Gouvernement du Québec

O.C. 644-2010, 7 July 2010

An Act respecting clinical and research activities related to assisted procreation (2009, c. 30)

Clinical activities related to assisted procreation

Regulation respecting clinical activities related to assisted procreation

WHEREAS paragraphs 1, 2, 4, 5, 6 and 7 of section 30 of the Act respecting clinical and research activities related to assisted procreation (2009, c. 30) empower the Government to make regulations on the matters set forth therein;

WHEREAS, in accordance with sections 10 and 11 of the Regulations Act (R.S.Q., c. R-18.1), a draft Regulation respecting clinical activities related to assisted procreation was published in Part 2 of the *Gazette officielle du Québec* of 24 March 2010 with a notice that it could be made by the Government on the expiry of 45 days following that publication;

WHEREAS it is expedient to make the Regulation with amendments;

IT IS ORDERED, therefore, on the recommendation of the Minister of Health and Social Services:

THAT the Regulation respecting clinical activities related to assisted procreation, attached to this Order in Council, be made.

GÉRARD BIBEAU,
Clerk of the Conseil exécutif

Regulation respecting clinical activities related to assisted procreation

An Act respecting clinical and research activities relating to assisted procreation
(2009, c. 30, s. 30, pars. 1, 2, 4, 5, 6 and 7)

1. This Regulation applies only to clinical activities related to assisted procreation.

DIVISION I
LICENCE

2. A physician referred to in section 4 of the Act respecting clinical and research activities relating to assisted procreation (R.S.Q., c. A-5.01) who applies for a licence for the class of clinical activities to operate a centre for assisted procreation must

(1) be solvent;

(2) not have been found guilty, in the 3 years preceding the application, of an offence against the Act;

(3) not have been the holder of a licence that, in the 3 years preceding the application, was revoked or not renewed under section 32 of the Act;

(4) not have been found guilty of a criminal offence in connection with the performance of activities for which a licence is applied for in the 5 years preceding the application or, if so, a pardon was granted;

(5) not have had his or her right to practise medicine limited or suspended or been temporarily struck off the roll in the 3 years preceding the application in connection with clinical activities related to the application;

(6) have a liability insurance contract in the amount of not less than $1,000,000 per claim providing coverage against the pecuniary consequences of the liability the physician may incur for fault or negligence committed while operating the centre for assisted procreation, and undertake to maintaining such a contract in force for the entire term of the licence; and

(7) have entered into a service agreement with an institution operating a hospital centre referred to in the Act respecting health services and social services (R.S.Q., c. S-4.2) or the Act respecting health services and social services for Cree Native persons (R.S.Q., c. S-5) so that a person who shows complications resulting from an assisted procreation activity may be directed there.

3. A licence application made by a physician referred to in section 2 must be accompanied by the physician's membership number at the Collège des médecins du Québec and by proof that the physician has an insurance contract provided for in paragraph 6 of that section and has entered into an agreement provided for in paragraph 7 of that section.

4. A legal person or partnership referred to in section 4 of the Act that applies for a licence for the class of clinical activities to operate a centre for assisted procreation must

(1) be solvent;

(2) not, nor must any of its directors, have been found guilty of an offence against the Act in the 3 years preceding the application;

(3) not have been the holder of a licence that, in the 3 years preceding the application, was revoked or not renewed under section 32 of the Act;

(4) not, nor must any of its directors, have been found guilty of a criminal offence in connection with the performance of activities for which a licence is applied for in the 5 years preceding the application or, if so, a pardon was granted;

(5) not have any physician sitting on the board of directors or on the internal management board who has had his or her right to practise medicine limited or suspended or been temporarily struck off the roll in the 3 years preceding the application in connection with clinical activities related to the application;

(6) have a liability insurance contract in the amount of not less than $1,000,000 per claim providing coverage against the pecuniary consequences of the liability it may incur for fault or negligence committed while operating the centre for assisted procreation, and undertake to maintaining such a contract in force for the entire term of the licence; and

(7) have entered into a service agreement with an institution operating a hospital centre referred to in the Act respecting health services and social services or the Act respecting health services and social services for Cree Native persons so that a person who shows complications resulting from an assisted procreation activity may be directed there.

