



Guidance Document

Reimbursement Related to Assisted Human Reproduction Regulations

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Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document *may be* acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant programme area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable Guidance documents.

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Introduction

Purpose/Overview

This Guidance document provides information on the interpretation and application of the *Reimbursement Related to Assisted Human Reproduction Regulations* (the Regulations) which are made under the *Assisted Human Reproduction Act* (AHR Act).

Scope and application

The Regulations and this Guidance document apply to persons who make reimbursements under the AHR Act. The AHR Act provides that the following persons may be reimbursed provided receipts are provided for the expenditure and the reimbursement is made in accordance with the Regulation:

- 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 Regulations may be reimbursed; 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 Regulations may also be reimbursed.

Furthermore, the AHR Act allows a surrogate mother to be reimbursed in accordance with the 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.

Policy objectives

The objective of the reimbursement regulatory framework under the AHR Act is to provide parameters for the reimbursement of expenditures and loss of work-related income for surrogate mothers. For the most part this is accomplished in two ways:

- The Regulations set out categories of reimbursable expenditures that could be incurred by a sperm or ova donor or surrogate mother in relation to their donation or surrogacy.
- The Regulations establish a verifiable process by which reimbursements that are subject to s.12 may be made. Specifically, they require evidence that a reimbursement has been made in accordance with the Act and Regulations, which is to be documented by the parties involved. This is to enable compliance and enforcement activities, as well as to provide clarity and structure to the reimbursement process for stakeholders.

Policy statements

The principles of reimbursements made under the AHR Act are as follows:

- Eligible expenditures incurred in the course of sperm or ova donation, in the maintenance or transportation of an *in vitro* embryo, or, for surrogate mothers, eligible expenditures incurred by her in relation to her surrogacy and the loss of work-related income, may be reimbursed only if it is done in accordance with the regulations.
- There is no obligation to reimburse, meaning that only persons who wish to reimburse eligible expenditures will do so.
- Reimbursement must not involve monetary gain by involved parties, nor should it be a disguised form of payment or purchase.
- Payment of "anticipated expenses" or an "unaccountable allowance" would be considered by Health Canada as a contravention of the prohibition in the AHR Act.
- Whether or not a specific expenditure is incurred in the course of a donation or in relation to a surrogacy depends on the particular circumstance(s) of the donation or surrogacy.
- Except where an exemption is provided for in the Regulations, a receipt for the eligible expenditure must be provided to the reimbursing party as a condition of the reimbursement.

Health Canada is of the view that reimbursements made in respect of matters not set out in section 12 of the AHR Act are not automatically prohibited by section 6 or 7 of the Act. Certain reimbursements may be reasonably justified, such as reimbursing an ova donor for the loss of work-related income, or reimbursing an *in vitro* embryo donor for expenditures such as those incurred for counselling or legal services.

However, care must be taken by persons making such reimbursements to ensure that they can demonstrate that the reimbursement is not a disguised form of payment that is prohibited by sections 6 or 7 of the AHR Act. This may be achieved in part by taking the following suggested measures:

- ensuring that a receipt is provided for all expenditures that are reimbursed;
- completing a signed declaration form prior to issuing a reimbursement; and
- ensuring that, where applicable (e.g., if a person reimburses an ova donor for the loss of work-related income), a certification from a qualified medical practitioner is provided to the reimbursing party prior to their issuing a reimbursement.

Background

The AHR Act received royal assent on March 29, 2004. The AHR Act was based on recommendations made by the 1993 Royal Commission on New Reproductive Technologies, which had the mandate to examine the ethical, legal, social and economic implications of reproductive technologies and their impact on Canadian society, and in particular on women, children and families.

The AHR Act was written to be a comprehensive legislative framework that established provisions to help protect and promote the health, safety, dignity, and rights of Canadians who use or are born of AHR technology. The goal of the AHR Act is to help protect Canadians by setting out prohibited activities related to assisted human reproduction that may pose significant human health and safety risks to Canadians or that were deemed to be ethically unacceptable or incompatible with Canadian values.

