THE PARLIAMENT OF ROMANIA

THE CHAMBER OF DEPUTIES **THE SENATE**

LAW
regarding reproductive health and medically assisted human reproduction

The Parliament of Romania adopts the present law.

CHAPTER I
General provisions

Article 1. – The present law acknowledges, regulates and guarantees the rights of the population regarding reproductive health as well as the legal regime of medically assisted human reproduction trough the method of artificial insemination or the method of in vitro fertilization.

Article 2. – (1) The activities regarding reproductive health that are organized and coordinated by the Ministry of Health are the following:

a) family planning;

b) abortion and services for the interruption of pregnancy under safe conditions;

c) maternity without risk, as well as prenatal care, care during the pregnancy, delivery and puerperal period, postnatal care and neonatal care under safe conditions;

d) correct nutrition of the child, focusing on breath feeding;

e) prevention and treatment of sexually transmitted diseases (STD´s) and of HIV / AIDS infection;

f) reproductive and sexual health for adolescents and youth;

g) sexual health of elderly person;

h) early detection and treatment of genital and breath cancer;

i) prevention and treatment of infertility;

j) medically assisted human reproduction;

(2) In the area of human reproduction, the Ministry of Health, in collaboration with the Ministry of Education and Research have the following authority:

a) setting up the reproductive health protection system;

b) ensuring sexual education and family life skills training for adolescents and youth;

c) preparation of norms regulating the activities in the area of reproductive health, including prophylaxis of sexually transmitted diseases (STD´s) and HIV / AIDS infection.

Article 3. – For the purposes of the present law the terms and expressions below have the following definitions:

a) the *right to reproduction* is construed as the right of couples and individuals to decide freely and responsibly on the number, frequency and moment in which they wish to have children, as well as the right to have access to information, education and means that should enable them to take such a decision;

b) *human reproductive health* is construed as state of complete physical, mental and social wellbeing that cannot be defined by the mere absence of illness or infirmity and which regards everything that concerns the reproductive systems, the functions or processes performed by this system.

c) *medically assisted human reproduction* is construed as the medical act that comprises the entirety of treatments and artificial insemination or in vitro fertilization procedures, procedures

for the medical manipulation in the laboratory of the female and male genetic material with a view to artificial fecundation of the ovum, manipulation of sperm and/ or embryos obtained from extracorporeal fecundation and their implanting;

d) *sexual health* is construed as the maintaining or improving of sexual and reproductive functions as well as of the relations between the partners of the couple;

e) *family planning* is construed as the capacity of couples and individuals to anticipated and decide on the number of children, the date of and the period between deliveries;

f) *voluntary interruption of pregnancy* is construed as the method of interruption of an unplanned or unwanted pregnancy upon the woman´s request;

g) *technologies for medical assistance of human reproduction* is construed as the complex of medical services targeted at correcting the state of infertility, including artificial insemination, in vitro fertilization and transfer of embryos.

h) *carrying mother* is construed as the women who consents to the embryo obtained by medically assisted human reproduction to being implanted in her uterus and carry the pregnancy to term, deliver and voluntarily give up her legal rights to that child based on a contract with an infertile couple;

i) *surrogate mother* is construed to be the woman that consents to being artificially inseminated with the sperm of the man of the infertile couple;

j) *information* is construed as the provision of essential data, in a manner that the patient should understand and to which he can refer to; the purpose of the information is to ensure that the patient´s decision is voluntary and informed and to obtain the legal permission for certain medical procedures in the form of an informed written consent;

k) *counseling* is construed as the extensive discussion on the feelings and worries of a patient who undergoes a crisis situation, exploring his feelings, clarifying values and aid in making a decision, choice of a medical procedure, preparation for a procedure by reducing the level of anxiety; the counseling should not create a barrier for the medical services, but should be voluntary;

l) *medically assisted reproductive couple* is construed as the infertile couple that is provided medically assisted human reproductive services and that contributed in full, in part genetic material required for the reproduction or did not contribute such material at all;

m) *in vitro fertilization* is construed as the technique of medically assisted reproduction by fecundation of a female gamete (ovum) and a male gamete (sperm cell) that is conducted in the laboratory, the resulting embryo being transferred into the uterus with a view to its implanting and future development into a fetus;

n) *infertility* is construed as the involuntary and significant reduction of the natural reproductive capacity of a viable couple, at the biological reproductive age and that can prove the existence of a common stable life of the two heterosexual members;

