



NATIONAL ASSEMBLY

FIRST SESSION

THIRTY-NINTH LEGISLATURE

Bill 26
(2009, chapter 30)

An Act respecting clinical and research activities relating to assisted procreation

Introduced 22 April 2009
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EXPLANATORY NOTES

The object of this Act is to regulate clinical and research activities relating to assisted procreation in order to ensure high-quality, safe and ethical practices. The Act is also designed to encourage the ongoing improvement of services in that area.

In that respect, the Act provides that any assisted procreation activity, allowing for exceptions, 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 and which is under the direction of a physician. The director must ensure that the activities carried out in the centre reflect high-quality, safe and ethical practices. The Act also states that a centre must have its activities accredited by a body recognized by the Minister.

This Act requires that a research project on assisted procreation activities be approved and supervised by a research ethics committee.

The Act also requires a centre to prepare an annual activity report. It grants inspection powers to the Minister and provides that the Minister may request the board of directors of the Ordre professionnel des médecins du Québec to provide opinions on the quality, safety and ethical nature of the assisted procreation activities and on the professional competence of the physicians in a centre, as well as on the standards to be adopted to improve the quality, safety and ethical nature of assisted procreation activities.

The Act grants regulatory powers to the Minister and the Government as regards centres for assisted procreation and their activities, and prescribes administrative and penal sanctions to ensure that the provisions of the law are respected.

Lastly, the Act amends the Health Insurance Act in order to provide, in particular, that the assisted procreation services determined by regulation are insured services within the meaning of that Act.

LEGISLATION AMENDED BY THIS ACT:

- Health Insurance Act (R.S.Q., chapter A-29);
- Act respecting administrative justice (R.S.Q., chapter J-3);
- Act respecting medical laboratories, organ, tissue, gamete and embryo conservation, and the disposal of human bodies (R.S.Q., chapter L-0.2);
- Medical Act (R.S.Q., chapter M-9);
- Act to amend the Public Health Protection Act (1997, chapter 77).

Bill 26

AN ACT RESPECTING CLINICAL AND RESEARCH ACTIVITIES RELATING TO ASSISTED PROCREATION

THE PARLIAMENT OF QUÉBEC ENACTS AS FOLLOWS:

CHAPTER I

OBJECT, DEFINITIONS AND OTHER INTRODUCTORY PROVISIONS

1. This Act recognizes the necessity of preventing infertility and promoting reproductive health and is designed to protect the health of persons and more particularly the health of women who resort to assisted procreation activities that may be medically required and of children born of such activities, whose filiation is then established according to the provisions of the Civil Code.

For that purpose, the object of this Act is to regulate clinical and research activities relating to assisted procreation in order to ensure high-quality, safe and ethical practices. The Act is also designed to encourage the ongoing improvement of services in that area.

2. For the purposes of this Act,

(1) “assisted procreation activities” means any support given to procreation by medical or pharmaceutical techniques or laboratory manipulation, whether clinical, to create a human embryo, or in the field of research, to improve clinical procedures or acquire new knowledge.

The following activities are targeted in particular: the use of pharmaceutical procedures to stimulate the ovaries; the removal, treatment, *in vitro* manipulation and conservation of human gametes; artificial insemination with a spouse’s or a donor’s sperm; preimplantation genetic diagnosis; embryo conservation; embryo transfer in women.

However, the surgical procedures to restore normal reproductive functions in a woman or a man are not targeted; and

(2) “centre for assisted procreation” means any premises designed for carrying out assisted procreation activities, except activities determined by regulation and carried out on the conditions set out in the regulation. Such premises may be located in a facility maintained by an institution or in a private health facility within the meaning of the Act respecting health services and social services (R.S.Q., chapter S-4.2), in an institution or in a professional’s private consulting office within the meaning of the Act respecting health services

and social services for Cree Native persons (R.S.Q., chapter S-5) or in a laboratory within the meaning of the Act respecting medical laboratories, organ, tissue, gamete and embryo conservation, and the disposal of human bodies (R.S.Q., chapter L-0.2).

3. Only a person or a partnership may operate a centre for assisted procreation. However, if a centre is located in a facility maintained by an institution within the meaning of the Act respecting health services and social services, it may be operated by that institution only, in accordance with the provisions of that Act and to the extent that they are not inconsistent with this Act.

The same applies to a centre located in an institution within the meaning of the Act respecting health services and social services for Cree Native persons.

