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Compliance approach for the Reimbursement Related to Assisted Human Reproduction Regulations

POL-0124

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Canada

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Disclaimer

This document does not constitute part of the *Assisted Human Reproduction Act* (AHR Act) or its regulations and in the event of any inconsistency or conflict between the AHR Act or regulations and this document, the AHR Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the AHR Act, the regulations and the applicable administrative policies.

Table of contents

The following shows the icon used in this document, and the way it is intended to be used.

Information: Supplementary information like quotes and legal references.

1. Introduction

The *Reimbursement Related to Assisted Human Reproduction Regulations* (Reimbursement Regulations) came into force on June 9, 2020 and apply to persons who make reimbursements under the *Assisted Human Reproduction Act* (AHR Act). The AHR Act allows the following persons to be reimbursed for expenditures, on condition that receipts are provided for the expenditures and the reimbursement is made in accordance with the Reimbursement Regulations:

- sperm and ova donors and surrogate mothers who incur expenditures in the course of their donation and in relation to their surrogacy, respectively, that fall within the scope of eligible expenditures set out in the Reimbursement Regulations; and
- persons who incur expenditures for the maintenance and transport of an *in vitro* embryo that also fall within the scope of eligible expenditures set out in the Reimbursement Regulations.

Furthermore, the AHR Act allows a surrogate mother to be reimbursed, in accordance with the Reimbursement Regulations, for the loss of work-related income incurred during her pregnancy if 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.

Although there is no obligation to reimburse, the AHR Act allows the reimbursement of eligible expenditures, provided a receipt for the expenditure is provided and the reimbursement is made in accordance with the Reimbursement Regulations. For more information regarding the Reimbursement Regulations, please refer to the *Guidance Document: Reimbursement Related to Assisted Human Reproduction Regulations*.

Health Canada is the federal authority responsible for the administration and enforcement of the AHR Act and its associated Regulations. Health Canada's Regulatory Operations and Enforcement Branch (ROEB) is responsible for compliance and enforcement activities in relation to the AHR Act. The *Compliance and enforcement policy for the Assisted Human Reproduction Act* (POL-0100) describes the national compliance and enforcement approach for materials and activities subject to the AHR Act and its Regulations.

2. Purpose

The purpose of this policy is to outline the compliance activities that Health Canada will conduct with regards to:

- section 12 of the AHR Act
- the Reimbursement Regulations

Health Canada will promote and monitor compliance and address areas of non-compliance with regulated parties in order to minimize the potential risks to Canadians that are involved in the reimbursements under the AHR Act and the Reimbursement Regulations. Any enforcement action taken will be in accordance with Health *Canada's* *Compliance and enforcement policy for the Assisted Human Reproduction Act* (POL-0100).

3. Scope

This policy applies to the compliance activities undertaken by Health Canada to promote and monitor compliance with the Reimbursement Regulations and applicable sections of the AHR Act.

This policy applies to any persons that are conducting activities governed by the Reimbursement Regulations. Specifically, it applies to persons that do any of the following activities:

- Reimburse surrogate mothers for expenditures incurred by such mothers in relation to their surrogacy
- Reimburse surrogate mothers for loss of work-related income incurred during their pregnancy
- Reimburse sperm and ova donors for expenditures incurred in the course of donating sperm or ova
- Reimburse persons for expenditures incurred in the maintenance and transport of in-vitro embryos

4. Compliance activities

Compliance promotion

Health Canada has found that compliance promotion is an effective tool to facilitate compliance. Compliance promotion focuses on raising awareness and educating regulated parties about their obligations under the AHR Act and its Regulations. Health Canada publishes policies and guidance documents to share with regulated parties its interpretation of the legislation, the processes to be followed, and the principles that will generally be applied. Health Canada promotes compliance through educational activities and information-sharing on legislative and regulatory matters.

Compliance monitoring

Health Canada monitors the activities of regulated parties to verify they are complying with the AHR Act and its Regulations, to respond to issues of non-compliance, and to address potential risks posed to Canadians. When a regulated activity does not comply with the law, Health Canada makes an assessment to determine the most appropriate type of intervention to mitigate the risk of the non-compliance. Inspectors designated under the AHR Act have the authority, under section 47, to verify compliance or prevent non-compliance with section 12 of the AHR Act. Any enforcement action taken will be in accordance with *the Compliance and enforcement policy for the Assisted Human Reproduction Act* (POL-0100). Such enforcement actions could range from issuing compliance letters or conducting inspections, to seizure or prosecution under the AHR Act.