Sections 6 and 7 of the AHR Act contain prohibitions aimed at preventing the commercialization of surrogacy and sperm and ova donation. These prohibitions are consistent with one of the key principles that underpin the Act, in which the Parliament of Canada recognizes and declares that, “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.”

The AHR Act prohibits the purchase of sperm and ova from a donor or person acting on behalf of a donor and prohibits the payment to a female person to be a surrogate mother. Despite these prohibitions, Health Canada recognizes that sperm and ova donors and surrogate mothers should not be out-of-pocket for expenditures they incur as a result of their donation or surrogacy. Similarly, while the purchase and sale of *in vitro* embryos is prohibited by the AHR Act, any person involved in the donation of an *in vitro* embryo should not be out-of-pocket for expenditures related to the maintenance and transport of that embryo for the purpose of the donation.

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 done in accordance with the regulations.

Guidance for Implementation

Note: The statements enclosed in the boxes are sections taken directly from the Regulations. If there is a discrepancy between the text in this guidance and the Regulations, the Regulations will take precedence.

Interpretation

Definitions

1 The following definitions apply in these Regulations.

Act means the *Assisted Human Reproduction Act*. (*Loi*)

dependant means, in respect of a donor of sperm or ova or a surrogate mother, a person who resides with them and is dependent on them by reason of age or mental or physical incapacity. (*personne à charge*)

The purpose of defining dependant is to permit sperm and ova donors and surrogate mothers to be reimbursed for expenditures related to providing care for not only their children but also someone else who may be under their care, for example, an aging parent.

Reimbursement of Expenditures

Expenditures — donating sperm or ova

2 The following expenditures incurred by a donor in the course of donating ova or sperm may be reimbursed under subsection 12(1) of the Act:

- (a)** travel expenditures, including expenditures for transportation, parking, meals and accommodation;
- (b)** expenditures for the care of dependants or pets;
- (c)** expenditures for counselling services;
- (d)** expenditures for legal services and disbursements;
- (e)** expenditures for obtaining any *drug* or *device* as defined in section 2 of the *Food and Drugs Act*;
- (f)** expenditures for obtaining products or services that are provided or recommended in writing by a person authorized under the laws of a province to practise medicine in that province;
- (g)** expenditures for obtaining a written recommendation referred to in paragraph (f).
- (h)** expenditures for health, disability, travel, or life insurance coverage; and
- (i)** expenditures for obtaining or confirming medical or other records.

Note: Section 2 of the Regulations sets out expenditures for sperm and ova donors. However, many of the expenditures set out in section 2 are also included in section 4, which applies to surrogate mothers. Where there is overlap between the categories, this is indicated in this document and an explanation of those categories appears within this section.

Counselling services

This category of expenditures applies to sperm and ova donors and surrogate mothers, in recognition that prior to the donation of sperm or ova or agreeing to become a surrogate mother or entering into a surrogacy arrangement, donors and surrogate mothers may choose to, or be required to undergo counselling. Furthermore, donors and surrogate mothers may wish to undergo counselling during the post-donation or post-pregnancy period. This may include (but is not limited to) psychosocial and genetic counselling. This category of expenditure allows donors and surrogate mothers to be reimbursed for the costs associated with such services.

Health Canada is of the view that expenditures for counselling services that may be incurred prior to or following the actual donation or pregnancy are sufficiently incurred “in the course of donating” and “in relation to” the surrogacy, respectively. This means that donors and surrogate mothers may be reimbursed for these expenditures, provided the reimbursement is done in accordance with the regulations.

Drug or device as defined in section 2 of the *Food and Drugs Act*

This category of expenditure, which applies to both donors and surrogate mothers, allows donors and surrogate mothers to be reimbursed for expenditures they incur for obtaining a drug or device in the course of their donation or in relation to their surrogacy.

This includes prescription and non-prescription drugs and natural health products, such as:

- over-the-counter drugs (e.g., cough and cold remedies, antacids, laxatives);
- behind-the-counter drugs (e.g., certain heartburn drugs);
- vitamins and minerals;
- nutritional supplements;
- herbal remedies;
- homeopathic medicines;
- traditional medicines;
- probiotics; and
- other products, such as amino acids and essential fatty acids.