4. A physician who is a member of the Collège des médecins du Québec is the only natural person who may operate a centre for assisted procreation. If the operator of the centre is a legal person or a partnership, more than 50% of the voting rights attached to the shares of the legal person or the interests in the partnership must be held

(1) by physicians who are members of that professional order;

(2) by a legal person or partnership all of whose voting rights attached to the shares or interests are held

(a) by physicians described in subparagraph 1; or

(b) by another legal person or partnership all of whose voting rights attached to the shares or interests are held by such physicians; or

(3) both by physicians described in subparagraph 1 and by a legal person or partnership referred to in subparagraph 2.

The affairs of a legal person or a partnership that operates a centre for assisted procreation must be administered by a board of directors or an internal management board that includes a majority of physicians who practise at the centre; those physicians must at all times form the majority of the quorum of the board.

The shareholders of a legal person or the partners in a partnership that operates a centre for assisted procreation may not enter into an agreement that restricts the power of the directors of the legal person or partnership.

This section does not apply to a centre for assisted procreation operated by an institution within the meaning of the Act respecting health services and social services or the Act respecting health services and social services for Cree Native persons.

5. For the purposes of this Act, the expression “centre for assisted procreation” is used to designate the premises referred to in section 2 or, if used as the subject of rights or obligations, to designate the person or partnership operating the centre.

CHAPTER II

ASSISTED PROCREATION ACTIVITIES

6. No assisted procreation activities, except those determined by regulation and carried out on the conditions set out in the regulation, may be carried out elsewhere than in a centre for assisted procreation for which a licence has been issued by the Minister under this Act.

7. A person carrying out an assisted procreation activity must respect the conditions and standards for carrying out such activities determined by regulation.

8. A research project on assisted procreation activities must be approved and supervised by a recognized research ethics committee or a research ethics committee established by the Minister. The Minister determines the composition and the operating conditions of the committee, which are published in the *Gazette officielle du Québec*.

The same applies to a research project involving embryos resulting from assisted procreation activities and not used for that purpose. In addition, such a research project must respect the conditions determined by regulation.

9. If an assisted procreation activity raises social and ethical questions on fundamental issues concerning Québec society, the Minister may bring the matter before a competent body, such as the Health and Welfare Commissioner, to request an opinion.

10. In order to comply with recognized medical standards, which aim in particular to protect the health of both the woman and the child, no embryo may be transferred to a woman who is no longer of childbearing age.

CHAPTER III

CENTRE FOR ASSISTED PROCREATION

DIVISION I

GENERAL PROVISIONS

11. A centre for assisted procreation must appoint a member of the Ordre professionnel des médecins du Québec as its director. That physician must hold a specialist’s certificate in obstetrics-gynaecology or be trained in another field considered equivalent by the centre, and be chosen from among the physicians who practise at the centre.

Under the authority of the operator, the director must ensure that the assisted procreation activities carried out in the centre reflect high-quality, safe and ethical practices, and that the centre and the persons carrying out those activities in the centre comply with this Act and any other applicable Act or standard. The director must also comply with the obligations determined by regulation.

A centre must notify the Minister in writing of the director's name, and must also immediately notify the Minister in writing of any change of director.

12. A centre must respect the standards governing equipment, operation and the disposal of biological material, and any other standard governing assisted procreation activities determined by regulation.

13. A centre must establish standard operating procedures in the cases determined by regulation and forward a copy of those procedures to the Minister as soon as possible. The same applies when any change is made to the procedures.

14. Not later than 31 March each year, a centre must forward to the Minister an annual activity report for the preceding calendar year. The report must be produced in the form determined by the Minister and contain any information and be accompanied by any document required by regulation.

DIVISION II

LICENCE AND ACCREDITATION

15. A person may not operate a centre for assisted procreation without holding a licence issued by the Minister for that purpose.

16. Within three years after the licence is issued, a centre must have its assisted procreation activities accredited by an accreditation body recognized by the Minister and retain its accreditation at all times afterwards.

17. The Minister issues to the centre a licence for one of the following classes of activities:

- (1) clinical activities;
- (2) research activities; or
- (3) clinical and research activities.

The licence may be issued for a subclass provided for by regulation.

18. A centre applying for a licence or the modification or renewal of a licence must forward the application to the Minister, using the prescribed form, respect the conditions determined by regulation and include the information, documents or reports required by regulation.

19. The Minister may issue, modify or renew a licence for a centre that meets the conditions provided for in this Act. However, the Minister may refuse to issue such a licence in the public interest.

