Republic of Moldova

parliament

LAW No. 138
of 15-06-2012

regarding reproductive health

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ADJUSTED
LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23

Parliament adopts this organic law.

This law recognizes, regulates and guarantees the rights of individuals to reproduction, which are an integral part of human rights. The provisions of this law derive from the constitutional right to respect and protect intimate, family and private life and ensure the state's non-interference in family planning issues.

Chapter I
GENERAL DISPOSITIONS

Article 1. Subject of the law

This law establishes the legal framework in the field of population reproductive health protection for the purpose of ensuring fundamental human rights to health protection and medical assistance, based on the following objectives:

a) determining the principles of state policy in the field of reproductive health protection;

b) establishing legal guarantees for the realization of the sexual-reproductive rights of the population;

c) formulating the rights, obligations, powers and responsibilities of legal entities and natural persons active in the field of reproductive health protection;

d) establishing the legal framework of medically assisted human reproduction through the methods of artificial insemination and in vitro fertilization.

Article 2. Main notions

For the purposes of this law, the following main notions are defined:

reproductive health – a state of physical, mental and social well-being in everything related to the reproductive system, in all stages of human life. As a result, reproductive health implies a safe sex life, the possibility of people to procreate, as well as the freedom to decide when,

if and how often they want to procreate; reproductive health includes the right of women and men to be informed about and have access to safe, effective, affordable and acceptable methods of family planning that they can choose for themselves, as well as the right to access appropriate health services that allow women to have a safe pregnancy and birth;

reproductive rights – rights based on the recognition of the right of all heterosexual couples and individuals to decide freely and responsibly on the number of children they want to have, on the interval between pregnancies and on the moment they want to have children, as well as the right to use contraception methods, access to quality reproductive health protection services, education and information in this field;

sexual health - a state of physical, emotional, mental and social well-being related to sexuality, consisting not only in the absence of a disease, dysfunction or infirmity. Sexual health involves a positive and respectful approach to sexuality and sexual relations, as well as the possibility of having safe sexual experiences, without coercion, discrimination and violence;

protection of reproductive health - methods, technologies and services that contribute to establishing, preserving and improving reproductive health by preventing and eliminating disorders of reproductive function throughout the entire human life;

contraception - methods and means for preventing unwanted pregnancy;

family planning – actions that determine the conscious choice of the number of children, the interval between pregnancies and the time of birth of children in the family;

infertility – the inability of a woman to conceive or a man to induce a pregnancy during a year of regular sexual intercourse without the use of contraceptive methods;

medically assisted reproductive technologies (ART/ART) – all interventions that include in vitro manipulation of human oocytes and spermatozoa or embryos for the purpose of reproduction. These include but are not limited to: in vitro fertilization (IVF/IVF), embryo transfer (ET), intracytoplasmic sperm injection (ICSI), embryo biopsy, preimplantation genetic testing (PGT), assisted hatching, intrafallopian gamete transfer (GIFT), zygote intrafallopian transfer (TIFZ), gamete and embryo cryopreservation, sperm, oocyte or embryo donation, cycles with gestational carriers. ART/ART do not include artificial insemination using sperm from the woman's partner or a sperm donor;

[Art.2 notion in the redaction of LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

reproductive cells – all tissues and cells intended for use in medically assisted reproduction;

[Art.2 notion introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

sex cells (gametes) – reproductive human cells, carrying sex chromosomes (sperm in men, ovules/oocytes in women);

[Art.2 notion introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

cryopreservation or fertility preservation – cryopreservation of reproductive tissues or cells to preserve their reproductive capacity. The process of saving or protecting a person's oocytes, sperm, and/or reproductive tissue (ovarian tissue, testicular tissue) so that they can use them to try to have biological children later in life;

[Art.2 notion introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

institutions responsible for human use – health center or unit of a hospital or another body that uses human tissues and cells;

[Art.2 notion introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

medically assisted reproductive couple – infertile couple, consisting of a man and a woman, who benefit from medically assisted reproduction and who contributed totally, partially or not at all with gametes and gonadal tissue necessary for reproduction;

[Art.2 notion introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

medically assisted reproduction (RAM/MAR) – reproduction achieved through various interventions, procedures, surgeries and technologies to treat various forms of fertility impairment and infertility. These include ovulation induction, ovarian stimulation, ovulation induction, all ART/ART procedures, uterus transplantation and intrauterine, intracervical and intravaginal insemination with husband/partner or donor sperm;