5. An application for a licence made by a legal person or a partnership referred to in section 4 must be accompanied by

(1) a resolution from the board of directors or the internal management board authorizing the filing of a licence application;

(2) a copy of the constituting act or contract of partnership;

(3) the name and address of every shareholder or partner referred to in subparagraph 1 or 2 of the first paragraph of section 4 of the Act, the percentage of their shares in the legal person or partnership and the voting rights attached to the shares;

(4) the name and profession of the members of the board of directors or the internal management board;

(5) the membership number at the Collège des médecins du Québec of any physician referred to in paragraph 3 or 4;

(6) proof that the legal person or partnership has an insurance contract provided for by paragraph 6 of section 4; and

(7) proof that the legal person or partnership has entered into an agreement provided for in paragraph 7 of section 4.

6. An institution referred to in section 3 of the Act that applies for a licence to operate a centre for assisted procreation must hold a permit issued under the Act respecting health services and social services or the Act respecting health services and social services for Cree Native persons and provide a resolution from its board of directors authorizing the filing of a licence application.

7. A licence application made by a physician, a legal person, a partnership or an institution must also be accompanied by

(1) the name under which the centre intends to carry on activities;

(2) the name of the centre's director;

(3) the names of the physicians who will carry on assisted procreation activities in the centre, their specialty and their status as professionals subject to the application of an agreement or as non-participating professionals;

(4) a description of how the centre is organized and a list of the various specialties of staff members involved in the centre's clinical activities; and

(5) the state of the accreditation and, where applicable, the assessment report provided by the accreditation body.

8. A licence application must state the clinical activities that the centre intends to engage in.

9. A centre for assisted procreation for which a licence is required under the Act must group together either exclusively physicians subject to the application of an agreement entered into under section 19 of the Health Insurance Act (R.S.Q., c. A-29), or exclusively non-participating physicians within the meaning of that Act.

10. An application for renewal of the licence of a centre for assisted procreation must be made at least 6 months before the licence's date of expiry.

A permit holder seeking renewal must fulfil requirements and provide the documents and information provided for in section 2, 3, 4, 5, 6, 7, 8 or 9, as the case may be, except those already provided to the Minister if the applicant certifies that they are complete and accurate.

11. A licence holder must apply for a licence modification in the event of

(1) a change in the legal status of the centre; or

(2) a planned change of activities since the licence was issued.

The second paragraph of section 10 applies to an application for a licence modification.

12. A centre for assisted procreation must inform without delay the Minister in writing of any change in the state of the centre's accreditation.

13. The fees payable for the issue or renewal of a licence to operate a centre for assisted procreation to a physician, a legal person or partnership are $1,500.

14. Beginning 1 January 2011, the fees payable under section 13 are adjusted on 1 January of each year based on the percentage change, in relation to the preceding year, in the Consumer Price Index for Canada, as published by Statistics Canada under the Statistics Act (R.S.C. 1985, c. S-19). For that purpose, the Consumer Price Index for a year is the annual average calculated from the monthly indexes for the 12-month period ending on 30 September of the preceding year.

If the amounts obtained contain a fraction of a dollar, that fraction is cancelled. The amount is then rounded down to the nearest 10 dollars if the last figure is lower than 5, or rounded up to the nearest 10 dollars in all other cases.

The Minister is to inform the public of the adjustment under this section through Part 1 of the *Gazette officielle du Québec* or by such other means as the Minister considers appropriate.