Complaint-based compliance monitoring

Health Canada is committed to verifying complaints from Canadians (e.g., donors, surrogates, intended parents, children born of assisted human reproduction (AHR), healthcare professionals, and clinics) and industry regarding materials or activities or any matters that are subject to the AHR Act or its Regulations. All complaints are prioritized according to the nature of the non-compliance.

When a complaint is received by Health Canada, the information will be reviewed to determine if it falls under the AHR Act and its associated Regulations. If it does, an acknowledgement will be sent to confirm that the complaint was received and will be reviewed. If a complaint does not fall under the AHR Act and the Regulations, Health Canada will notify the complainant. If appropriate, Health Canada may refer the complainant or the matter directly to the appropriate authority, provided consent has been obtained.

To report a complaint under the AHR Act, please refer to Complaint form for the *Assisted Human Reproduction Act*.

Proactive compliance monitoring

Proactive compliance monitoring activities may vary and can include, gathering and analyzing information, carrying out compliance verification activities for a possible non-compliance, collaborating with other regulatory agencies, and may include inspections, as appropriate.

Health Canada takes a risk-based approach to compliance and enforcement activities, therefore the frequency, intensity and nature of compliance monitoring activities may vary according to the type and level of risks identified and other Health Canada priorities. Health Canada uses

information gathered through compliance monitoring to determine if further regulatory action is required. In particular, Health Canada may:

- gather and analyze a range of information, including information shared by foreign regulators
- carry out activities to verify compliance in response to information regarding known or possible non-compliance with the applicable requirements in the AHR Act or Regulations
- collaborate with other regulatory authorities (i.e. Provincial and Territorial Governments), as appropriate
- conduct planned information gathering projects that may focus on specific areas of the regulations or target specific regulated parties to help determine if there are additional problems or areas of non-compliance that require enforcement actions
- consult with additional subject matter experts, as needed

5. Contact information

For questions about the compliance and enforcement approach, please contact the Biological Product Compliance Program: hc.bpcp-pcpb.sc@canada.ca

Appendices

Appendix A – Glossary

Acronyms

AHR Act: *Assisted Human Reproduction Act*

ROEB: Regulatory Operations and Enforcement Branch

Terms

These definitions explain how terms are used in this document. If there is a conflict with a definition in the *Assisted Human Reproduction Act* or associated Regulations, the definition in the AHR Act or Regulations prevails.

Compliance – The state of conformity of a regulated party (including a corporation, institution, individual or other legal entity) with a legislative or regulatory requirement.

Compliance monitoring – Actions planned to maintain regular surveillance in order to evaluate compliance with applicable requirements of the *Assisted Human Reproduction Act* and its associated Regulations. This includes a wide variety of fact gathering and assessment activities such as inspections, market surveys and product sampling program.

Compliance promotion – Actions taken to educate about roles and responsibilities prescribed by the *Assisted Human Reproduction Act* and Regulations.

Enforcement – Actions that may be taken to compel or induce compliance in order to mitigate the risk identified by non-compliance with the *Assisted Human Reproduction Act* and its associated Regulations.

Inspection – With respect to verifying compliance or preventing non-compliance with sections 8,10 or 12, monitoring and assessment against the applicable requirements of the *Assisted Human Reproduction Act* and its associated Regulations. Inspections may also be routinely conducted based on risk to assess compliance.

Inspector – Any person designated as an inspector under section 46 of the *Assisted Human Reproduction Act*.

Appendix B – References

Laws and regulations

Assisted Human Reproduction Act
https://laws-lois.justice.gc.ca/eng/acts/a-13.4/

Reimbursement Related to Assisted Human Reproduction Regulations
https://laws-lois.justice.gc.ca/eng/regulations/SOR-2019-193/index.html

All regulations made under the AHR Act can be accessed by clicking on the link attached to the *Assisted Human Reproduction Act*.

Other related information

Assisted Human Reproduction
canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/legislation-guidelines/assisted-human-reproduction.html

Assisted Human Reproduction Compliance and Enforcement
canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/assisted-human-reproduction.html

Compliance and Enforcement policy for the Assisted Human Reproduction Act (POL-0100)
canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/compliance-enforcement-policy-assisted-human-reproduction.html

Guidance Document: Reimbursement Related to Assisted Human Reproduction
canada.ca/en/health-canada/programs/consultation-reimbursement-assisted-human-reproduction/document.html