



PARLIAMENT ITALIAN



Act Feb. 19, 2004 , No 40

" Rules on medically assisted procreation "

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CHAPTER I GENERAL PRINCIPLES

ART . 1. (*Purpose*) .

1. In order to facilitate resolution of problems stemming from infertility or reproductive human infertility has allowed the use of medically assisted procreation , the conditions and in the manner prescribed by this Law, which guarantees the rights of all stakeholders, including the unborn .

2. The use of medically assisted procreation is allowed if there is no other effective treatment methods to remove the causes of sterility or infertility .

ART . 2. (*Measures against sterility and infertility*) .

1. The Minister of Health , after consulting the Minister for Education, Universities and Research , may promote research into the causes of disease , psychological , environmental and social phenomena of sterility and infertility and to promote the necessary action to remove them and to reduce the ' incidence, may encourage studies and research on techniques for cryopreservation of gametes and may also promote information campaigns and prevention of the phenomena of sterility and infertility.

2. For the purpose referred to in paragraph 1 is authorized spending up to 2 million euros from 2004 .

3. Burden arising from the implementation of paragraph 2 is provided by the corresponding reduction in appropriations for the 2004-2006 three-year budget , in unit forecast based on current " Special Fund " of the estimate of the Ministry Economy and Finance for the year 2004 , to partially using the provision for the Ministry of Health. Minister of Economy and Finance is authorized to introduce, by decree, the necessary budgetary changes.

ART . 3. (*Amendment to the Law of 29 July 1975 No. 405*) .

1. In the first paragraph of Article 1 of Law July 29, 1975 , No 405, are added at the end , the following points :

D- ca) information and assistance with problems of infertility and human infertility and assisted reproduction techniques ;

d- b) Information on the procedures for adoption and foster care . "

2. Implementation of this Article shall not derive new or increased burdens on public finances.

CHAPTER II ACCESS TO TECHNICAL

ART . 4. (*Access to technical*) .

1. The use of techniques of assisted reproduction is allowed only when it is found impossible to remove otherwise causes impeditive procreation and is still confined to cases of infertility or unexplained infertility documented medical act and the cases of sterility or infertility Case proven and certified by medical procedure .

2. The techniques of assisted reproduction are applied on the following principles :

a) gradually, to avoid the use of interventions with a degree of invasiveness technical and psychological burden for most recipients , applying the principle of less invasive ;

b) informed consent, be carried out under Article 6.

3. It prohibited the use of techniques of medically assisted procreation of heterologous type .

ART . 5. (*Requirements subject*) .

1. Notwithstanding the provisions of Article 4, paragraph 1 , have access to medically assisted procreation techniques for adults of different sex couples , married or cohabiting , potentially fertile age , both living .

ART . 6. (*Informed Consent*) .

1. For the purposes described in paragraph 3, before application and at each stage of application of techniques of medically assisted procreation inform your doctor in detail the entities referred to in Article 5 of the methods on bioethical issues and possible side effects and health caused by application of psychological techniques themselves , the probability of success and risks deriving from the same well as on legal implications for women, for man and for the baby. The couple must be qualified the opportunity to use procedures of adoption or custody under the law of May 4, 1983 , No 184, as amended, as an alternative to medically assisted procreation. The information in this paragraph and those on the degree of invasiveness of the techniques against Women and men must be provided for each of the techniques applied and in order to ensure the emergence of a conscious will and consciously expressed .

2. The couple must be clearly projected the economic cost of the entire procedure in the case of private structures authorized .

3. The willingness of both parties to have access to medically assisted reproduction techniques is given in writing together with the physician in charge of the facility, in a manner determined by decree of the Ministers of Justice and Health , adopted under Article 17, paragraph 3, of Act Aug. 23, 1988 , No 400, within three months from the date of entry into force of this Act. Between the manifestation of the will and the application of the technique , a delay of at least seven days. The will may be revoked by each of the persons mentioned in this paragraph until the time of fertilization.