DIVISION II
CONDITIONS AND STANDARDS GOVERNING ASSISTED PROCREATION CLINICAL ACTIVITIES

15. In addition to the obligations provided for in the Act, the director of a centre for assisted procreation must

(1) see that all information, including consents and expressions of intention, are adequately kept by the centre;

(2) see that the privacy of personal information held by the centre is preserved and require a written undertaking to that effect from each staff member;

(3) ensure that the information and documents provided for in the Act are sent to the Minister; and

(4) approve any use of biological material derived from assisted procreation and any transfer of such material to a physician or another centre.

16. The assisted procreation clinical activities referred to in section 2 of the Act that may be carried out outside a centre for assisted procreation are the following:

(1) the prescription of ovulatory stimulants or ovulation induction;

(2) folliculograms;

(3) sperm sampling and treatment for insemination purposes;

(4) sperm freezing and storage; and

(5) artificial insemination.

17. Following an *in vitro* fertilization activity, only one embryo may be transferred into a woman.

However, taking into account the quality of embryos, a physician may decide to transfer a maximum of 2 embryos if the woman is 36 years of age or under and a maximum of 3 embryos including no more than 2 blastocysts if the woman is 37 years of age or over.

A physician who transfers more than one embryo must justify his or her choice.

18. A preimplantation genetic diagnosis may be made on embryos only for the purpose of identifying serious monogenic diseases and chromosomal abnormalities.

19. At every stage of all assisted procreation activities, a free and enlightened consent must be given in writing, particularly from

(1) the donor, in the case of gamete donation;

(2) the person who undergoes the intervention, in the case of any clinical intervention relating to assisted procreation, particularly ovarian stimulation, egg retrieval or embryo transfer;

(3) the person to whom the gametes belong, the woman for whom the embryos were intended and any spouse, in cases involving assisted procreation activities relating to gamete or embryo cryoconservation and their storage;

(4) the woman for whom the embryo was intended and not transferred into her and any spouse, in cases of embryo donation for a parental project or research purposes; and

(5) the person concerned by the research project, in the case of a research project relating to assisted procreation activities, other than a research project involving embryos.

Such consent is also required where gametes or embryos are disposed of, from the person to whom the gametes belong or from the woman for whom the embryos were intended and from any spouse.

For the purposes of this Regulation, "spouse" means the spouse who is a party to the parental project.

20. Prior to any consent required for an assisted procreation activity, a person must be informed by a physician or a health professional of

(1) the adverse effects of the clinical intervention and the related risks, in particular risks of multiple pregnancy and the person's own morbidity risks;

(2) the procedures and their rates of success;

(3) the possibility that the number of eggs and embryos exceeds the person's and any spouse's needs and of the necessity to plan what will become of them;

(4) the possibility, for the person and any spouse, of withdrawing their consent and of the situations in which it will no longer be possible;

(5) the necessity to obtain the spouse's consent before disposing of an embryo, in particular for a parental project or for research purposes;

(6) the fact that gamete donation may involve a use for clinical or research purposes;

(7) the necessity for the person and any spouse to express their intents should death, the dissolution of the union or disagreement occurs;

(8) the fact that the centre will dispose of unused biological material should the person and any spouse fail to establish contact, after the time period provided for in section 24;

(9) the fact that the biological material will always be used according to the intents expressed, provided that the person and any spouse remain in contact with the centre and pay the conservation fees, where applicable;

(10) the physician's obligation to declare information on the treatment in order to provide surveillance of the health of persons who resorted to assisted procreation activities and of the children born of such activities;

(11) the possibility of long-term follow-up of *in vitro* fertilization activities, which involves that the person could be contacted again from time to time after the end of activities; and

(12) the availability of psychological support at the centre.

21. Where gametes have not been used or embryos not transferred, the gamete donor or the woman for whom the embryos were intended and any spouse must express their intent in writing regarding the donation, conservation or disposal of those gametes or embryos, in case of death, dissolution of the union, disagreement or where the woman is no longer of childbearing age or no longer has the physical capacity to bear children.

The persons referred to in the first paragraph may decide to change their previously expressed intents at all times, in writing.

