate mother, offer to pay such consideration or advertise the payment of it.
>
> **(4)** No person shall counsel or induce a female person to become a surrogate mother, or perform any medical procedure to assist a female person to become a surrogate mother, knowing or having reason to believe that the female person is under 21 years of age.
>
> **(5)** This section does not affect the validity under provincial law of any agreement under which a person agrees to be a surrogate mother.

In addition, section 7 of the AHR Act, which also came into force on April 22, 2004, prohibits the purchase of sperm or ova from a donor and the purchase or sale of *in vitro* embryos. As these prohibitions are not retroactive, sperm, ova or *in vitro* embryos currently in storage, that were paid for prior to this date, do not contravene section 7.

> **7. (1)** No person shall purchase, offer to purchase or advertise for the purchase of sperm or ova from a donor or a person acting on behalf of a donor.
>
> **(2)** No person shall (a) purchase, offer to purchase or advertise for the purchase of an *in vitro* embryo; or (b) sell, offer for sale or advertise for sale an *in vitro* embryo.

Altruistic donation is consistent with Canadian values whereby human organs or tissues are donated for the use of those in need. While, as noted above, the AHR Act prohibits the payment for sperm, ova, *in vitro* embryos and surrogacy, it is recognized that there are expenditures incurred by sperm and ova donors, persons maintaining or transporting *in vitro* embryos and surrogate mothers in the course of undertaking these activities. Therefore, when section 12 comes into force[1], it will provide for the reimbursement of receipted expenditures in accordance with the regulations and a licence. Additional provisions will also allow for the reimbursement of loss of work-related income incurred during the pregnancy of a surrogate mother. Section 12 provides:

> **12. (1)** No person shall, except in accordance with the regulations and a licence,(a) reimburse a donor for an expenditure incurred in the course of donating sperm or an ovum; (b) reimburse any person for an expenditure incurred in the maintenance or transport of an *in vitro* embryo; or (c) reimburse a surrogate mother for an expenditure incurred by her in relation to her surrogacy.
>
> **(2)** No person shall reimburse an expenditure referred to in subsection (1) unless a receipt is provided to that person for the expenditure.
>
> **(3)** No person shall reimburse a surrogate mother for a loss of work-related income incurred during her pregnancy, unless (a) a qualified medical practitioner certifies, in writing, that continuing to work may pose a risk to her health or that of the embryo or foetus; and (b) the reimbursement is made in accordance with the regulations and a licence.

[1] As section 12 is not yet in force, reimbursement of expenditures relating to donation, surrogacy and the transportation or maintenance of *in vitro* embryos may presently occur without a licence.

4. What We've Heard so Far

On November 5-6, 2004, Health Canada held a consultation workshop on the reimbursement of expenditures for sperm and ova donors. Participants who attended the workshop included representatives from fertility clinics, sperm banks, health practitioners and representatives of non-governmental organizations. The workshop objectives were to gather information on the practice of sperm and ova donation utilized by clinics and sperm banks, and information relating to the reimbursement of expenditures. The workshop also served to engage stakeholders early on in the regulatory development process.

During the consultation workshop, Health Canada gave a presentation on the policy intent of the reimbursement of expenditures. Participants expressed their concern about the implications of section 12 on the supply of donor sperm and ova in Canada. Participants were asked to identify expenditures for sperm and ova donors and to describe administrative issues for the processing of expenditures.

There was general consensus among participants that Health Canada develop a list of expenditures to be made available to them for guidance. Most participants felt that a regulated limit on the amount of expenditures is not necessary and that clinics, which reimburse expenditures, should be permitted to set their own limits.

The policy proposals and options for the regulation of the reimbursement of expenditures set out below are based on input from this consultation workshop and from other consultations with stakeholders. To consult the Workshop Report, please visit: http://hc-sc.gc.ca/hl-vs/pubs/reprod/section12_e.html.

5. Proposals for Regulations and Licensing Relating to the Reimbursement of Expenditures

Section 12 requires that reimbursement of expenditures be carried out in accordance with the regulations and a license. Part A of this paper outlines the proposed categories of receipted expenditures eligible for reimbursement as well as a proposal for the reimbursement of loss of work-related income for surrogate mothers, while Part B outlines the proposed licensing scheme.