4. Subject to the requirements of this law, the physician in charge of property may decide not to proceed with assisted reproduction , only for reasons of healthcare . In this case the couple must provide written justification of that decision.

5. Applicants , when access to medically assisted procreation techniques , must be clearly spelled out and signed by the legal consequences of Article 8 and Article 9 of this Act.

ART . 7. (*Guidelines*) .

1. The Minister of Health , using the Higher Institute of Health , and after consulting the Board of Health , defines , by decree to be issued within three months from the date of entry into force of this Act , guidelines detailing the procedures and techniques of medically assisted procreation.

2. The guidelines referred to in paragraph 1 shall be binding on all facilities authorized .

3. The guidelines are updated periodically, at least every three years , in relation to the technical - scientific , with the same procedures described in paragraph 1.

CHAPTER III PROVISIONS CONCERNING protect the unborn child

ART . 8. (*Legal status of born*) .

1. Those born as a result of assisted reproduction techniques have the status of legitimate children or children recognized the couple who have expressed a willingness to use the same techniques in accordance with Article 6.

ART . 9. (*Prohibition of denial of paternity and the mother of anonymity*) .

1. Where reference is made to medically assisted procreation techniques of heterologous type in violation of the prohibition in Article 4 , paragraph 3, the spouse or whose consent is obtained from conclusive acts can not perform the action of disavowal of paternity in cases covered by Article 235, first paragraph , points 1) and 2) of the Civil Code or an appeal under Article 263 of the Code.

2. The mother was born following the application of techniques of medically assisted procreation can not declare a desire not to be appointed under Article 30, paragraph 1 of the Rules of the Decree of President of the Republic November 3, 2000 , n . 396.

3. In case of application of techniques such heterologous in violation of the prohibition in Article 4 , paragraph 3, the donor gametes shall not acquire any legal parental relationship with the birth and can not assert against the holder of any rights or be obligations.

CHAPTER IV REGULATORY STRUCTURES PERMITTED application of the technique of medically assisted procreation

ART . 10. (*Facilities authorized*) .

1. Interventions medically assisted reproduction are made in public and private areas authorized by and entered in the register referred to in Article 11.

2. The regions and autonomous provinces of Trento and Bolzano define its place within three months from the date of entry into force of this Law :

a) technical and scientific requirements and organizational structures ;

b) the characteristics of the facility staff ;

c) criteria for determining the duration of authorizations and cases of revocation of same ;

d) the criteria for performing the checks on compliance with the provisions of this Act and the continuing requirements of scientific-technical and organizational structures .

ART . 11. (*Register*) .

1. It is established by decree of the Minister of Health , at the Higher Institute of Health , the national register of facilities authorized the application of techniques of assisted reproduction , embryos formed and born as a result of applying the same techniques .

2. The entry in the register referred to in paragraph 1 shall be compulsory .

3. The Higher Institute of Health will collect and disseminate , in cooperation with the regional epidemiological observatories , the information necessary to enable transparency and publicity techniques of medically assisted procreation taken and results achieved .

4. The Higher Institute of Health collects instances , information, suggestions, proposals and users of scientific societies on medically assisted procreation .

5. The structures mentioned in this article are required to provide regional epidemiological observatories and Istituto Superiore di Sanità data necessary for the purposes specified in Article 15 and any other information necessary to discharge its functions of monitoring and inspection by the authorities.

6. The amount associated with this article, given the extent of up to 154,937 euros from the year 2004, is provided by the corresponding reduction in appropriations for the 2004-2006 three-year budget , in unit forecast basic current account " Special Fund " of the estimate of the Ministry of Economy and Finance for the year 2004 , to partially using the provision for the Ministry of Health. Minister of Economy and Finance is authorized to introduce, by decree, the necessary budgetary changes.

CHAPTER V PROHIBITIONS AND PENALTIES

ART . 12. (*General Prohibitions and penalties*) .