It also includes medical devices, such as blood pressure monitors, breast pumps and postpartum pads.

Products or services provided by or recommended in writing by a person authorized under the laws of a province to practise medicine in that province

This category of expenditure is intentionally broad, as Health Canada recognizes that the individual circumstances may vary from donation to donation. The purpose of this category is to allow sperm and ova donors to be reimbursed for the cost of obtaining any product or service in the course of the donation that are provided by or prescribed by or recommended in writing by their doctor. For instance, this category would cover expenditures associated with the retrieval for ova donors.

Obtaining or confirming medical or other records

This category of expenditure, which applies to both sperm and ova donors and surrogate mothers, is intended to permit donors and surrogate mothers to be reimbursed for the cost of obtaining or confirming medical records that may be required as a result of their donation or surrogacy, as well as other records such as, for example, a proof of citizenship.

Expenditures — maintenance and transport of *in vitro* embryo

3 The following expenditures incurred by any person may be reimbursed under subsection 12(1) of the Act:

- (a) expenditures for the maintenance of an *in vitro* embryo, including storage; and
- (b) expenditures for the transport of an *in vitro* embryo, including expenditures for preparing it for transport, for the shipping container and for preparing the container for transport.

The purpose of this section of the Regulations is to set out the expenditures incurred in the maintenance and transport of an *in vitro* embryo for which a person may be reimbursed. These expenditures could be incurred by individuals who have decided to donate their own embryos. They could also be incurred by a fertility clinic that transfers an *in vitro* embryo to another clinic or to a laboratory for research purposes.

Expenditures — surrogacy

4 The following expenditures incurred by a surrogate mother in relation to her surrogacy may be reimbursed under subsection 12(1) of the Act:

- (a)** travel expenditures, including expenditures for transportation, parking, meals and accommodation;
- (b)** expenditures for the care of dependants or pets;
- (c)** expenditures for counselling services;
- (d)** expenditures for legal services and disbursements;
- (e)** expenditures for obtaining any *drug* or *device* as defined in section 2 of the *Food and Drugs Act*;
- (f)** expenditures for obtaining products or services that are provided or recommended in writing by a person authorized under the laws of a province to assess, monitor and provide health care to a woman during her pregnancy, delivery or the post-partum period;
- (g)** expenditures for obtaining a written recommendation referred to in paragraph (f);
- (h)** expenditures for the services of a midwife or doula;
- (i)** expenditures for groceries, excluding non-food items;
- (j)** expenditures for maternity clothes;
- (k)** expenditures for telecommunications;
- (l)** expenditures for prenatal exercise classes;
- (m)** expenditures related to the delivery;
- (n)** expenditures for health, disability, travel, or life insurance coverage; and
- (o)** expenditures for obtaining or confirming medical or other records.

Products or services that are provided by or recommended in writing by a person who is authorized under the laws of a province to assess, monitor and provide health care to a woman during her pregnancy, delivery or the post-partum period

Like the similar category for sperm and ova donors, this category of expenditure is intentionally broad, as Health Canada recognizes that individual circumstances will vary.

For example, this category could permit a surrogate mother to be reimbursed for the cost of household maintenance (e.g., snow removal, cleaning) to support their doctor's written recommendation of bedrest or avoiding strenuous activity.

Likewise, for example, if their doctor recommends alternative or complementary health care services (e.g., chiropractor, massage therapy) to support the surrogate mother's pregnancy, expenditures for such services may be reimbursed.

This category was also designed in recognition that a surrogate mother's primary health care provider may not always be a physician. For example, if a surrogate mother is under the care of a midwife, in provinces where a midwife is authorized to assess, monitor and provide health care to a woman during her pregnancy, delivery or the postpartum period, the midwife can provide or recommend in writing products or services that would protect or promote the health of the surrogate mother and the baby.