Furthermore, the issue, modification or renewal of a licence may be subjected to any condition, restriction or prohibition the Minister determines.

20. The licence is issued for three years and may be renewed for the same period.

The licence specifies the class and, where applicable, the subclass of activities for which it is issued, the premises, the period of validity and any conditions, restrictions or prohibitions attached to the licence.

The Minister must make the information provided for by this section public.

21. A centre must carry out its activities in accordance with the licence.

A centre must immediately notify the Minister in writing of any change in its activities.

22. The holder of a licence must respect the conditions determined by regulation, supply the information and produce the documents and reports prescribed by regulation within the time specified.

23. A centre may not transfer its licence without the written authorization of the Minister.

24. A centre that wishes to cease its activities must first notify the Minister in writing and respect any conditions the Minister sets.

CHAPTER IV

INSPECTION AND OVERSIGHT

25. A person authorized in writing by the Minister to inspect centres for assisted procreation may, at any reasonable time, enter a centre or any premises on which the person has reason to believe that assisted procreation activities are carried out, to ascertain whether this Act and the regulations are being respected.

The inspector may

(1) examine and make a copy of any document relating to the assisted procreation activities carried out on those premises; and

(2) demand any information relating to the application of this Act and the production of any document connected with it.

A person having custody, possession or control of such documents must, on request, make them available to the inspector.

The inspector must, on request, produce a certificate signed by the Minister attesting to the authorization received.

26. It is forbidden to hinder in any way an inspector carrying out the functions of office, to mislead the inspector by concealment or false declarations, or to refuse to hand over a document or information the inspector may demand under this Act or under a regulation under this Act.

27. An inspector may not be prosecuted for an act performed in good faith while carrying out the functions of office.

28. If, following an inspection, the Minister is informed that a centre is being operated without a licence, the Minister must immediately notify the Régie de l'assurance maladie du Québec in writing for the purposes of the prohibition against remuneration provided for in the second paragraph of section 22.0.0.0.1 of the Health Insurance Act (R.S.Q., chapter A-29). On receiving the notice, the Régie must inform the physicians who practise at the centre concerned of the prohibition against remuneration.

29. The Minister may apply to the board of directors of the Ordre professionnel des médecins du Québec for an opinion on the quality, safety and ethical nature of the assisted procreation activities carried out in a centre and on the professional competence of the physicians carrying out those activities.

The Minister may also request an opinion on the standards to be adopted to improve the quality, safety and ethical nature of assisted procreation activities.

CHAPTER V

RÉGULATIONS

30. The Government may, by regulation,

(1) determine the assisted procreation activities that may be carried out outside a centre for assisted procreation, and the conditions to be respected;

(2) determine the conditions a person carrying out assisted procreation activities must respect, and the standards governing those activities, which may vary, in particular, with the age of the person resorting to those activities;

(3) determine the conditions a research project referred to in the second paragraph of section 8 must respect;

(4) determine the obligations with which the director of a centre must comply;

(5) prescribe the standards governing equipment, operation and the disposal of biological material, and any other standard governing assisted procreation activities that a centre must respect;

(6) prescribe the information that a centre's annual report must contain and the documents that must accompany the report;

(7) establish subclasses of licences and, for each class and subclass of a licence, the conditions of issue, maintenance or renewal, as well as the information to be provided and the documents and reports to be produced within the time specified;

(8) determine the assisted procreation activities on which information need not be kept permanently;

(9) determine the provisions of a regulation under this Act the violation of which constitutes an offence; and

(10) prescribe any measure to facilitate the application of this Act.

31. The Minister may, by regulation,

(1) determine the cases in which a centre must establish standard operating procedures; and

(2) determine the provisions of a regulation under this Act the violation of which constitutes an offence.

