



NATIONAL ASSEMBLY OF QUÉBEC

FIRST SESSION

FORTY-SECOND LEGISLATURE

Bill 73

**An Act to amend various provisions
relating to assisted procreation**

Introduction

**Introduced by
Mr. Lionel Carmant
Minister for Health and Social Services**

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EXPLANATORY NOTES

This bill amends the Act respecting clinical and research activities relating to assisted procreation to introduce new provisions concerning mainly the quality, safety, ethics and planning of assisted procreation clinical activities.

In that respect, the bill provides that all assisted procreation activities, except the prescription of oral ovarian stimulants in the course of basic infertility treatments, must be carried out in a centre for assisted procreation for which a licence has been issued by the Minister of Health and Social Services. The Minister is granted the power to refuse to issue such a licence if the needs of the region where the centre for assisted procreation is to be situated do not warrant issuing one. A central clinical ethics committee is established whose function is to advise any professional who consults it on ethical issues associated with assisted procreation clinical activities.

Certain rules concerning the conservation of gametes and embryos by centres for assisted procreation are modified, as are certain rules concerning the exceptional transfer of two embryos into a woman in the course of in vitro fertilization activities. The Minister's inspection powers are strengthened and investigation powers are granted to the Minister. Centres for assisted procreation are required to communicate to the Minister the information the Minister prescribes by regulation that is necessary for public health, service planning and resource allocation purposes. The bill also provides, among other things, that a physician who applies for a licence to operate a centre for assisted procreation must submit a certificate attesting to the physician's good professional conduct, and defines the scope of the guidelines that the Collège des médecins du Québec must establish as regards assisted procreation.

The Health Insurance Act is amended to provide that the physician-rendered assisted procreation services determined by regulation are insured services the cost of which is assumed by the Régie de l'assurance maladie du Québec. The Regulation respecting the application of the Health Insurance Act is amended to prescribe which services are considered insured services as regards artificial insemination, in vitro fertilization and fertility preservation. In addition, the bill determines the persons for whom those services are considered insured services, by, among other things, establishing

criteria relating to their age, and the conditions that must be met for the services to be considered insured services, in particular that they be provided in centres for assisted procreation that hold a licence.

Lastly, the bill includes certain transitional provisions.

LEGISLATION AMENDED BY THIS BILL:

- Act respecting clinical and research activities relating to assisted procreation (chapter A-5.01);
- Health Insurance Act (chapter A-29).

REGULATIONS AMENDED BY THIS BILL:

- Regulation respecting clinical activities related to assisted procreation (chapter A-5.01, r. 1);
- Regulation respecting the application of the Health Insurance Act (chapter A-29, r. 5).

Bill 73

AN ACT TO AMEND VARIOUS PROVISIONS RELATING TO ASSISTED PROCREATION

THE PARLIAMENT OF QUÉBEC ENACTS AS FOLLOWS:

ACT RESPECTING CLINICAL AND RESEARCH ACTIVITIES RELATING TO ASSISTED PROCREATION

1. The Act respecting clinical and research activities relating to assisted procreation (chapter A-5.01) is amended by inserting the following section after section 8:

“8.1. A central clinical ethics committee is established by the Minister or designated by the Minister from among the existing clinical ethics committees. The function of the committee is to advise any professional who consults it on ethical issues associated with clinical activities relating to assisted procreation. The committee’s composition and operating conditions are determined by the Minister and published in the *Gazette officielle du Québec*.”

2. Section 10 of the Act is amended

(1) by replacing “and ensures that they are followed” in the first paragraph by “, ensures that they are followed and updates them in keeping with advances in scientific knowledge”;

(2) by inserting “the use of pharmaceutical procedures to stimulate the ovaries, the reasons which justify transferring two embryos in the course of an *in vitro* fertilization activity,” after “diagnosis,” in the second paragraph.

3. Section 10.3 of the Act is amended by replacing the second paragraph by the following paragraph:

“However, the physician may, if acting in accordance with the guidelines drawn up under section 10, transfer two embryos into a woman. The reasons justifying the decision must be entered in the woman’s medical record.”