Groceries

Health Canada recognizes that a woman's nutritional and overall health, before and during pregnancy, influences the health of her developing baby. The nutrient intake for pregnant women and women who are breastfeeding are generally greater than those of other women. For instance, women who have a normal body weight at the start of their pregnancy need about 350 extra calories a day in their second trimester and 450 extra calories a day in their third trimester¹. These extra calories help them provide the nutrition needed to support the baby's growth and development. This category of expenditure allows a surrogate mother to be reimbursed for the additional costs for groceries needed to support a healthy pregnancy.

Surrogate mothers may also be asked by intended parents to adopt a special diet for the duration of their pregnancy that may result in a more expensive grocery bill for the surrogate mother. This category of expenditure allows for a surrogate mother to be reimbursed for these out-of-pocket expenditures.

A person who reimburses a surrogate mother for this category of expenditure must be able to demonstrate that the amount reimbursed is consistent with the out-of-pocket expenditure incurred by the surrogate mother in relation to their surrogacy.

Health Canada will not prescribe the manner by which this amount is calculated, but care should be taken to ensure that such reimbursements are only for the cost of additional groceries that are required to support a healthy pregnancy and not disguised forms of payment (e.g., paying the grocery bill for a surrogate mother's entire family for the duration of the pregnancy), and thus a possible contravention of the AHR Act.

Telecommunications costs

Surrogate mothers may incur expenditures related to communicating with the intended parents (e.g., long distance phone charges if the intended parents do not live in the same city as the surrogate mother). This category allows surrogate mothers to be reimbursed for

¹ <https://www.canada.ca/en/health-canada/services/publications/food-nutrition/prenatal-nutrition-guidelines-health-professionals-background-canada-food-guide-2009.html>

those expenditures. However, much like for groceries, the person who reimburses must be able to demonstrate that the amount being reimbursed is for the costs that are directly related to the surrogacy and not disguised forms of payment (e.g., paying a surrogate mother's entire telecommunications bill, including for cable TV, high speed internet, etc.).

Expenditures — use of an automobile

5 In the case of expenditures referred to in paragraphs 2(a), 3(b) and 4(a), the maximum amount that may be reimbursed for the use of an automobile, other than an automobile used by a transportation service that provides a receipt, is the amount that is calculated on the basis of the distance driven in kilometres and the applicable automobile allowance rate posted on the Canada Revenue Agency's website for the year in which the transport or transportation occurred.

Sperm and ova donors and surrogate mothers may incur an out-of-pocket expenditure when they use their own vehicle to, for example, travel to a medical appointment. Likewise, a person who transports an *in vitro* embryo using their own vehicle may also wish to be reimbursed for the cost of doing so. This section establishes the means by which the amount to be reimbursed must be calculated.

The Canada Revenue Agency's [automobile allowance rates](#) may be found online.

Preliminary requirements for reimbursement

6 A person may only reimburse the applicable expenditure referred to in sections 2 to 4 to the person requesting reimbursement if they have obtained the following documents:

- (a)** a declaration dated and signed by the person who requests the reimbursement that sets out
 - (i)** their name and address,
 - (ii)** the nature of each expenditure incurred,
 - (iii)** with respect to each expenditure, the amount incurred and, if less than the amount incurred, the amount requested for reimbursement,
 - (iv)** the date on which each expenditure was incurred,
 - (v)** in the case of a transport or transportation expenditure for the use of an automobile, other than an automobile used by a transportation service that provides a receipt, with respect to each trip,
 - (A)** the addresses of the points of departure and destination, and
 - (B)** the total distance in kilometres driven between those two points,

(vi) a statement indicating that each expenditure was incurred in the course of donating sperm or ova, in the maintenance or transport of an *in vitro* embryo or in relation to a surrogacy, as applicable,

(vii) a statement for each expenditure indicating that the amount has not been paid to them by any other source, in full or in part, and

(viii) a statement confirming that all of the information contained in the declaration is accurate and complete to the best of their knowledge;

(b) if applicable, a copy of the written recommendation of a person authorized under the laws of a province to practise medicine in that province and obtained in relation to a product or service for which a request for reimbursement has been made;

(c) if applicable, a copy of the written recommendation of a person authorized under the laws of a province to assess, monitor and provide health care to a woman during her pregnancy, delivery or the postpartum period and obtained in relation to a product or service for which a request for reimbursement has been made; and

(d) a receipt for each expenditure for which the reimbursement is requested that identifies the date on which the expenditure was incurred, except in the case of transport or transportation expenditures for the use of an automobile in accordance with section 5.

