NATIONAL ASSEMBLY

FIRST SESSION THIRTY-SEVENTH LEGISLATURE

Bill 89

An Act respecting clinical and research activities as regards assisted human reproduction and amending other legislative provisions

Introduction

Introduced by
Mr. Philippe Couillard
Minister of Health and Social Services

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EXPLANATORY NOTES

The object of this bill is to provide a supervisory framework for clinical and research activities relating to assisted human reproduction in order to ensure high-quality, safe and ethical practices. The bill is also designed to encourage the ongoing improvement of services in this area.

In that respect, the bill provides that an assisted human reproduction activity must be carried out in a centre for assisted human reproduction 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 bill also states that a centre must have its activities accredited by an accreditation body recognized by the Minister.

This bill requires that a research project on assisted human reproduction activities be approved and supervised by a research ethics committee.

The bill provides for a centre's accountability by requiring an annual report of activities. It grants inspection powers to the Minister and provides that the Minister may request the Bureau of the Ordre professionnel des médecins du Québec for opinions on the quality, safety and ethical nature of the assisted human reproduction activities and on the professional competence of the physicians in a centre, as well as on the standards to be followed in a centre in the interests of higher quality, greater safety and stronger ethics.

The bill grants regulatory powers to the Minister and the Government as regards assisted human reproduction activities and centres for assisted human reproduction, and prescribes administrative and penal sanctions to ensure that those provisions are respected.

Lastly, the bill introduces consequential amendments to the Act respecting administrative justice and other Acts dealing with medical matters.

LEGISLATION AMENDED BY THIS BILL:

– 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 89

AN ACT RESPECTING CLINICAL AND RESEARCH ACTIVITIES AS REGARDS ASSISTED HUMAN REPRODUCTION AND AMENDING OTHER LEGISLATIVE PROVISIONS

THE PARLIAMENT OF QUÉBEC ENACTS AS FOLLOWS:

CHAPTER I

OBJECT, DEFINITIONS AND OTHER INTRODUCTORY PROVISIONS

1. The object of this Act is to provide a supervisory framework for clinical and research activities relating to assisted human reproduction 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,

"assisted human reproduction activities" means any support given to human reproduction 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; embryo implantation in women.

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

"centre for assisted human reproduction" means any premises designed for carrying out assisted human reproduction activities. 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 human reproduction, subject to legislation respecting the professions. However, if a centre for assisted human reproduction 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, to the extent that they are not inconsistent with this Act.

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

4. For the purposes of this Act, the expression "centre for assisted human reproduction" is used, depending on the context, 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 HUMAN REPRODUCTION ACTIVITIES

5. A person may not carry out an assisted human reproduction activity elsewhere than in a centre for assisted human reproduction for which a licence is issued by the Minister under this Act.

6. A person carrying out an assisted human reproduction activity must respect the conditions for carrying out such activities determined by regulation.

7. A research project on assisted human reproduction 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 on embryos and embryonic stem cells resulting from assisted human reproduction activities and not used for that purpose. In addition, such a research project must respect the conditions determined by regulation.

CHAPTER III

CENTRE FOR ASSISTED HUMAN REPRODUCTION

DIVISION I

GENERAL PROVISIONS

8. A centre for assisted human reproduction 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.

The director must ensure that the assisted human reproduction 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 for assisted human reproduction must immediately notify the Minister in writing of any change of director.

9. A centre for assisted human reproduction must respect the standards governing equipment, operation and the disposal of biological material, and any other standard relating to assisted human reproduction activities determined by regulation.

10. A centre for assisted human reproduction must establish standard operating procedures in the cases established 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.

11. A centre for assisted human reproduction must forward to the Minister, not later than 31 March each year, an annual report of activities 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

12. A person may not operate a centre for assisted human reproduction without holding a licence issued by the Minister for that purpose.

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

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

(1) clinical activities;

(2) research activities;

(3) clinical and research activities.

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

15. 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.

16. The Minister may issue, modify or renew a licence for a centre that meets the conditions specified in this Act if the Minister considers it to be 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.

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

18. 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.

A centre for assisted human reproduction must carry out its activities in accordance with the licence.

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

19. 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 indicated.

20. A centre for assisted human reproduction may not transfer its licence without the written authorization of the Minister.

21. A centre for assisted human reproduction that wishes to cease its activities must first notify the Minister in writing and respect any conditions the Minister sets.