4. Section 14 of the Act is repealed.

5. Section 14.1 of the Act is amended by replacing “a facility maintained by a health and social services institution within the meaning of the Act respecting health services and social services (chapter S-4.2)” by “a centre operated by an institution referred to in section 3 or having entered into a service agreement in that respect with an institution referred to in that section”.

6. Section 19 of the Act is amended by replacing “in the public interest” at the end of the first paragraph by “if the Minister considers it is in the public interest to do so, in particular in light of the needs of the region in which the centre is to be situated”.

7. The heading of Chapter IV of the Act is amended by replacing “OVERSIGHT” by “INVESTIGATION”.

8. Section 25 of the Act is amended by replacing the second, third and fourth paragraphs by the following paragraphs:

“The inspector may, in carrying out the functions of office,

(1) examine the premises and the property found on them and take photographs or make recordings;

(2) require any information relating to the application of this Act or the regulations and the communication of any related document for examination or reproduction;

(3) conduct tests or analyses and take measurements;

(4) open a container or any equipment used in the course of assisted procreation activities, or request that it be opened; and

(5) order any person on the premises to provide reasonable assistance to the inspector and accompany him or her.

An inspector may be accompanied by a person with special expertise or ask the centre for assisted procreation under inspection to have an expert assessment conducted and to provide the inspector with the resulting report, if such an assessment is considered necessary. The expenses incurred for the expert assessment are assumed by the centre.”

9. The Act is amended by inserting the following sections after section 25:

“26. An inspector may, by a request sent by registered mail or personal service, require any person to communicate by registered mail or personal service, within a reasonable time specified by the inspector, any information or document relating to the application of this Act or the regulations.

“26.1. The Minister may designate any person to investigate any matter relating to the application of this Act or the regulations.

“26.2. On request, an inspector or investigator must identify himself or herself and produce a certificate of authority.”

10. Section 27 of the Act is amended by inserting “, a person with special expertise accompanying an inspector, or an investigator” after “inspector”.

11. Section 28 of the Act is amended by inserting “or an investigation” after “inspection”.

12. Section 30 of the Act is amended

(1) by replacing “outside” in paragraph 1 by “elsewhere than”;

(2) by replacing paragraph 6 by the following paragraph:

“(6) prescribe the personal and non-personal information that a centre for assisted procreation must provide to the Minister;”.

13. Section 39 of the Act is replaced by the following section:

“39. Any person who hinders or attempts to hinder, in any way, the exercise of the functions of an inspector or investigator, particularly by deceiving the inspector or investigator by concealment or misrepresentation or, in the case of an inspector, by refusing to provide to the inspector information or a document the inspector is entitled to require, by concealing or destroying a document or property the inspector is entitled to require or examine or by refusing to provide reasonable assistance to the inspector or to accompany the inspector is guilty of an offence and is liable to a fine of \$5,000 to \$50,000 in the case of a natural person and \$15,000 to \$150,000 in all other cases.”

14. Section 42 of the Act is amended by inserting “and section 44” after “Chapter IV” in the first paragraph.

15. Section 44 of the Act is replaced by the following section:

“44. The Minister may require that a centre for assisted procreation communicate, at the time and in the form the Minister determines, the personal and non-personal information the Minister prescribes by regulation that is necessary

(1) for carrying out the functions of the Minister under section 431 of the Act respecting health services and social services (chapter S-4.2); or

(2) for carrying out the functions of the Minister and of the national public health director under the Public Health Act (chapter S-2.2).

Information communicated to the Minister that allows a person who resorted to assisted procreation activities, or a child born of such activities, to be identified is confidential and may not be communicated again by the Minister, even with the consent of the person concerned, except to the following persons and for the following reasons:

(1) to a public health director if its communication is necessary for carrying out the latter's functions of office under the Public Health Act; or

(2) to any person or body if its communication is necessary for carrying out a mandate or performing a contract of enterprise or for services entrusted to the person or body by the Minister.