This section sets out the main documentation requirements for a person who reimburses a sperm or ova donor, a surrogate mother, or a person maintaining or transporting an *in vitro* embryo, for an out-of-pocket expenditure that is subject to the Act. Prior to making the reimbursement, the person must obtain the signed declaration form that sets out, among other things, the expenditures being reimbursed, the dates on which they were incurred, and the amount being requested. They must also obtain, if applicable, a copy of the written recommendation for products or services, and a receipt for each expenditure, unless otherwise exempted (see section 2.4 of the Guidance).

Persons who reimburse are to ensure that they have the required documents prior to reimbursing. Health Canada will not prescribe the format of the declaration form. To help guide persons requesting reimbursements, a sample [Reimbursement of Expenditures Declaration Form](#) is available from Health Canada. Note that, provided they are made in accordance with the regulations, Health Canada leaves the frequency with which reimbursements are made entirely to the parties involved. For sperm and ova donors, reimbursing at the time of each donation may be the most practical. Whereas, for surrogate mothers, a weekly or monthly reimbursement schedule may make the most sense.

Reimbursement — sign and affirm

7 A person who reimburses an expenditure set out in a declaration must indicate on the declaration the amount of each expenditure that they reimbursed and the date of the reimbursement and must sign it to affirm that information.

This section sets out the requirement that the person who issues the reimbursement must indicate the amount they are reimbursing and sign the declaration form.

Reimbursement of Surrogate Mother for Loss of Work-Related Income

The AHR Act prohibits a person from reimbursing a surrogate mother for the 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.

Provided those conditions are met, Health Canada does not prescribe limitations around the amount of time a surrogate mother must not be able to work before they may be reimbursed for the loss of work-related income.

In other words, surrogate mothers may be reimbursed for the loss of work-related income both for extended absences from work (e.g., doctor-prescribed bedrest) and short absences from work (e.g., to attend regular doctor appointments), provided they obtain the required written certification and the reimbursement is made in accordance with the regulations.

Similarly, Health Canada is of the view that surrogate mothers may be reimbursed for the loss of work-related income during the pre-pregnancy and the post-partum period, provided they obtain the required written certification from the qualified medical professional and provided the reimbursement is made in accordance with the regulations. Such an interpretation gives primacy to the health and safety of the surrogate mother and the child, which is consistent with key principles underpinning the AHR Act.

Preliminary requirements for reimbursement

8 A person may only reimburse a surrogate mother for a loss of work-related income incurred during her pregnancy under subsection 12(3) of the Act if they have obtained the following documents:

- (a)** a declaration dated and signed by the surrogate mother that sets out
 - (i)** her name and address,
 - (ii)** the start and end dates of the period when she did not work for a reason certified by a qualified medical practitioner under paragraph 12(3)(a) of the Act,
 - (iii)** the amount requested for reimbursement,
 - (iv)** a statement indicating that she has not received compensation from any other source, in full or in part, for the loss of income, and

- (v) a statement indicating that all of the information submitted in the declaration is accurate and complete to the best of her knowledge;
- (b) supporting evidence of the income that she would have earned had she not been absent from work for the period specified in subparagraph (a)(ii); and
- (c) a copy of the certification provided in paragraph 12(3)(a) of the Act.

This section sets out the main documentation requirements for a person who reimburses a surrogate mother for the loss of work-related income incurred during her pregnancy. Prior to making the reimbursement, the person must obtain the signed declaration form that sets out, among other things, the beginning and end dates of the period the surrogate mother did not work for a reason certified by a qualified medical practitioner and the amount requested for reimbursement. They must also obtain supporting evidence of income and a copy of the written certification.