Part A: Options for Eligible Expenditure Categories

Reimbursement of Expenditures for Donation of Sperm or Ova, Maintenance or Transportation of *in vitro* Embryos and Surrogacy

Health Canada is proposing categories of receipted expenditures eligible for reimbursement by licensed persons in relation to sperm and ova donation, maintenance or transportation of *in vitro* embryos and surrogacy. The use of categories would provide flexibility on a practical level, yet still provide a transparent framework for the reimbursement of expenditures.

The regulations will provide that expenditures be reasonable[2], proven with a receipt, and, where appropriate, only reimbursable to the extent the expenditure is not otherwise reimbursable under provincial/territorial and/or private or employment related medical/health insurance plan. The regulations will establish the categories of expenditures that are eligible for reimbursement with receipts, however, there is no obligation to provide reimbursement for any expenditures.

Proposed Categories of Expenditures Related to Sperm Donation
The categories are suggested areas of expenditures eligible for reimbursement when directly related to sperm donation: • travel expenses (such as transportation, meals and accommodation) • child care costs (for attending clinic appointment) • counselling services • health care services (provided and prescribed by health care providers)

Questions:

1. Are there additional or alternative categories you feel have not been included? If "yes," please specify which are missing and explain why.

2. Are there categories of expenditures that should be removed? If "yes," please specify which and explain why.

[2] Paragraph 65(1)(e) of the AHR Act.

Proposed Categories of Expenditures Related to Ova Donation
The categories are suggested areas of expenditures eligible for reimbursement when directly related to ova donation: • travel expenses (such as transportation, meals and accommodation) • child care costs (for attending clinic/medical appointments and receiving medical treatments) • medication • counselling services • health care services (provided and prescribed by health care providers)

Questions:

1. Are there additional or alternative categories you feel have not been included? If "yes," please specify which are missing and explain why.

2. Are there categories of expenditures that should be removed? If "yes,"please specify which and explain why.

Proposed Categories of Expenditures Related to Surrogacy
The categories are suggested areas of expenditures eligible for reimbursement when directly related to the surrogacy: • travel expenses (such as transportation, meals and accommodation) • medication • maternity clothes • child care costs (for attending clinic/medical appointments, receiving medical treatments, and for the delivery) • independent legal services • counselling services • health care services (provided and prescribed by health care providers)

Questions:

1. Are there additional or alternative categories you feel have not been included? If "yes," please specify which are missing and explain why.

2. Are there categories of expenditures that should be removed? If "yes," please specify which and explain why.

Reimbursement of Expenditures for the Maintenance or Transportation of *in vitro* Embryo(s)

Typically during the process of *in vitro* fertilization, a number of *in vitro* embryos are created. The number of *in vitro* embryos created may be in excess of the reproductive needs of the individual or couple for whom they were created. In some cases, the individual or couple may

decide to donate their *in vitro* embryo(s) to a third party for reproductive use, to a researcher for research purposes or for improving or providing instruction in assisted reproduction procedures. Once an individual or couple has consented to donate their *in vitro* embryo(s), there could be expenditures incurred by them or by a clinic in relation to the maintenance or transportation of those *in vitro* embryo(s) to the person to whom the *in vitro* embryo(s) are donated. Expenditures associated with the cost of maintaining or transporting *in vitro* embryo(s) are not reimbursable unless the expenditures are in accordance with the regulations and a licence. The person from whom *in vitro* embryo(s) is provided may be reimbursed for eligible, receipted expenditures associated with the maintenance or transportation of the donated *in vitro* embryo(s), however, there is no obligation to reimburse these expenditures.

Proposed Categories of Expenditures Related to the Maintenance of *In Vitro* Embryo(s)
The categories are suggested areas of expenditures eligible for reimbursement when incurred in relation to the maintenance of an *in vitro* embryo: • Cryopreservation fees • Storage fees

Question:

1. Are there other expenditures incurred in the maintenance of an *in vitro* embryo that should be considered for reimbursement? If yes, please specify and explain.