Information communicated by the Minister to a public health director may be communicated by the public health director to another person or body only for the reasons set out in subparagraph 2 of the second paragraph."

16. Section 45 of the Act is replaced by the following section:

"45. Statistics on assisted procreation activities compiled from the information a centre for assisted procreation provides to the Minister must appear in a separate chapter of the department's annual report."

HEALTH INSURANCE ACT

17. Section 3 of the Health Insurance Act (chapter A-29) is amended by replacing subparagraphs *e* and *f* of the first paragraph by the following subparagraph:

"(e) assisted procreation services determined by regulation and rendered by a physician."

18. The Act is amended by inserting the following section after section 65.0.4:

"65.0.5. Before providing insured services referred to in subparagraph *e* of the first paragraph of section 3 to a person, a physician to whom an agreement applies is bound to provide to the Board all the information and documents the Board requires in order to verify whether the person is eligible for such services.

The Board shall communicate to the physician the result of the verification, including which of the insured services are available to that person."

19. Section 69 of the Act is amended by replacing subparagraph *c.2* of the first paragraph by the following subparagraph:

"(c.2) determine in which cases and on which conditions assisted procreation services must be considered insured services for the purposes of subparagraph *e* of the first paragraph of section 3, in particular by specifying the age at which insured persons may receive those services;"

REGULATION RESPECTING CLINICAL ACTIVITIES RELATED TO ASSISTED PROCREATION

20. Section 3 of the Regulation respecting clinical activities related to assisted procreation (chapter A-5.01, r. 1) is amended by replacing “the physician’s membership number at” by “a certificate of professional conduct concerning the physician issued by”.

21. Section 5 of the Regulation is amended

(1) by striking out “or 4” in paragraph 5;

(2) by inserting the following paragraph after paragraph 5:

“(5.1) a certificate of professional conduct issued by the Collège des médecins du Québec concerning any physician referred to in paragraph 4;”.

22. Section 7 of the Regulation is amended by inserting “and a certificate of professional conduct concerning the director issued by the Collège des médecins du Québec” at the end of paragraph 2.

23. The Regulation is amended by inserting the following sections after section 7:

“**7.1.** In the 3 years preceding the licence application, the centre’s director must not have had his or her right to practise medicine limited or suspended or have been temporarily struck off the roll in connection with clinical activities related to the licence application.

“**7.2.** In the class of clinical activities, a licence may be issued for the following subclasses of activities:

(1) sperm, egg or embryo freezing and storage;

(2) *in vitro* fertilization; and

(3) preimplantation genetic diagnosis.”

24. Section 15 of the Regulation is amended by striking out “physician or another” in paragraph 4.

25. Section 16 of the Regulation is replaced by the following section:

“**16.** The prescription of oral agents for ovarian stimulation in the course of basic infertility treatments is the only assisted procreation clinical activity within the meaning of section 2 of the Act which may be carried on elsewhere than in a centre for assisted procreation.”

26. Section 20 of the Regulation is amended by replacing “should death, the dissolution of the union or disagreement occurs” in paragraph 7 by “in case of death, dissolution of the union or disagreement or should they fail to make contact with the centre for more than 5 years”.

27. Section 21 of the Regulation is amended by replacing “, disagreement or where” in the first paragraph by “or disagreement, or should those persons fail to make contact with the centre for more than 5 years or when”.

28. Section 23 of the Regulation is amended by inserting “donation,” after “regarding the”.

29. Section 24 of the Regulation is amended by replacing “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” by “donate or dispose of those persons’ gametes or embryos according to the intent expressed by those persons provided it is done in an ethically acceptable manner that is recognized by the Minister”.

30. Section 25 of the Regulation is amended

(1) in the introductory clause of the first paragraph,

(a) by striking out “or, in the case of sperm transfer, to a physician,”;

(b) by inserting “only” after “embryos”;

(2) by striking out “physician or” in the second paragraph.