1. Anyone in any capacity for procreation using gametes of the couple requesting foreign entities , in violation of the provisions of Article 4, paragraph 3, shall be punished by fine of between 300,000 to 600,000.

2. Anyone in any capacity, in violation of Article 5 applies techniques of medically assisted procreation for couples whose components are either living or one of whose components is a minor or which are composed of individuals of the same sex or unmarried or not living with you punishable by fine of from 200,000 to 400,000 euros.

3. To establish the requirements of paragraph 2, the doctor uses a statement signed by those applicants. In case of false statements , Article 76, paragraphs 1 and 2 of the consolidated text of the laws and regulations on administrative records , by Decree of the President December 28, 2000 , No 445.

4. Anyone who applies techniques of medically assisted procreation without having obtained the consent in the manner provided for in Article 6 shall be punished with a fine of between 5,000 and 50,000.

5. Anyone in any way apply techniques of assisted reproduction in facilities other than those referred to in Article 10 shall be punished with fine of from 100,000 to 300,000 euros.

6. Whoever, in any form, produces, arranges or advertises the sale of gametes or embryos or subrogation of motherhood is punished with imprisonment from three months to two years and a fine ranging from 600,000 to one million euros.

7. Anyone who performs a process designed to give a human being descended from a single starting cell , possibly the same as the nuclear genetic inheritance , to another human being alive or dead, is punished with imprisonment from ten to twenty years and fine ranging from 600,000 to one million euros. The doctor is punished likewise , with permanent exclusion from the profession.

8. Are not punishable man or woman to whom techniques are applied in the cases referred to in paragraphs 1, 2 , 4 and 5.

9. Is the suspension of one to three years from the professional to the operator a health profession convicted of offenses under this article except as provided in paragraph 7.

10. The authorization granted under Article 10 of the framework in which it is performed one of the practices prohibited under this Article shall be suspended for one year. If multiple violations of the prohibitions referred to in this article or recur, the authorization may be revoked.

CHAPTER VI
PROTECTION MEASURES FOR EMBRYO

ART . 13.
(Experimentation on human embryos) .

1. Any testing each human embryo .
2. The clinical and experimental research on each human embryo is permitted provided that they pursue diagnostic and therapeutic purposes which are exclusively associated with it for the protection of health and development of the embryo itself , and if no available alternative methodologies.
3. They are, however , prohibited:
 - a) production of human embryos for research or experimental purposes or in any other than that provided by this Act ;
 - b) any form of eugenic selection for the purpose of gametes or embryos and interventions that, through breeding techniques , handling or otherwise using artificial processes , are intended to alter the genetic heritage of the embryo or gamete or to predetermine genetic characteristics , except assistance with diagnostic and therapeutic purposes , under paragraph 2 of this article;
 - c) interventions cloning through nuclear transfer or embryo splitting or early ectogenesis is for procreation and research ;
 - d) fertilization of a human gamete with a gamete of different species and the production of hybrids or chimeras.
4. Violation of the prohibitions referred to in paragraph 1 shall be punished with imprisonment from two to six years and a fine ranging from 50,000 to 150,000 euros. In case of violation of the prohibitions referred to in paragraph 3, the penalty is increased. Mitigating circumstances competing with aggravating circumstances provided for in paragraph 3 shall be deemed equivalent or outweigh these .
5. Is the suspension of one to three years from the professional to the operator a health profession convicted of offenses under this article.

ART . 14.
(Limits the application of techniques of embryo) .