Proposed Categories of Expenditures Related to the Transportation of *In Vitro* Embryo(s)
The categories are suggested areas of expenditures eligible for reimbursement when incurred in relation to the transportation of *in vitro* embryo(s): • Administrative costs to prepare the embryo for transportation • Cost for laboratory staff to prepare the embryo and the container transfer • Cost of container (dry shipper) • Cost of preparing the shipping container • Cost of courier/transportation services

Questions:

1. Are there other expenditures that should be added to the list? If "yes", please specify which and explain why.

2. Are there expenditures that should be removed from the list? If "yes", please specify which and explain why.

Reimbursement of Loss of Work-Related Income for Surrogate Mothers

Subsection 12(3) of the AHR Act provides that a surrogate mother may be reimbursed for the loss of work-related income incurred during her pregnancy, provided that a qualified medical practitioner certifies in writing that continuing to work may pose a risk to her health or to the health of the embryo or foetus, and that such reimbursement is made in accordance with the regulations and a licence.

It is proposed that the loss of work-related income for a surrogate mother is only reimbursable to the extent that the loss is not otherwise covered or reimbursable under a federal, provincial, territorial or private employment, disability or work supplement insurance or income plan. The regulations will establish a method of determining the amount that may be reimbursed with appropriate receipts, however, there is no obligation to reimburse for such an income loss.

Proposal for Reimbursement for Loss of Work-Related Income for Surrogate Mothers
A surrogate mother may be reimbursed for loss of work-related income in an amount that cannot be greater than the amount she would have received from her employer or self-employment during the period of certified medical leave. Proof of income such as pay stub or other receipts, would need to be provided in order to be eligible for reimbursement. For example: A qualified medical practitioner certifies (in writing) that continuing to work may pose a risk to the health of the surrogate mother or that of the embryo or foetus. This surrogate mother normally earns $1000 per pay period. She applies for employment insurance (EI), which provides her with $300 in EI benefits over the same period as her normal pay. As a result, a person licensed to reimburse may reimburse this surrogate mother up to $700 for that period while she is on certified leave. (Normal pay amount) less (other related income source) equals (maximum eligible for reimbursement) Therefore, $1000 - $300 = $700 for that pay period.

Questions:

1. Is this method of determining loss of work-related income appropriate? If not, please explain.

2. Is there another method of determining loss of work-related income that may be more appropriate? If "yes", please specify and explain.

Part B: Options for Licensing Relating to Reimbursement of Expenditures

As described earlier, under the AHR Act it is prohibited to reimburse expenditures related to the donation of sperm or ovum, *in vitro* embryos or surrogacy unless the reimbursements are carried out with a licence and in accordance with the regulations. In this section of the paper, we are seeking feedback on proposals related to the licensing of the four reimbursement activities outlined in section 12 of the AHR Act including the qualifications required to obtain a reimbursement licence, the period of licences, and a proposal related to premises licences.

Licensing under the AHR Act

The AHR Act provides a framework for a licensing system that will be administered by the Agency. Licensing systems are widely used in Canada to support federal, provincial, territorial and municipal regulatory requirements. For instance, the Canadian health sector uses licensing systems to authorize people to do activities such as practising medicine or to authorize establishments in which pharmaceutical drugs are manufactured. Licensing systems are seen as important mechanisms for ensuring that certain activities are performed by qualified persons under appropriate conditions and that there is an oversight system in place to respond to identified and potential problems.

Under the AHR Act, the Agency may issue two kinds of licences: a licence to undertake a controlled activity, and a licence to permit the use of premises for a controlled activity. The Agency is responsible for issuing, amending, renewing, suspending, and revoking licences as set out in sections 40 to 44 of the Act. In addition to the administration of licensing under the Act, the Agency also has responsibility for inspections and enforcement under the Act.

Controlled Activities Licences

Section 12 of the AHR Act outlines the four reimbursement controlled activities (see Box 1) and imposes two general requirements on persons wishing to reimburse - they must have a licence and they must conduct the activity in accordance with the applicable regulations made under the AHR Act.