CHAPTER VI

ADMINISTRATIVE SANCTIONS

32. The Minister may suspend, revoke or refuse to modify or renew the licence of a centre for assisted procreation

(1) if the centre no longer meets the conditions required for the issue of a licence or does not respect a condition, restriction or prohibition attached to the licence;

(2) if the centre does not have its activities accredited within three years after the issue of the licence or if it does not maintain its accreditation;

(3) if the centre made a false declaration or distorted a material fact upon applying for the issue, modification or renewal of a licence, or in a report, a document or information required by the Minister under this Act or under a regulation under this Act;

(4) if the centre does not comply with any other provision of this Act or with a regulation under this Act;

(5) if the director does not respect the obligations imposed by this Act or by a regulation under this Act;

(6) if it is in the public interest;

(7) if the assisted procreation activities carried out in the centre do not reflect high-quality, safe and ethical practices in the opinion of the board of directors of the Ordre professionnel des médecins du Québec;

(8) if the operator fails to maintain control over the operation of the centre for assisted procreation, in particular if the Minister ascertains that the operator is not the owner or lessee of the centre's facilities, is not the employer of the personnel required for the operation of the centre or does not have the authority required to allow physicians who apply to practise at the centre to do so; or

(9) if the centre or a physician who practises at the centre has been convicted of an offence under the fourth or ninth paragraph of section 22 or section 22.0.0.1 of the Health Insurance Act (R.S.Q., chapter A-29) for an act or an omission concerning the centre.

33. Before suspending, revoking or refusing to modify or renew the licence of a centre, the Minister may order the centre to take the necessary corrective action within a specified period of time.

If the centre fails to comply with the order within the time specified, the Minister may suspend, revoke or refuse to modify or renew the licence.

The Minister must make public the decision to suspend, revoke or refuse to renew the licence of a centre for assisted procreation.

34. Except in emergencies, before refusing to issue, modify or renew a licence, or before suspending or revoking a licence, the Minister must notify the centre in writing as prescribed by section 5 of the Act respecting administrative justice (R.S.Q., chapter J-3) and allow the centre at least 10 days to submit observations.

The Minister must notify the centre in writing of the decision to suspend, revoke or refuse to renew the licence, giving the reasons.

The Minister's notice must also mention that the prohibition against remuneration if a licence is suspended, revoked or not renewed, provided for in the second paragraph of section 22.0.0.0.1 of the Health Insurance Act (R.S.Q., chapter A-29), applies. The notice may be sent to the physicians practising at the centre concerned. Similarly, a decision by the Minister to suspend, revoke or refuse to renew the licence must state that the prohibition against remuneration applies. The Minister must send a copy of the decision without delay to the Régie de l'assurance maladie du Québec, which, upon receiving it, must inform the physicians practising at the centre concerned that the prohibition against their being remunerated applies.

The operator whose licence is suspended, revoked or not renewed must immediately inform the clientele of the centre concerned.

35. A centre whose application for a licence or the modification or renewal of a licence is refused, or whose licence is suspended or revoked, may contest the Minister's decision before the Administrative Tribunal of Québec within 60 days following the date on which the centre received notification of the decision.

When assessing the facts or the law, the Tribunal may not substitute its assessment of the public interest for the assessment the Minister made in reaching a decision.

CHAPTER VII

PENAL PROVISIONS

36. A person that contravenes section 6 or 15 is guilty of an offence. A natural person is liable to a fine of \$2,000 to \$30,000 and a legal person is liable to a fine of \$6,000 to \$90,000.

37. A person that contravenes a provision of a regulation the violation of which constitutes an offence under paragraph 9 of section 30 or paragraph 2 of section 31 is liable to a fine of \$1,000 to \$10,000.

38. A person that fails or refuses to provide any information, report or other document that must be made available under this Act is guilty of an offence and is liable to a fine of \$1,000 to \$10,000.

39. A person that contravenes section 26 is guilty of an offence and is liable to a fine of \$1,000 to \$10,000.

40. A person that aids, abets, counsels, allows, authorizes or orders another person to commit an offence under this Act or under a regulation under this Act is guilty of an offence.

A person convicted of an offence under this section is liable to the same penalty as that prescribed for the offence the person aided or incited another person to commit.

41. In the case of a subsequent offence, the minimum and maximum fines prescribed in this Act are doubled.

CHAPTER VIII

INFORMATION ON ASSISTED PROCREATION ACTIVITIES

42. Subject to Chapter IV, the information contained in the forms, documents, reports or opinions forwarded to the Minister under this Act must not allow a person who resorted to assisted procreation activities, or a child born of such activities, to be identified.

The Minister may forward that information to a person or body for the purposes of study, research or statistics, as long as the information cannot be used to identify a centre for assisted procreation.

43. Any information on assisted procreation activities, except those determined by regulation, concerning a person who resorted to such activities, or a child born of such activities, must be kept permanently by the person that carried out those activities.

44. In order to provide ongoing surveillance of the health of persons who resorted to assisted procreation activities and of the children born of such activities, the Minister must collect information, both personal and non-personal, in accordance with the Public Health Act (R.S.Q., chapter S-2.2).