o) *transfer of embryos* is construed as the re-implanting of the embryo from the gametes of the beneficiary couple to another women, who carries the pregnancy, insemination of a women outside the couple who wants the child and extraction of the fecundated ovum and subsequent re-implanting into the uterus of the beneficiary woman;

p) *artificial fertilization* is construed as the medical procedure by which the ovum of the carrying mother is fecundated with male gametes, either of her husband´s or of a donor, or the mother is a third person from outside the marriage and the child is adopted by the beneficiary mother;

r) *artificial insemination* is construed as the medically assisted human reproduction technique which is used in some cases of couple sterility, when the seminal fluid stems from the husband or concubine of the woman the artificial insemination being called conjugal insemination, and when the sperm stems from another donor, artificial insemination is called donor insemination;

s) *donation of gametes* is construed as the confidential and free of charge contract by which a man, in principal anonymous, donates sperm to an insemination center, accepting that a woman who is not his partner be fecundated.

CHAPTER II
Human reproductive health

Article 4. – (1) Any person is free to decide on the number of children and the moment of their birth, as well as on the matters regarding her own reproductive health, without constraint and free of any influence.

(2) Any person is entitled to be informed on her reproductive health condition.

(3) The information of the persons is conducted all throughout the period they are provided human reproductive health services.

(4) Health facilities that provide reproductive health services should post in a visible place the rights of the persons regarding their reproductive health.

Article 5. – All information regarding the reproductive health condition of the patient, the investigation results, diagnosis, prognosis and treatment are confidential.

Article 6 – (1) Persons requesting a contraceptive method are entitled to a medical consultation with a view to choosing the contraceptive method, taking into consideration the health condition, age and individual features.

(2) The categories of women that are entitled to receive free modern contraceptives are determined by order of the minister of health.

(3) Counseling services for contraception are provided by trained personnel and on premises that should ensure confidentiality.

(4) Surgical voluntary contraceptive methods can be performed only upon request and on the basis of the informed consent of the applicant.

Article 7. – (1) Any woman is entitled to request and undergo a voluntary interruption of pregnancy up until the chronological age of the pregnancy of 14 weeks since the first day of the last menstrual cycle.

(2) The tariff for the voluntary interruption of pregnancy in public health facilities is determined by order of the minister of health.

(3) Public or private health facilities that provide services for the interruption of pregnancies shall ensure the necessary safety and quality requirements, including electrical, manual vacuum aspiration method or the method of interruption of pregnancies based on drugs, if no other method is prescribed.

(4) Each woman who undergoes an interruption of pregnancy shall be informed accordingly in order to make an informed decisions that should be documented in the form of a written informed consent.

(5) The information is compulsory and shall comprise:

a) alternatives to pregnancy interruption;

b) the rights to which pregnant woman are entitled to;

c) the techniques for undertaking interruption of pregnancy and potential risks of each procedure, including those regarding the anaesthesia used.

d) Complications and possible sequela;

e) contraceptive options after the termination of the pregnancy;

(6) The partners are entitled, upon request, to receive information and counseling regarding the termination of pregnancy.

(7) Any woman who has undergone a procedure for the interruption of pregnancy is entitled to free contraceptives during the first 6 month after the interruption.

Article 8. – (1) Adolescents and youth are entitled to the same reproductive and sexual rights as adults do, including the right to information and access to reproductive health services according to their needs.

(2) Adolescent and young woman shall be informed on the risks connected with the interruption of pregnancy, irrespective of their decision with regard to the evolution of the pregnancy.

(3) Adolescent and young woman that have legal competence are entitled to undergo a procedure for the voluntary interruption of the pregnancy under safe conditions without the consent of their parents or their legal tutor.

(4) Adolescents and youth are entitled to sexual education, reproductive health education and family life skills training.

(5) Sexual education and family life skills training is offered in educational establishments and in other institutions where adolescents or youth with special needs are located, according to curricula drawn up for this very purpose and taking into account their age, gender and psychological make-up.

(6) The Ministry of Education and Research in collaboration with the ministry of Health are in charge of preparing the curricula for sexual education, reproductive health education and family life skills training.

(7) Adolescent and young women are entitled to continue their education during and after the pregnancy.

Article 9. (1) Any woman is entitled to a free annual medical consultation for the early detection of genital and breath cancer, irrespective of whether or not she has paid the contribution to the social health insurance.

(2) Any woman is entitled to screening, early detection, treatment and post-treatment care for genital and breath cancer.