[Art.2 notion introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

in vitro fertilization (IVF) – medically assisted reproduction procedure involving extracorporeal fertilization. Includes conventional in vitro insemination and intracytoplasmic sperm injection;

[Art.2 notion introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

artificial insemination (AI) – the medical procedure by which the sperm from the partner or donor is introduced, after processing it in the laboratory, into the woman's uterus or vagina, fertilization following its natural course;

[Art.2 notion introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

embryo donation – process by which a woman (or couple) donates embryos to allow another woman (or couple) to conceive;

[Art.2 notion introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

oocyte donation – process by which a woman (the donor) donates oocytes to enable another woman (the recipient) to conceive, as part of a medically assisted reproductive treatment;

[Art.2 notion introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

supernumerary oocyte (oocyte sharing)/supernumerary embryo donation – type of oocyte/embryo donation in which a woman undergoing medically assisted reproduction donates part of her oocytes/embryos to the clinic where she is undergoing treatment, so that they can be used by another woman (or couple) for medically assisted reproduction;

[Art.2 notion introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

supernumerary embryos – the excess of embryos after embryo transfer;

[Art.2 notion introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

in vitro oocyte maturation (IVM) – sequence of laboratory procedures that allow the extracorporeal maturation of immature oocytes into fully mature oocytes, capable of being fertilized with the potential to develop into embryos;

[Art.2 notion introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

embryo transfer/embryo transfer (ET) – procedure in which one or more embryos are placed in the uterus or fallopian tube;

[Art.2 notion introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

informed consent – a person's voluntary agreement to donate, to participate in research studies or to be subjected to a diagnostic, therapeutic or preventive procedure, based on adequate knowledge and understanding of the relevant information related by the competent personnel;

[Art.2 notion introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

cryopreservation – the preservation and storage of tissues and viable reproductive cells, including gametes and embryos, to preserve their viability, either by slow freezing or by vitrification;

[Art.2 notion introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

distribution – the transport and delivery of tissues or reproductive cells intended for human use;

[Art.2 notion introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

procurement – the process by which reproductive tissues or cells are made available for storage in a tissue and/or cell bank or for human use. This process includes identifying and evaluating the donor, obtaining consent for donation, maintaining the donor, and extracting reproductive tissues or cells;

[Art.2 notion introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

storage – maintaining a product in appropriate, controlled conditions until distribution;

[Art.2 notion introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

transport – the act of transferring or transporting reproductive tissues and cells from one place to another within an institution or between institutions. It may include transportation between facilities and/or tissue and/or cell banks within the same country or to another state that is party to international agreements or conventions for further processing or storage.

[Art.2 notion introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

Article 3. Health care services
reproductive

Human reproductive health activities are organized and coordinated by the Ministry of Health and include:

a) family planning and contraception;

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

c) motherhood without risk, including prenatal care, care during pregnancy, birth and childbirth, postnatal care and newborn care under safe conditions;

d) the correct nutrition of the child/newborn, with an emphasis on breastfeeding;

e) prevention, diagnosis and treatment of sexually transmitted diseases (STDs) and HIV/AIDS infection;

f) reproductive and sexual health in adolescents and young people;

g) the sexual health of the elderly;

h) prevention, early diagnosis and treatment of cancer of the urogenital system in women and men and of breast cancer;

i) the sexual-reproductive health of men;

j) prevention and treatment of infertility;

k) medically assisted reproduction;

l) cervical cancer prevention through cervical screening.

[Art.3 in the redaction of LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

Chapter II
REPRODUCTIVE HEALTH

Article 4. Rights in the field of reproductive health

(1) In the Republic of Moldova, the following is ensured:

a) access to safe and effective reproductive health protection services as an integral part of the right to health protection, provided by the Constitution;

b) respect from the institutions/organizations that carry out activity in the field of reproductive health protection;

c) respect for dignity, spiritual and religious values, national and social affiliation, gender, age and other particularities;

d) the freedom to choose the doctor and the institution/organization empowered with the right to offer reproductive health protection services;

e) obtaining truthful information regarding the rights and obligations in the field of reproductive health, the state of reproductive health, including the results of investigations, the prognosis, the treatment methods, the risks related to them, the possible variants of medical interventions, the consequences and the results of the treatment performed. In exceptional cases, provided by the legislation in force, limitations may be applied to the realization of this right in the interest of the patient;

f) the right to a safe pregnancy and qualified antenatal, intranatal and postnatal care.