22. The consents referred to in section 19 and the intents expressed in accordance with section 21 must be filed in the record of the person who resorted to assisted procreation activities and be kept by the centre for assisted procreation where those activities take place in such a centre.

23. A person and any spouse must contact the centre for assisted procreation at least once a year to express their intents again regarding the conservation or disposal of the gametes or embryos conserved there. Those persons must also inform the centre of any change of address.

24. Should the persons referred to in section 23 fail to make contact for more than 5 years, a centre for assisted procreation may conserve, donate, transfer or dispose of those persons' gametes or embryos in a manner that is acceptable in terms of ethics and recognized by the Minister.

25. A centre for assisted procreation may transfer eggs, sperm or embryos to another centre for assisted procreation or, in the case of sperm transfer, to a physician, for clinical or research purposes, provided that

(1) the applicant for biological material has provided his or her name and contact information, the date of the application and the expected date of transfer, the purpose, the identity of the physician responsible for using the material in a clinical environment or of the person responsible for the research project, the type of material requested and the quantity and state of that material;

(2) the centre's director ensured that the biological material will be used only for the purposes of a parental or research project approved by a committee on ethics recognized by the Minister; and

(3) the donors of biological material consented to the purpose for which the transfer will be made.

The director must record the information in the application and the information related to the transfer, in particular the name and contact information of the physician or centre that receives the eggs, sperm or embryos, the date of the application and the effective date of transfer, the purpose, the identity of the physician responsible for using the material in a clinical environment or of the person responsible for the research project, the type of material transferred and the quantity and state of that material.

That information must be kept within the centre permanently so as to ensure the traceability of biological material at all times.

26. Every centre for assisted procreation must, following an *in vitro* fertilization activity, gather information enabling it to know the fertilization results, particularly a birth, and send that information to the Minister in accordance with the Public Health Act (R.S.Q., c. S-2.2).

27. The annual report sent to the Minister by a centre for assisted procreation must contain and be accompanied, where applicable, by the following information and documents:

(1) the name of the centre;

(2) the state of the accreditation;

(3) the number of patients, the type and number of treatments administered;

(4) the distribution of treatments for each person and each of the centre's clinical activities;

(5) the number of multiple pregnancies and their type, in particular twins and triplets;

(6) detail about the type, state and quantity of biological material transferred to a physician or another centre, including the name of the physician or centre, the person in charge and the purpose for which the material was transferred; and

(7) the number of persons per sector of activity;

28. This Regulation comes into force on the fifteenth day following the date of its publication in the *Gazette officielle du Québec*.

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Gouvernement du Québec

O.C. 645-2010, 7 July 2010

Health Insurance Act
(R.S.Q., c. A-29)

Regulation
— Amendments

Regulation to amend the Regulation respecting the application of the Health Insurance Act

WHEREAS, under subparagraph *c*.2 of the first paragraph of section 69 of the Health Insurance Act (R.S.Q., c. A-29), enacted by section 48 of chapter 30 of the Statutes of 2009, the Government may, after consultation with the Régie de l'assurance maladie du Québec or upon its recommendation, make regulations to determine in which cases and on which conditions, such as age, assisted procreation services must be considered as insured services for the purposes of subparagraph *e* of the first paragraph of section 3 of the Act;

WHEREAS, in accordance with sections 10 and 11 of the Regulations Act (R.S.Q., c. R-18.1), a draft of the Regulation to amend the Regulation respecting the application of the Health Insurance Act was published in Part 2 of the *Gazette officielle du Québec* of 24 March 2010 with a notice that it could be made by the Government on the expiry of 45 days following that publication;

WHEREAS the Board was consulted regarding the amendments;

WHEREAS it is expedient to make the Regulation with amendments;

IT IS ORDERED, therefore, on the recommendation of the Minister of Health and Social Services:

THAT the Regulation to amend the Regulation respecting the application of the Health Insurance Act, attached to this Order in Council, be made.

GÉRARD BIBEAU,
Clerk of the Conseil exécutif