1. It prohibited the removal and cryopreservation of embryos , except as provided by law May 22, 1978 , No 194.
2. The techniques of embryo production , taking account of technical- scientific and the provisions of Article 7 , paragraph 3 , shall not create a number of embryos than is absolutely necessary for a unique, contemporary facility , not exceeding three.
3. When the transfer of embryos in the uterus is not possible for serious and documented reasons of force majeure on the health status of women is not foreseeable at the time of fertilization is allowed the cryopreservation of embryos themselves until the date of transfer , to be implemented as soon as possible .
4. For the purposes of this law on medically assisted procreation is prohibited embryonic reduction of multiple pregnancies , except as provided by law May 22, 1978 , No 194.
5. The entities referred to in Article 5 shall be informed about the number and, upon their request, the health of embryos and transferred into the uterus .
6. The violation of the prohibitions and obligations in the preceding paragraphs shall be punished with imprisonment up to three years and a fine ranging from 50,000 to 150,000 euros.
7. Is the suspension up to one year from the professional to the operator a health profession convicted of an offense under this article.

8. Permission is granted to male and female gamete cryopreservation , and written informed consent .
9. Violation of the provisions of paragraph 8 shall be punishable by fine of between 5,000 and 50,000.

CHAPTER VII
FINAL AND TRANSITIONAL PROVISIONS

ART . 15.

(Report to Parliament).

1. The Higher Institute of Health shall, no later than February 28 of each year, an annual report to the Minister of Health based on data collected under Article 11 , paragraph 5 , on the activities of authorized facilities , with particular reference to epidemiological assessment techniques and interventions .

2. The Minister of Health, based on the data indicated in paragraph 1 shall submit by June 30 of each year a report to Parliament on the implementation of this Act.

ART . 16.

(conscientious objection) .

1. Medical staff and health care activities ancillary operator is not required to take part in the procedures for applying the techniques of assisted reproduction covered by this law when conscientious objection raised by prior declaration. The statement objector must be notified within three months from the date of entry into force of this Act to the director of the local health unit or hospital company in the case of employees , the medical director , in the case of employees from authorized or accredited private structures .

2. The argument can always be withdrawn or be proposed outside of the periods referred to in paragraph 1, but in this case the declaration takes effect after a month of its submission to the bodies referred to in paragraph 1.

3. Conscientious objection exempts health care professionals and health care activities auxiliary operator on completion of the procedures and activities specifically and necessarily designed to determine the involvement of medically assisted procreation and not from assistance antecedent and consequent action .

ART . 17.

(Transitional Provisions) .

1. Structures and centers on the list prepared at the Higher Institute of Health under the order of the Minister of Health, March 5, 1997 , published in *Official Gazette* No 55, March 7, 1997 , are authorized to apply the techniques of medically assisted procreation , in accordance with the provisions of this Act , until the ninth month following the date of entry into force of this Act.

2. Within thirty days from the date of entry into force of this law , structures and facilities referred to in paragraph 1 shall submit to the Ministry of Health a list indicating the number of embryos produced through the application of techniques of medically assisted procreation in the period preceding the date of entry into force of this Act and in compliance with current requirements for protecting the confidentiality of personal information to provide the names of those who have used the same techniques after which the embryos were formed . Violation of this subparagraph shall be punished by a fine of between 25,000 to 50,000.

3. Within three months from the date of entry into force of this Act the Minister of Health , using the Higher Institute of Health , defines , by decree , the terms and conditions of storage of embryos referred to in paragraph 2.

ART . 18.

(Fund for the techniques of medically assisted procreation) .

1. In order to facilitate access to medically assisted procreation techniques by persons under Article 5 , the Ministry of Health has established the Fund for the techniques of medically assisted procreation. The Fund is distributed among the regions and autonomous provinces of Trento and Bolzano on the basis of criteria established by decree of the Minister of Health, to be issued within sixty days from the date of entry into force of this Act , after consultation with the Permanent Conference for relations between state , regions and autonomous provinces of Trento and Bolzano .

2. For the endowment fund under paragraph 1 is authorized spending of 6.8 million from the year 2004.

3. The amount associated with this article is provided by the corresponding reduction in appropriations for the 2004-2006 three-year budget , in unit forecast based on current " Special Fund " of the estimate of the Ministry Economy and Finance for the year 2004 , to partially using the provision for the same Ministry . Minister of Economy and Finance is authorized to introduce, by decree, the necessary budgetary changes.