CHAPTER IV

INSPECTION AND SUPERVISION

22. A person authorized in writing by the Minister to make an inspection may, at any reasonable time, enter a centre for assisted human reproduction or any premises in which the person has reason to believe that assisted human reproduction 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 human reproduction activities carried out in those premises;

(2) require 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.

23. 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 refuse to hand over a document or information the inspector may require under this Act or a regulation under this Act.

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

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

The Minister may also request an opinion on the standards to be followed to improve the quality, safety and ethical nature of the assisted human reproduction activities in a centre.

CHAPTER V

REGULATIONS

26. The Government may, by regulation,

(1) determine the conditions a person carrying out assisted human reproduction activities must respect;

(2) determine the conditions a research project referred to in the second paragraph of section 7 must respect;

(3) determine the obligations with which the director of a centre for assisted human reproduction must comply;

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

(5) prescribe the information that the annual report must contain and the documents that must accompany the report;

(6) 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;

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

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

27. The Minister may, by regulation,

(1) determine the cases in which a centre for assisted human reproduction must establish standard operating procedures;

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

28. A regulation under this Act may provide that any reference it makes to a standard established by another government or by a body includes any amendment subsequently made to that standard.

CHAPTER VI

ADMINISTRATIVE SANCTIONS

29. The Minister may suspend, modify, revoke or refuse to renew a centre's licence

(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 a regulation under this Act;

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

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

(6) if it is in the public interest;

(7) if the assisted human reproduction activities carried out in the centre do not reflect high-quality, safe and ethical practices in the opinion of the Bureau of the Ordre professionnel des médecins du Québec.

30. Before suspending, modifying, revoking or refusing to 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, modify, revoke or refuse to renew the licence.

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

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

32. A licence holder whose application for a licence is refused or whose licence is suspended, modified, revoked or not renewed may contest the Minister's decision before the Administrative Tribunal of Québec within 60 days following the date on which the holder 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

33. A person that contravenes section 5 or 12 is guilty of an offence and is liable to a fine of $2,000 to $30,000 in the case of a natural person and of $6,000 to $90,000 in the case of a legal person.

34. A person that contravenes a provision of a regulation the violation of which constitutes an offence under paragraph 7 of section 26 or paragraph 2 of section 27 is liable to a fine of $500 to $10,000.

35. 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.

36. A person that contravenes section 23 is guilty of an offence and is liable to a fine of $1,000 to $10,000.

37. A person that aids, abets, counsels, allows, authorizes or orders another person to commit an offence under this Act or a regulation under this Act is guilty of an offence. The same applies to a person that attempts to commit such 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 attempted to commit or aided or incited another person to commit.

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

CHAPTER VIII

MISCELLANEOUS PROVISIONS

39. 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 human reproduction activities to be identified.

Despite sections 23 and 24 of the Act respecting Access to documents held by public bodies and the Protection of personal information (R.S.Q., chapter A-2.1), the Minister may forward that information to the Bureau of the Ordre professionnel des médecins du Québec to enable it to give an opinion on a matter referred to in section 25 and, as long as the information cannot be used to identify a centre for assisted human reproduction, forward it to a person or body for the purposes of study, research or statistics.

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

CHAPTER IX

AMENDING, TRANSITIONAL AND FINAL PROVISIONS

41. Schedule I to the Act respecting administrative justice (R.S.Q., chapter J-3) is amended by inserting the following paragraph before paragraph 1 of section 3:

"(0.1) proceedings under section 32 of the Act respecting clinical and research activities as regards assisted human reproduction and amending other legislative provisions (*insert the year and chapter number of this Act*);".

42. 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".

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

44. 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 human reproduction": a centre within the meaning of the Act respecting clinical and research activities as regards assisted human reproduction and amending other legislative provisions (*insert the year and chapter number of this Act*)."

45. Section 15 of the said 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 human reproduction activities carried out in a centre for assisted human reproduction, the professional competence of the physicians carrying out those activities and the standards to be followed to improve the quality, safety and ethical nature of those activities in any centre."

46. Section 16 of the said Act is amended

(1) by replacing "paragraph *a*" in the first line by "paragraphs *a* and *e*";

(2) by inserting "and into the quality and safety of the activities carried out in centres for assisted human reproduction" after "institutions" in the third line.

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

48. A person or partnership operating a centre for assisted human reproduction on (*insert the date of coming into force of section 12 of this Act*) may continue operating the centre provided the person or partnership obtains, in accordance with this Act, a centre for assisted human reproduction licence within six months of that date.

A person who carries out assisted human reproduction activities in such a centre may continue to carry out those activities until the centre obtains its licence in accordance with the first paragraph.

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

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