Under subsection 40(1) of the AHR Act, the Agency may, in accordance with the regulations, issue a licence to any person having the qualifications provided under the regulations, authorizing the person to undertake any controlled activity specified in the licence. Regulations are being developed which will set out the qualifications required to obtain a licence for each controlled activity.[3] To obtain a licence, an applicant would submit an application with the required documentation to the Agency for the reimbursement activity to be undertaken with a licence. We anticipate that applicants will be individuals or corporations.

[3] Paragraph 65(1)(j) of the AHR Act.

BOX 1: Reimbursement Controlled Activities

- Reimburse a donor for an expenditure incurred in the course of donating sperm or an ovum - paragraph 12(1)(a)
- Reimburse any person for an expenditure incurred in the maintenance or transport of an *in vitro* embryo - paragraph 12(1)(b)
- Reimburse a surrogate mother for an expenditure incurred by her in relation to her surrogacy - paragraph 12(1)c)
- Reimburse a surrogate mother for a loss of work-related income incurred during her pregnancy - paragraph 12(3)(b)

Question:
1. Aside from individuals and incorporated entities or persons, are you aware of any other kinds of organizations or entities that may require a licence for a reimbursement activity? Yes/No If yes, please explain and, where possible, provide specific examples.

Qualifications of individual applicants

It is proposed that individuals who reside in Canada and/or who make payment within Canada will be required to obtain a licence for reimbursement activities under the AHR Act.

In determining whether or not to issue a licence, it is proposed that the Agency consider the applicant's compliance history (if there is one). For example, regulations may prohibit the Agency from issuing a licence to an individual who has been convicted of a criminal offence under the AHR Act or who has had a licence issued under the AHR Act revoked.

With respect to a licence to reimburse a surrogate mother for an expenditure incurred by her in relation to her surrogacy (paragraph 12(1)c)), it is proposed that licences only be issued to a qualified commissioning individual. A commissioning individual is an individual who wishes to raise a child as the child's parent after the child's birth under the surrogacy arrangement. The commissioning individual may or may not be genetically related to the child.

With respect to a licence to reimburse a surrogate mother for a loss of work-related income incurred during her pregnancy (paragraph 12(3)(b)), it is proposed that licences only be issued to a qualified commissioning individual.

In all cases, in order to qualify, the applicant would be required to have and to acknowledge the ability to record and track reimbursement transactions and maintain receipts in a way that would comply with regulatory requirements and permit the Agency to carry out inspections.

Questions:

1. Are the proposed qualifications for individuals reasonable?

a) Summary of qualifications
- resident of Canada or make payment in Canada
- able to track reimbursements
- compliance history

Activity
Reimburse a donor for an expenditure incurred in the course of donating sperm or an ovum - paragraph 12(1)(a). If no, please explain:

b) Summary of qualifications
- resident of Canada or make payment in Canada
- able to track reimbursements
- compliance history

Activity
Reimburse any person for an expenditure incurred in the maintenance or transport of an *in vitro* embryo - paragraph 12(1)(b). If no, please explain:

c) Summary of qualifications
- resident of Canada or make payment in Canada
- commissioning individual
- able to track reimbursements
- compliance history

Activity
Reimburse a surrogate mother for an expenditure incurred by her in relation to her surrogacy - paragraph 12(1)c). If no, please explain:

d) Summary of qualifications
- resident of Canada or make payment in Canada
- commissioning individual
- able to track reimbursements
- compliance history

Activity

Reimburse a surrogate mother for a loss of work-related income incurred during her pregnancy - paragraph 12(3)(b). If no, please explain:

2. Do you think any of the proposed qualification should be removed from the list?

a) Summary of qualifications
- resident of Canada or make payment in Canada
- able to track reimbursements
- compliance history

Activity
Reimburse a donor for an expenditure incurred in the course of donating sperm or an ovum - paragraph 12(1)(a). If yes, please explain:

b) Summary of qualifications

- resident of Canada or make payment in Canada
- able to track reimbursements
- compliance history