(3) Any woman is entitled to free prenatal care, medical care for the delivery and neonatal care under safe conditions, postnatal care and breastfeeding care, irrespective of whether or not she has paid the contribution to the social health insurance and irrespective of whether the respective medical services constitutes an emergency or not.

(4) Any person is entitled to free consultations and investigations for the prevention and treatment of sexually transmitted diseases (STD´s) and of HIV / AIDS infection, irrespective of whether or not she/ he has paid the contribution to the social health insurance.

CHAPTER III
Medically assisted human reproduction

Article 10. – In the area of medically assisted human reproduction health care services answer the parental request of a couple to remedy diagnosed infertility with a pathological character or to avoid the transmission of a serious disease to the child.

Article 11. – In order to receive medically assisted human reproduction services the man and the woman need to fulfill, cumulatively the following conditions:

a) to be alive, the artificial insemination of the woman with the sperm of the deceased husband being prohibited;

b) to be at the biological reproductive age;

c) to fulfill the medical criteria regarding physical health and mental health condition.

d) to me married or able to probe a common life together of at least 2 years.

e) to consent previously to the transfer of embryos or to artificial insemination.

Article 12. – (1) Before resorting to one of the medically assisted reproduction techniques, the multidisciplinary medical team of the health facility that is going to undertake the technical and medical procedures shall inform the members of the couple on the outlook of success or failure, on the risk for the mother and the child, check the motivation of the couple and inform them on the existing possibilities regarding adoption that are provided by law.

(2) The couple shall receive a guidebook that should comprise a description of all medical techniques that are going to be undertaken as well as a legal information regarding medically assisted reproduction.

(3) Medically assisted human reproduction grants the physician a fundamental role in selecting the beneficiary couples and the donors and requires a correct assessment of their health condition, of their physical and mental characteristics, analyses of genetic and family antecedents, making sure that the test are conducted in good conditions, a subjective assessment of the couples´ capacity to be parents.

(4) The couple´s request can be confirmed or refuted by the gynecologist, one month after the date the request was submitted.

Article 13. – (1) Access to medically assisted human reproduction is granted to any woman or man suffering from sterility, that cannot be treated with a classic

method of treatment or surgical intervention in the following cases:

a) immunological incompatibilities;

b) the establishment that no possibility of contact exists between the two germination cells.

c) sterility due to unknown causes.

(2) In all cases provided under paragraph (1) the physician can intervene only with the previous consent of both the donor and the receiver, taking into consideration the protection of the child resulting from the use of this procedure.

Article 14. – The following activities are prohibited in the area of medically assisted human reproduction:

a) abusive production of embryos;

b) absence of consent at any stage of the procedure, as well as the absence of the required authorizations;

c) intermediating agreements for substitutive maternity;

d) genetic manipulation on embryos;

e) post-mortem insemination;

g) illegal donation of embryos;

h) gametes trafficking;

i) Collection of gametes without consent;

j) mixing gametes;

k) violating the confidentiality of the data regarding donations;

l) non-detection of possible communicable or infectious diseases;

m) selective abortion of embryos of a certain sex, as provided in the international regulations on bioethics;

Article 15. – (1) The allowed techniques of medically assisted human reproduction are:

a) artificial insemination;

b) in vitro fecundation;

c) transfer of embryos;

(2) The prohibited techniques of medically assisted human reproduction are:

a) post-mortem artificial insemination;

b) post-mortem transfer of embryos;

c) interventions in cases of infertility due to age;

d) interventions in the case of couples that cannot prove a common stable life together;

Article 16. – The artificial insemination procedure can be performed by:

a) the insemination with the sexual cell of the partner;

b) insemination by using the cell of a donor, which applies in the case of genetic or communicable diseases of the partner;

Article 17. – In vitro fecundation can be performed in one of the following situations:

a) with gametes collected from the partners of the beneficiary couple, followed by the implant of the embryo into the uterus of the beneficiary woman, provided that this cannot be achieved naturally, although both of the partners are fertile;

b) with gametes collected from persons that are completely foreign to the couple that wishes the child and implant into the uterus of the beneficiary woman;

c) with the intervention of a third person, who is the donor woman, in case the woman of the beneficiary couple does not have eggs and therefore, the ovum is being donated but the pregnancy carried by the beneficiary mother;

d) with the intervention of a third person, who can be the carrying mother, in case the woman of the beneficiary couple cannot carry the pregnancy, but donates the ovum.