Information 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 disclosed, even with the consent of the person concerned, except for the purposes of the Public Health Act.

45. Statistical data on assisted procreation activities gleaned from the annual activity reports of centres for assisted procreation must appear in a separate chapter of the department's annual report.

CHAPTER IX

AMENDING, TRANSITIONAL AND FINAL PROVISIONS

46. Section 3 of the Health Insurance Act (R.S.Q., chapter A-29) is amended by inserting the following subparagraph after subparagraph *d* of the first paragraph:

“(e) the assisted procreation services determined by regulation.”

47. Section 22.0.0.0.1 of the Act, enacted by section 30 of chapter 29 of the statutes of 2009, is amended

(1) by replacing “operated without a permit or whose permit” in the second paragraph by “or a centre for assisted procreation within the meaning of the Act respecting clinical and research activities relating to assisted procreation (2009, chapter 30) that is operated without a permit or licence or whose permit or licence” and by adding “or revoked,” after “cancelled”;

(2) by replacing “cancel or refuse to renew the permit or the Minister’s notice informing it that the specialized medical centre or the laboratory is being operated without a permit” in the third paragraph by “cancel or revoke, or refuse to renew, the permit or licence, or the Minister’s notice informing it that the specialized medical centre, laboratory or centre for assisted procreation is being operated without a permit or licence”.

48. Section 69 of the Act is amended by inserting the following subparagraph after subparagraph *c.1* of the first paragraph:

“(c.2) 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;”.

49. Section 25 of the Act respecting administrative justice (R.S.Q., chapter J-3) is amended by inserting “0.1,” after “paragraphs” in the first line of the first paragraph.

50. Schedule I to the Act is amended by inserting the following paragraph before paragraph 1 of section 3:

“(0.1) proceedings under section 35 of the Act respecting clinical and research activities relating to assisted procreation (2009, chapter 30);”.

51. The title of the Act respecting medical laboratories, organ, tissue, gamete and embryo conservation, and the disposal of human bodies (R.S.Q., chapter L-0.2) is amended by replacing “, tissue, gamete and embryo” by “and tissue”.

52. Section 1 of the Act is amended by striking out subparagraph *m.1* of the first paragraph.

53. Section 1 of the Medical Act (R.S.Q., chapter M-9) is amended by adding the following paragraph at the end:

“(h) “centre for assisted procreation”: a centre within the meaning of the Act respecting clinical and research activities relating to assisted procreation (2009, chapter 30).”

54. Section 15 of the Act is amended by adding the following paragraph at the end:

“(e) give an opinion to the Minister of Health and Social Services, on its own initiative or at the request of the Minister, on the quality, safety and ethical nature of the assisted procreation activities carried out in a centre for assisted procreation, the professional competence of the physicians carrying out those activities and the standards to be adopted to improve the quality, safety and ethical nature of those activities.”

55. Section 16 of the Act is amended

(1) by replacing “paragraph *a* or *a.1*” in the first line by “paragraphs *a*, *a.1* and *e*”;

(2) by inserting “, the quality and safety of the activities carried out in centres for assisted procreation” after “institutions” in the third line.

56. Sections 2, 8, 9 and 10 of the Act to amend the Public Health Protection Act (1997, chapter 77) are repealed.

57. A person or partnership operating a centre for assisted procreation on (*insert the date of coming into force of section 15 of this Act*) may continue to do so provided that, within six months of that date, the person or partnership, in accordance with this Act, obtains a licence to operate a centre for assisted procreation.

A person who carries out assisted procreation activities in such a centre may continue to do so until the centre obtains a licence in accordance with the first paragraph.

58. In any Act or statutory instrument, the title of the Act respecting medical laboratories, organ, tissue, gamete and embryo conservation and the disposal of human bodies must read as the Act respecting medical laboratories, organ and tissue conservation and the disposal of human bodies.

59. The Minister of Health and Social Services is responsible for the administration of this Act.

60. The Minister must, no later than (*insert the date that occurs 3 years after the date of coming into force of this Act*), report to the Government on the implementation of this Act and on the advisability of maintaining it in force or amending it.

The report must be laid before the National Assembly by the Minister within 30 days or, if the Assembly is not sitting, within 30 days of resumption.

The report must be referred to the appropriate parliamentary committee for consideration within 15 days of its tabling in the National Assembly.

61. This Act comes into force on the date or dates to be set by the Government.