(2) Any adult woman and any adult man have the freedom to decide on the number of their own children and on the moment of their birth, as well as on issues related to reproductive health, without coercion and without outside influence.

(3) Every person has the right to correct sexual education, to the use and refusal of contraceptive methods, to the diagnosis and treatment of sexually transmitted infection and HIV/AIDS infection, to the regulation of fertility and the termination of pregnancy under safe conditions, to assistance qualified perinatal, early diagnosis and treatment of genito-breast cancer, infertility treatment and medically assisted human reproduction, assistance during the menopause/andropause period.

Article 5. Reproductive health in women and men

The state ensures:

a) development and organization of assistance in the field of reproductive health protection so as to ensure equal access of women and men to quality medical services;

b) permanent information of the population through messages to prevent reproductive health problems, using all available informational channels and exempting social advertising messages from tax;

c) supplying the population with quality reproductive health products, including contraceptives for people from socially vulnerable groups. The categories of women who have the right to receive free modern means of contraception are established by order of the Minister of Health, Labor and Social Protection;

d) for people who request a method of contraception - medical consultations for the purpose of choosing the method of contraception, taking into account the state of health, age and individual characteristics. Counseling services for contraception are provided by staff specially trained in this regard and in spaces that ensure confidentiality;

e) methods of voluntary surgical contraception, which can be applied only at the request of the applicant and based on his informed consent;

f) for every woman - access to safe methods of termination of pregnancy, in accordance with the normative acts of the Ministry of Health;

g) for every woman – a free annual consultation for the early detection of genital-breast cancer, regardless of payment or non-payment of the mandatory health care insurance premium;

h) for every woman – genito-breast cancer screening, treatment and care after treatment;

i) for each man - screening for the pathology of the reproductive system, including genital cancer, treatment and rehabilitation;

j) to every couple, every single woman - free, in safe conditions, prenatal care, birth and newborn care, postnatal care, regardless of payment or non-payment of the mandatory health care insurance premium and regardless of whether or not it is emergency medical service;

k) improving the medico-genetic assistance of the population and implementing new prenatal diagnosis technologies to prevent and reduce the level of congenital malformations, and in the case of their detection during pregnancy, the pregnant woman is provided with the opportunity to terminate the pregnancy free of charge;

l) to any person - free consultations and investigations for the prevention and treatment of sexually transmitted infections and HIV/AIDS infection, regardless of payment or non-payment of the mandatory health care insurance premium;

m) measures to prevent sexual violence, to assist and rehabilitate victims of violence.

Article 6. Sexual-reproductive health of adolescents

(1) Adolescents have the right to information and access to reproductive health protection services adapted to their needs.

(2) Adolescents have the right to sex education adapted to their age to ensure correct psychosexual development, prevention of sexually transmitted infections and HIV/AIDS infection, unwanted pregnancy and for the formation of responsible parenting skills.

(3) Compulsory sexual education and preparation for family life are carried out in educational institutions and in other institutions where there are teenagers or young people, including those with special needs, according to specially developed programs, which are part of the compulsory curricula of educational institutions, taking into account age, sex and the particularities of psychosexual development.

(4) The development of age-appropriate sex education programs for correct psychosexual development, the prevention of sexually transmitted infections and HIV/AIDS infection, unwanted pregnancy and the formation of responsible parenting skills is ensured by the Ministry of Education and Research, in agreement with the Ministry Health.

(5) Medical services in the field of adolescent sexual-reproductive health are provided by youth-friendly health services and by other services authorized in accordance with the normative acts of the Ministry of Health.

(6) In the case of minors under the age of 16, voluntary consent to obtain reproductive health protection services is expressed by both the minor and his legal representative. In the case when it is impossible to obtain the consent of the minor's legal representative and when medical services are indicated to preserve his life and health, his voluntary consent is sufficient. In this situation, the decision is made consultatively by the service providers, in the best interest of the minor, in accordance with the normative acts of the Ministry of Health.

(7) In the event of teenage pregnancy, they are guaranteed and assured the right to continue their studies during the pregnancy and after the termination of the pregnancy.

Article 7. Sexual health of the elderly

(1) Women and men of the third age have the right to benefit from performance services regarding the protection of sexual health.

(2) Ministry of Health:

a) will implement measures to prevent women's and men's health problems during menopause and andropause;

b) will organize sexual health protection services in such a way as to ensure access to assistance in menopause and andropause-related problems for the elderly.