Article 18. – Conjugal insemination is used in the case of the husband´s impotence or biological incompatibility of the partners, as well as when the sperm does not have the quantity and quality of sperm cells required for fecundation;

Article 19. – (1) In the case of insemination with gametes collected from a donor, due to total male or female sterility or due to genetic problems of the partners that could be passed on to the child, it is compulsory that one of the gametes be of one of the members of the couple, and the donor to be a member of a couple that already has children. Gametes of a donor are used only for the reproduction of a limited number of children.

(2) The medical selection criteria for a donor respective to the quality and quantity of the sperm cells, the physical and mental health condition of the donor that may influence the genetic make-up of the child are approved by order of the minister of health and are identical for all clinics that perform artificial insemination as well as for all donors.

(3) The act of donation is free of charge and the identity of the donor is confidential.

(4) The donor must give his consent, which must be clear and precise.

(5) The donor may receive a reasonable remuneration to compensate the expenses incurred or the losses suffered as well as the stay in the hospital and the period out of employment.

(6) The donor of gametes is responsible under the criminal or civil law in case he / she does not disclose the existence of illnesses or affections that risk to compromise the integrity, health or life of the child.

Article 20. – In case of performing treatment and of preventing certain diseases for which it is important to know the genetic make-up of the child and of the biological parents, the physician performing the insemination procedure has access to information, being exonerated of the obligation of keeping the medical confidentiality, by invoking the incidence of cases of force majeure.

Article 21. – Before commencing the procedures for medically assisted human reproduction the following notarized papers need to be drawn up between the couple assisted for reproduction and the carrying mother or the surrogate mother – if the latter is not married:

a) consent of the carrying mother or the surrogate mother to help the reproductive couple to have one or more children, by participating in the process of in vitro fertilization, gestation and delivery;

b) statement of the carrying mother or surrogate mother regarding her renouncing of parental rights in favor of the reproductively assisted couple and her agreement to entrust the child, immediately after birth, to the reproductively assisted couple;

c) consent of the carrying mother or the surrogate mother regarding the non-disclosure of her personal information on the birth certificate of the child, in civil papers and in any other official document regarding the maternity of the child;

d) consent of the carrying mother or the surrogate mother in the case of an abortion during the first three month of pregnancy, upon request of the reproductively assisted couple and only upon medical prescription;

e) consent of the husband of the carrying mother or surrogate mother, if married, regarding the in vitro fertilization procedure, keeping the pregnancy resulted after the in vitro fertilization with genetic material stemming from third parties, selective abortion upon request of the beneficiary couple and assigning or all parental rights and obligations regarding the child, including the registration on the birth certificate of the child and the agreement to entrust the child to the reproductively assisted couple after delivery.

f) consent of the reproductively assisted couple to entrust be entrusted the child immediately after birth, irrespective of the child´s health condition.

g) a contract which should stipulate the interdiction for the carrying mother or the surrogate mother to abort the pregnancy in absence of a medical indication and without the consent of the reproductively assisted couple, and further the lifestyle of the carrying or surrogate mother with a view to a good evolution of the pregnancy and development of the fetus as well as the obligations of the reproductively assisted couple to pay the carrying or surrogate mother for the expenses related to the pregnancy.

Article 22. – (1) Before the birth of the child, the reproductively assisted couple has to file an application, together with the papers provided at article 21 with the court in view of obtaining a judgment to certify the fulfillment of the requirements stipulated by the present law.

(2) the judgment of the court must be final and irrevocable before the birth of the child and constitutes the basis for the issue of the birth certificate of the child that was conceived by means of medically assisted human reproduction with a carrying or surrogate mother.

Article 23. – (1) In the case of assisted human reproduction through a carrying or surrogate mother the reproductively assisted couple is registered as parents on the birth certificate of the child.

(2) Under the circumstances provided at paragraph (1) the parental status is attributed to the infertile couple.

(3) The recording of the new-born into the register of the registry office and issue of the birth certificate is performed only after previously obtaining the approval of the territorial directorate for child protection.

Article 24. – (1) Based on the papers provided at article 21 the child born by the carrying or surrogate mother by medically assisted human reproduction is to be entrusted to the medically assisted couple immediately after birth.

(2) The carrying mother or the surrogate mother are entitled to all rights provided by law.

Article 25. – (1) The legal affiliation is established by the simple statement of the infertile, assisted couple at the time of the child´s birth. In the event that one of the partners should decline to acknowledge the child, the interested person is entitled to start legal action to determine responsibility or for acknowledging paternity or maternity as well as legal action to contest the affiliation.