31. Section 27 of the Regulation is amended

(1) by replacing the introductory clause by the following:

“**27.** Every centre for assisted procreation must communicate the following information to the Minister:”;

(2) by replacing “physician or another centre, including the name of the physician or centre” in paragraph 6 by “centre, including the name of the centre”.

REGULATION RESPECTING THE APPLICATION OF THE HEALTH INSURANCE ACT

32. Section 22 of the Regulation respecting the application of the Health Insurance Act (chapter A-29, r. 5) is amended

(1) by inserting the following subparagraph after subparagraph iii of paragraph *q*:

“iv. this service is rendered for assisted procreation purposes under Division XII.2, in a centre for assisted procreation holding a licence issued under the Act respecting clinical and research activities relating to assisted procreation (chapter A-5.01);”;

(2) by striking out paragraph v.

33. Division XII.2 of the Regulation is replaced by the following division:

“DIVISION XII.2

“ASSISTED PROCREATION SERVICES

“34.3. For the purposes of this Division,

“assisted procreation project” means a project formed by a person alone or by spouses that consists in their obtaining assisted procreation services to have one or more children using, if needed, reproductive material from a person who is not party to the project;

“IVF” means *in vitro* fertilization;

“IVF cycle” means a cycle which begins at the time of the first ovarian stimulation or at the time of the ovarian puncture, as the case may be, and ends when no embryo was produced following the ovarian puncture or when all embryos produced following the ovarian puncture have been transferred;

“modified natural ovulatory cycle” means a cycle during which ovarian stimulation is performed to obtain one or more eggs;

“natural ovulatory cycle” means a cycle during which ovulation occurs spontaneously, without any ovarian stimulation;

“stimulated ovulatory cycle” means a cycle during which ovarian stimulation is performed to increase the number of eggs produced.

“34.4. Assisted procreation services required for artificial insemination and IVF purposes are considered insured services for the person alone or spouses party to the assisted procreation project if

(a) the person alone or spouses are insured persons;

(b) the person alone or either spouse has never before formed an assisted procreation project as part of which insured services referred to in sections 34.7 and 34.8 were provided;

(c) in the case of spouses, either is infertile or unable to reproduce; and

(d) the person alone or either spouse has not undergone voluntary surgical sterilization or had reanastomosis of the uterine tubes or the vas deferens, as the case may be, within the meaning of paragraphs *b* and *c* of section 34.2.

Every person party to the assisted procreation project must declare, using the form provided by the Board, that he or she meets the conditions prescribed in subparagraphs *a* to *d* of the first paragraph and that the information provided in the form is accurate and complete.

“34.5. Assisted procreation services required for artificial insemination and IVF purposes are considered insured services for an insured person who contributes to the assisted procreation project referred to in section 34.4, without being party to the project, by providing reproductive material free of charge.

“34.6. Assisted procreation services required for artificial insemination and IVF purposes are considered insured services only if

(a) the woman is 18 years of age or over and less than 41 years of age,

i. for artificial insemination, at the time of the ovarian stimulation during a stimulated ovulatory cycle or modified natural ovulatory cycle, on the first day of the menstrual cycle during a natural ovulatory cycle, and at the time of every insemination; or

ii. for IVF, at the time of the ovarian stimulation during a stimulated ovulatory cycle or modified natural ovulatory cycle, or at the time of the ovarian puncture during a natural ovulatory cycle;

(b) the woman is less than 42 years of age at the time of the last frozen embryo transfer; and

(c) the man is 18 years of age or over at the time of sperm retrieval.

“34.7. The following assisted procreation services required for artificial insemination purposes are considered insured services:

(a) according to medical indication, a maximum of six artificial inseminations, each of which includes the visit, sperm washing, technical procedures, and services required to retrieve sperm by medical intervention, including percutaneous epididymal sperm aspiration and surgical or microsurgical testicular sperm extraction;

(b) according to medical indication, a maximum of six stimulated ovulatory cycles or modified natural ovulatory cycles, whether the agents used are oral or injectable; and

(c) a maximum of six sperm straws from the spouse or a donor.