Article 8. The principles of realization of reproduction rights

Reproduction rights are realized according to the following basic principles:

a) realization of these rights according to the will and interests of the person without infringing the rights, freedoms and legitimate interests of other persons;

b) non-interference of the state in realizing the right to freely make decisions regarding the birth of children;

c) the integrity of private life and family secrecy;

d) confidentiality in matters related to the protection of reproductive health;

e) the accessibility of medical assistance in the field of reproductive health protection;

f) ensuring the guaranteed volume of services regarding the protection of reproductive health and family planning, as well as their quality and accessibility;

g) compliance with special professional requirements and standards in performing medical interventions in the field of reproductive health protection;

h) state support for families with children, in accordance with the legislation in force.

Chapter III
MEDICALLY ASSISTED REPRODUCTION AND METHODS OF USING MEDICALLY ASSISTED REPRODUCTION TECHNOLOGIES

[Name of chapter III in the redaction of LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

Article 9. Use of reproduction technologies medically assisted

(1) People have the right to infertility treatment, including the use of medically assisted reproductive technologies.

(2) The use of medically assisted reproduction technologies is allowed for citizens of the Republic of Moldova, foreign citizens and stateless persons who have reached the age of 18, who have medical indications and have no contraindications regarding the use of these technologies.

(3) Medically assisted reproduction services can be provided by public and/or private medical service providers accredited and authorized in accordance with the legislation.

(4) Public and/or private medical service providers may use (apply) reproductive tissues and cells for medically assisted reproduction, using medically assisted reproduction technologies, and/or for fertility preservation in accordance with the law.

(5) Tissue and/or cell banks that are not connected to public and/or private medical service providers must be authorized to carry out the activities of donation, sampling, testing, processing, preservation, storage and distribution of tissues and/ or reproductive cells in accordance with the law.

(6) The use of medically assisted reproduction technologies is possible only on the basis of the beneficiary's written informed consent, valid for a single procedure, which will include truthful and complete information regarding:

a) the essence of the medically assisted reproduction technologies to be used;

b) the medical and legal aspects of the procedures to be performed;

c) associated risks, side effects and possible complications;

d) the expected results following the treatment performed and the factors on which the result depends.

(7) The medically assisted reproductive couple, whether or not they are in a marriage registered in the manner established by law, has the right to use medically assisted reproductive technologies on the condition of mutual agreement and informed consent, written, signed by both spouses or partners.

(8) The informed consent is without legal effect if one of the spouses/partners submits a written request in this regard upon the occurrence of circumstances such as the dissolution of the legal marriage or the separation of the partners or the death of a member of the reproductive couple, which occurred before the completion of the services of medically assisted reproduction.

(9) Informed consent can be revoked in writing until the moment of insemination or transfer of the embryo into the woman's body, unilaterally by one of the members of the medically assisted reproductive couple, exclusively in the presence of the attending physician. Voluntary revocation of informed consent after the moment of insemination or transfer of the embryo into the woman's body is struck by absolute nullity.

(10) Single women have the right to use medically assisted reproduction technologies with the use of a donor's sperm based on the informed consent signed by them.

(11) Data related to the treatment of infertility through the application of medically assisted reproduction technologies are confidential and constitute a medical secret.

(12) The following medically assisted reproduction technologies are allowed:

a) artificial insemination with the husband's sperm;

b) artificial insemination with donor sperm;

c) in vitro fertilization with intrauterine transfer of embryos;

d) intracytoplasmic injection of spermatozoa;

e) assisted hatching;

f) microsurgical extraction of spermatozoa from the testicle and/or accessory glands;

g) cryopreservation of sperm, oocytes, embryos for medically assisted reproduction;

h) donation of sperm, oocytes, embryos;

i) preimplantation genetic testing;

j) reduction of the number of embryos in case of multiple pregnancy;

k) cryopreservation of gametes and reproductive gonadal tissue (testicular tissue, ovarian tissue) for fertility preservation;

l) in vitro maturation of oocytes.