Activity

Reimburse any person for an expenditure incurred in the maintenance or transport of an *in vitro* embryo - paragraph 12(1)(b). If yes, please explain:

c) Summary of qualifications

- resident of Canada or make payment in Canada
- commissioning individual
- able to track reimbursements
- compliance history

Activity

Reimburse a surrogate mother for an expenditure incurred by her in relation to her surrogacy - paragraph 12(1)c). If yes, please explain:

d) Summary of qualifications

- resident of Canada or make payment in Canada
- commissioning individual
- able to track reimbursements
- compliance history

Activity
Reimburse a surrogate mother for a loss of work-related income incurred during her pregnancy - paragraph 12(3)(b). If yes, please explain:

3. Are there additional or alternative qualifications that should be considered?

a) Summary of qualifications
- resident of Canada or make payment in Canada
- able to track reimbursements
- compliance history

Activity
Reimburse a donor for an expenditure incurred in the course of donating sperm or an ovum - paragraph 12(1)(a). If yes, please explain:

b) Summary of qualifications
- resident of Canada or make payment in Canada
- able to track reimbursements
- compliance history

Activity
Reimburse any person for an expenditure incurred in the maintenance or transport of an *in vitro* embryo - paragraph 12(1)(b). If yes, please explain:

c) Summary of qualifications

- resident of Canada or make payment in Canada
- commissioning individual
- able to track reimbursements
- compliance history

Activity

Reimburse a surrogate mother for an expenditure incurred by her in relation to her surrogacy - paragraph 12(1)c). If yes, please explain:

d) Summary of qualifications

- resident of Canada or make payment in Canada
- commissioning individual
- able to track reimbursements
- compliance history

Activity

Reimburse a surrogate mother for a loss of work-related income incurred during her pregnancy - paragraph 12(3)(b). If yes, please explain:

Question:

Do you have any additional comments related to the licensing of individuals for reimbursement activities (e.g., situations we may not have contemplated)?

Qualifications of corporate applicants

As noted previously, Health Canada is considering a proposal to require that licences for the two reimbursement activities related to surrogacy (paragraph 12(1)c) and paragraph 12(3)(b)) only be issued to commissioning individuals. As such, under this proposal corporations could not be issued a licence for either of these activities.

It is proposed that a corporate applicant for either of the two remaining reimbursement activities (paragraphs 12(1)a) and 12(1)b)) must be a corporation that is incorporated under the laws of a province or of Canada at the time of the application.

In determining whether or not to issue a licence, it is proposed that the Agency consider the compliance history (if there is one) of the corporation and its directors. For example, regulations may prohibit the Agency from issuing a licence to a corporation which has been convicted of a criminal offence under the AHR Act or which has had a licence issued under the AHR Act revoked.

In all cases, in order to qualify, the applicant would be required to have and to acknowledge the ability to record and track reimbursement transactions and maintain receipts that complies with regulatory requirements and permits the Agency to carry out inspections.

Questions:

1. Are the proposed qualifications for corporations reasonable?

a) Summary of qualifications
- incorporated in Canada
- able to track reimbursements
- compliance history

Activity
Reimburse a donor for an expenditure incurred in the course of donating sperm or an ovum - paragraph 12(1)(a). If no, please explain:

b) Summary of qualifications
- incorporated in Canada
- able to track reimbursements
- compliance history

Activity
Reimburse any person for an expenditure incurred in the maintenance or transport of an *in vitro* embryo - paragraph 12(1)(b). If no, please explain:

2. Do you think any of the proposed qualification should be removed from the list?

a) Summary of qualifications
- incorporated in Canada
- able to track reimbursements
- compliance history

Activity
Reimburse a donor for an expenditure incurred in the course of donating sperm or an ovum - paragraph 12(1)(a). If yes, please explain:

b) Summary of qualifications
- incorporated in Canada
- able to track reimbursements
- compliance history

Activity
Reimburse any person for an expenditure incurred in the maintenance or transport of an *in vitro* embryo - paragraph 12(1)(b). If yes, please explain:

3. Are there additional or alternative qualifications that should be considered?

a) Summary of qualifications
- incorporated in Canada
- able to track reimbursements
- compliance history

Activity
Reimburse a donor for an expenditure incurred in the course of donating sperm or an ovum - paragraph 12(1)(a). If yes, please explain:

b) Summary of qualifications
- incorporated in Canada
- able to track reimbursements
- compliance history

Activity
Reimburse any person for an expenditure incurred in the maintenance or transport of an *in vitro* embryo - paragraph 12(1)(b). If yes, please explain:

Question:
Do you have any additional comments related to the licensing of corporations for reimbursement activities (e.g., situations we may not have contemplated)?

Period of licences

The regulations related to the administration of the licensing system may specify the period or length of licences, or provide the Agency with options which may apply when issuing a licence. For the four reimbursement activities, it is proposed that a licence be issued for a period not to exceed five years.

Questions:
1. Is a proposal to issue licences for a period not to exceed five years reasonable? Yes/No, please explain.

2. Are there additional or alternative options related to the period or length of a licence that should be considered? Yes/No, please explain.

3. Do you have any additional comments related to the period of licences for reimbursement activities?

Premises Licences

The AHR Act provides that a person who is licensed to undertake a controlled activity (which would include one of the reimbursement activities) may only do so in premises that have been licensed, and thus authorized, for use for that activity.[4] The intent of this requirement is to protect human health and safety by ensuring that controlled activities, such as *in vitro* fertilization, are only undertaken in appropriate environments.[5]

It is understood that the four reimbursement controlled activities are administrative in nature and as such, are frequently undertaken in a range of premises including the administrative offices of AHR centres, hospitals, research facilities, and pharmaceutical companies as well as in the personal homes and offices of individuals who are directly reimbursing donors or surrogate mothers. As there do not appear to be any specific premises-related health and safety risks or requirements relating to the four reimbursement controlled activities, consideration is being given

[4]Section 13 of the AHR Act states, "*no person who is licensed to undertake a controlled activity shall undertake it in any premises except in accordance with a licence permitting the use of the premises for that controlled activity*." Under subsection 40(5) of the AHR Act, the Agency may issue premises licences to the owner or operator of any premises permitting the use of those premises for a controlled activity.

[5]As stated in paragraph 2(b) of the AHR Act's statutory declaration, *"the benefits of assisted human reproductive technologies and related research … can be most effectively secured by taking appropriate measures for the protection and promotion of human health, safety, dignity and rights in the use of these technologies and in related research."*

to excluding these activities from the requirement that they be undertaken in licensed premises.[6] As discussed above, persons who wish to undertake one of these four reimbursement activities would still be required to undertake the activity in accordance with the regulations and a licence; however, they would not be required to undertake the reimbursement activity in licensed premises.

Question:
1. Should each of the four reimbursement controlled activities be excluded from the requirement that they only be undertaken in licensed premises? Yes/No, please explain.

6. Health Canada is interested in collecting stakeholder contact information

This information will allow us to track responses from different stakeholder groups, and to contact you if we need clarification.

Providing contact information is voluntary. Note that the personal information you provide is protected under the *Privacy Act.* Please consult our privacy notice at the link below: http://www.hc-sc.gc.ca/home-accueil/important_e.html

Name (optional) _____

Organization (optional) _____

Address (optional) _____

Phone Number (optional) _____

Email (optional) _____

Which stakeholder group do you belong to? Please check all that apply.

__ General Public

__ Patient/Consumer Group

__ Surrogate Mother

__ Sperm/ova donors

__ Individual born of an AHR procedure

[6] As stated in paragraph 65(1)(z.2) of the AHR Act *"the Governor in Council may make regulations exempting controlled activities or classes of controlled activities, generally or in circumstances prescribed by the regulations, from the provisions of this Act, subject to any terms and conditions prescribed in the regulations."*

__ Health Professional

__ Health Professional Association

__ Academic/Researcher

__ Industry

__ Government

__ International Organization

Other: __

Thank you for your input.