Persons who reimburse are to ensure that they have the required documents prior to reimbursing. Health Canada will not prescribe the format of the declaration form. To help guide persons requesting reimbursements, a sample [Reimbursement of Loss of Work Related Income Declaration Form](#) is available from Health Canada.

As with other reimbursements, Health Canada leaves the frequency of reimbursements for the loss of work-related income to the parties involved. For instance, if the surrogate mother will miss one month of work due to being prescribed bedrest by a qualified medical practitioner, being reimbursed every two weeks to correspond with their usual pay schedule may be appropriate. More frequent reimbursements may be more fitting for shorter absences from work.

Reimbursement — sign and affirm

9 A person who reimburses a surrogate mother for a loss of work-related income must indicate on the declaration the amount of the loss of income that they reimbursed and the date of the reimbursement, and must sign it to affirm that information.

This section sets out the requirement that the person who issues the reimbursement must indicate the amount they are reimbursing and sign the declaration form.

Exemption

Exemption regarding receipt

10 A person who reimburses transport or transportation expenditures is exempt from the application of subsection 12(2) of the Act if the expenditures were incurred for the use of an automobile, other than an automobile used by a transportation service that provides a receipt.

The AHR Act prohibits a person from making a reimbursement that is subject to the Act unless a receipt is provided for the expenditure. Health Canada intends to take a broad view of what constitutes a receipt for the purposes of the Act and the Regulations. For most expenditures, a conventional receipt (i.e., as one would receive from a store after purchasing goods or services) should be available.

However, for other expenditures where a conventional receipt is not generated (e.g., paying a babysitter), a written and signed documentation acknowledging the receiving of goods or money that indicates the date upon which the expenditure occurred would be considered sufficient to satisfy the requirement.

The only expenditure for which any type of receipt cannot be obtained is in cases where a person uses their personal vehicle, such as a sperm or ova donor or a surrogate mother driving themselves in a private vehicle to clinic or medical appointments. The donor or surrogate mother would have purchased fuel, thus incurring an expenditure, but most likely would use fuel already in the gas tank, so no receipt is available for the exact amount of fuel used. It is for this reason that no receipt is required for this expenditure. Section 5 of the Regulations establishes how to calculate the amount to be reimbursed.

Maintenance of Records

Maintain records — reimbursement for expenditures

11 (1) A person who reimburses expenditures referred to in these Regulations must, for each reimbursement, maintain a record of all documents obtained for the purposes of that reimbursement for a period of six years after the date of the reimbursement.

Maintain records — reimbursement for loss of income

(2) A person who reimburses a surrogate mother for a loss of work-related income must, for each reimbursement, maintain a record of all documents obtained for the purposes of that reimbursement for a period of six years after the date of the reimbursement.

This means that a person who reimburses must keep all of the documentation required by the regulations for six years after the date of reimbursement.

Provision of Records to Minister

Notice from Minister

12 (1) The Minister may, by written notice, require a person who must maintain a record in relation to a reimbursement under section 11 to provide to the Minister any record or additional information related to the reimbursement by the date specified in the notice.

Obligation to provide records or information

(2) Any person who has been notified under subsection (1) must provide to the Minister any required records or additional information related to the reimbursement by the date specified in the notice.

The Minister may require a person who must maintain records pursuant to s.11 of the Regulation to submit their records or any additional information in relation to a reimbursement made under these Regulations. If a person receives a written notice under 12(1), the person is obligated to provide those records to the Minister, by the date specified in the notice.

The notice will include information on how the records or additional information can be submitted.

Coming into Force

13 These Regulations come into force on the day on which section 12 of the *Assisted Human Reproduction Act*, chapter 2 of the Statutes of Canada, 2004, comes into force.

This means that the regulations take effect on June 9, 2020. The reason for the one-year delay is to avoid impacting existing surrogacy contracts. However, any contracts entered into during the one-year period should reflect the Regulations and should account for their eventual coming into force.