(2) In the case of children born as a result of conjugal artificial insemination, the child has the same rights as the child born by natural reproduction.

Article 26. – (1) Medically assisted human reproduction by artificial insemination or in vitro fertilization creates rights and obligations for the mother of the child, the mother´s partner, the physician involved and the donor of gametes, before and after the medical procreation act.

(2) The written consent of the partners is compulsory with a view to providing information to the partners that should be as accurate as possible, with a view to verifying the motivation of the partners for artificial procreation and determining a time to think the matter through which should allow the couple to confirm or withdraw their consent in the presence of a legal representative, notary or judge.

(3) In the case of married couples or couples living together, the consent of both partners is required.

(4) The consent bears no legal effects in case of the death, divorce or separation of the couple preceding the acts of artificial procreation.

(5) The consent can be revoked in writing by one of the partners in the presence of the physician that performs the artificial procreation procedure.

Article 27. – The performing of in vitro fertilization is conditioned by the existence of a therapeutical or procreative motivation, the utility of the in vitro fecundation procedure, the assessment of the chances of success, the required character of the action, respectively treatment of sterility and the logical proportionality between the wish to have a child, the interest of the child to be born and the maintenance of the physical integrity of the mother.

Article 28. – The specific conditions for in vitro fecundation are the following:

a) the written consent of the infertile, medically assisted couple;

b) the obligation to prove the existence of the risk of transmitting an incurable genetic disease;

c) performance of the intervention in a specialized facility;

d) the obligation to establish the causes of infertility;

e) the examination of the embryo before implant with a view to detecting possible risks of transmitting genetic diseases.

Article 29. – The medical team performing the intervention has the obligation to inform the infertile, medically assisted couple on the risks for the mother and the child.

Article 30. – (1) The woman that is going to be implanted the embryo must have the possibility to withdraw her consent for the implant at any stage of the medical process.

(2) The beneficiary couple or the couple that are the parents of the embryo can revoke its consent previous to the implant procedure in order to avoid a situation in which the engagement of the beneficiary couple does no longer exist or conflicts between the beneficiary and the parental couple regarding the child.

Article 31. – The provisions of the present law also apply in case of twin pregnancies resulting after the medically assisted human reproduction, irrespective of the number of resulting children.

CHAPTER IV
Sanctions

Article 32. – (1) The interruption of the pregnancy by the specialist physician, without proof of previous information and without the existence of an informed consent is deemed as contravention and sanctioned with a fine between 3.000.000 ROL and 5.000.000 ROL.

(2) The provisions of the Government Ordinance No. 2/2001 regarding the legal regime of contraventions, approved with amendments and completions by Law No. 180/ 2002, as amended, also apply for the contraventions provided by the present law.

Article 33. – Failure to observe the provisions of the present law lead to disciplinary, contraventional or criminal action, as appropriate, according to the legal provisions.

CHAPTER V
Final provisions

Article 34. – (1) Reproductive health services are funded from the state budget the budget of the single fund of social health insurance, as applicable, personal contributions of the insured, donations, sponsoring.

(2) Medically assisted human reproduction services are funded from the state budget and the budget of the single fund of social health insurance only for the cases specifically provided by order of the minister of health.

(3) Medical services for the voluntary interruption of pregnancy for the categories of fee-exempt women that are established by order o the minister of health are covered from the single fund of social health insurance.

Article 35. – (1) For the coordination and surveillance of the medically assisted human reproduction activity the Commission for the surveillance of medically assisted human reproduction is established by order of the minister of health.

(2) The authority of the Commission for the surveillance of medically assisted human reproduction is determined by order of the minister of health.

Article 36. – (1) The health authorities shall publish annual reports on the reproductive health of the population.

(2) The Ministry of Health shall prepare the implementing regulations of the present law within 90 day of the date the present law comes into force, implementing regulations that shall be published in the Official Bulletin of Romania, Part I.

(3) Upon the coming into force of the present law, any contrary provisions are hereby annulled.

Article 37. – The present law comes into force 30 days after the date it is published in the Official Bulletin of Romania, Part I.

The present law was adopted by the Parliament of Romania observing the provisions of article 75 and article 76 paragraph (2) of the Romanian Constitution, as republished.

PRESIDENT OF	**pp. PRESIDENT**
THE CHAMBER OF DEPUTIES	**OF THE SENATE**
Valer Dorneanu	**Marin Dinu**