“34.8. The following assisted procreation services required for IVF purposes are considered insured services:

(a) the services required to retrieve sperm by medical intervention, including percutaneous epididymal sperm aspiration and surgical or microsurgical testicular sperm extraction;

(b) the services required for ovarian stimulation;

(c) the services required to retrieve eggs or ovarian tissue;

(d) the other services specific to IVF, including assisted hatching services and sperm microinjection (ICSI) services;

(e) the services required to transfer a fresh or frozen embryo or, in accordance with the guidelines drawn up under section 10 of the Act respecting clinical and research activities relating to assisted procreation (chapter A-5.01), a maximum of two fresh or frozen embryos;

(f) a maximum of one sperm straw from the spouse or a donor; and

(g) the freezing and storage of gametes and embryos for a maximum of one year.

Those services are considered insured services for a single IVF cycle, which may however include two ovulatory cycles if no egg is obtained at the end of the first ovulatory cycle.

“34.9. The following assisted procreation services required for fertility preservation purposes are considered insured services if they are provided to an insured person before any gonadotoxic treatment involving a serious risk of genetic mutation to the gametes or of permanent infertility or before the radical exeresis of the testicles or ovaries present:

(a) ovarian stimulation services;

(b) egg or ovarian tissue retrieval services;

(c) services to retrieve sperm or testicular tissue by medical intervention, including percutaneous epididymal sperm aspiration; and

(d) services to freeze and store sperm, eggs, ovarian or testicular tissue or embryos for a 5-year period or until the insured person has reached the age of 25, whichever is later.

“34.10. To be considered insured services for the purposes of subparagraph *e* of the first paragraph of section 3 of the Act, the assisted procreation services mentioned in sections 34.7 to 34.9 must be rendered in a centre for assisted procreation holding a licence issued by the Minister under the Act respecting clinical and research activities relating to assisted procreation (chapter A-5.01).

“34.11. The services required for the prescription of oral agents for ovarian stimulation as part of basic infertility treatments rendered by a physician must be considered insured services for the purposes of subparagraph *e* of the first paragraph of section 3 of the Act.”

TRANSITIONAL AND FINAL PROVISIONS

34. A person, partnership or health and social services institution that does not hold a licence to operate a centre for assisted procreation and that, on (*insert the date of coming into force of section 25*), operates premises carrying out assisted procreation clinical activities for which no licence was required before that date has until (*insert the date that is one year after the date of coming into force of section 25*) to obtain such a licence.

35. A centre for assisted procreation may donate or dispose of the gametes or embryos it conserves for a person and, as the case may be, the person’s spouse if, on (*insert the date of coming into force of section 29*) or after that date, more than five years have elapsed since those persons last contacted the centre to communicate their intent regarding the disposition of the gametes or embryos. The gametes or embryos must be donated or disposed of in an ethically acceptable manner recognized by the Minister.

36. A person receiving *in vitro* fertilization services on the date of coming into force of section 33 may ask his or her attending physician to have the remainder of the services for that *in vitro* fertilization cycle become services considered insured services within the meaning of section 34.8 of the Regulation respecting the application of the Health Insurance Act (chapter A-29, r. 5), provided the person is eligible for those services under sections 34.4 and 34.6 of the Regulation. Once the services have been received, a person may not obtain other services considered insured services under section 34.8 of the Regulation.

Any reference, in the first paragraph, to sections of the Regulation respecting the application of the Health Insurance Act applies to sections enacted by section 33 of this Act.

37. Persons who are under 21 years of age on (*insert the date of coming into force of section 33 of this Act*) and who, on the day immediately before that date, were receiving insured services listed in paragraph *d* of section 34.3 of the Regulation respecting the application of the Health Insurance Act, as it read at that time, continue to receive those services until they reach 25 years of age.

38. This Act comes into force on (*insert the date of assent to this Act*), except sections 17 to 19, 32 and 33, which come into force on the date to be determined by the Government.