(13) In the field of medically assisted reproduction, the following are prohibited:

a) choosing the sex of the future child, except in cases of risk of inheriting severe genetic diseases related to sex;

b) selective abortion of embryos of a certain sex, specified in international bioethical regulations;

c) cloning the human being, creating chimeras and transplanting them into the human body;

d) using sex cells to create human embryos exclusively for scientific research;

e) application of medically assisted reproductive treatments or medically assisted reproductive technologies without the person's consent;

f) the provision of medically assisted reproduction services in the absence of a sanitary operation authorization issued by the National Agency for Public Health and in the absence of an authorization issued by the Ministry of Health at the proposal of the Transplantation Agency;

g) violation of data confidentiality regarding sperm, oocyte or embryo donations;

h) obtaining gametes and/or reproductive gonadal tissues from persons under the age of 18 (except in cases of cryopreservation of fertility based on medical indications).

(14) The persons who have given their written informed consent for the use of medically assisted reproduction technologies, in the case of birth by this method of one or more children, are registered as his/her parents in the manner established by the Family Code and have not the right to contest his maternity and/or paternity by reference to these circumstances.

(15) Children born as a result of artificial insemination or in vitro fertilization have the same rights as children born through natural reproduction.

(16) Activities regarding medically assisted reproduction are coordinated by the National Council for Medically Assisted Reproduction and monitored by the Transplantation Agency.

[Art.9 in the redaction of LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

Article 10. Artificial insemination with the husband's or donor's sperm

(1) The artificial insemination procedure can be carried out by:

a) insemination with the sperm of the husband/partner;

b) insemination with a donor's sperm.

(2) Artificial insemination with the husband's/partner's sperm is used in case of impotence or biological incompatibility between the partners, as well as in case the sperm does not have the quality and quantity of spermatozoa necessary for fertilization.

(3) Artificial insemination with sperm taken from the donor is performed in the case of male infertility, which cannot be treated by any other method, or in the case of the presence of genetic problems with a high risk of transmission to the fetus.

(4) Couples whose infertility is caused by the male factor can benefit from both anonymous sperm donation and non-anonymous donation (sperm obtained from a relative of the husband).

(5) Single women also have the right to the insemination procedure with donated sperm.

(6) Couples suffering from infertility and who have medical indications for the medically assisted reproduction procedure with donor sperm, as well as single women who wish to get pregnant and give birth to a child, can benefit from donated sperm from a tissue bank and/or cells located on the territory of the Republic of Moldova as well as outside it.

[Art. 10 para. (6) introduced by LP339 of 08.12.22, MO440-444/30.12.22 art. 809; in force 01.01.23]

Article 11. In vitro fertilization with intrauterine transfer of embryos

(1) In vitro fertilization with intrauterine transfer of embryos is a basic method in the treatment of infertility.

(2) The main indications for in vitro fertilization are female and/or male infertility, when other treatment methods are impossible or ineffective.

(3) Any couple, any single woman, suffering from infertility has access to in vitro fertilization, if they have made an informed decision to use this method.

(4) In order to resort to in vitro fertilization, the woman and the man must meet the necessary medical criteria regarding the state of physical and mental health.

(5) The age limit for in vitro fertilization with one's own oocytes is 45 years, and for the use of donated oocytes - 50 years.

(5^{1}) To obtain embryos through the application of in vitro fertilization technology, the following can be used:

a) the gametes (oocytes and spermatozoa) of the married couple or of the cohabiting couple, who requested, by mutual agreement, the application of in vitro fertilization;

b) own sperm of the married couple or of the cohabiting couple and the donated oocytes;

c) the own oocytes of the married couple or the couple in cohabitation and the donated sperm (in the case of single women – only sperm from an anonymous donor);

d) donated oocytes and donated spermatozoa.

[Art. 11 para. (5^{1}) introduced by LP339 of 08.12.22, MO440-444/30.12.22 art. 809; in force 01.01.23]

(6) The necessary conditions for carrying out the in vitro fertilization program are:

a) the written informed consent of the reproductive couple or of the single woman, if he/she uses the sperm of a donor;

b) the application of medically assisted reproduction technologies by public and/or private medical service providers accredited and authorized according to the legislation;

c) lack of medical contraindications for the use of medically assisted reproduction technologies and/or artificial insemination and/or for having a pregnancy;

d) performing mandatory medical examinations and laboratory tests for medically assisted reproductive couples and single women benefiting from medically assisted reproductive treatments;

e) compliance with the requirements for the selection, evaluation, examination and mandatory testing of gamete and embryo donors in the donation from non-partners;

f) evaluation, examination and mandatory testing of patients who resort to fertility cryopreservation.

[Art. 11 para. (6) in the wording of LP339 of 08.12.22, MO440-444/30.12.22 art. 809; in force 01.01.23]

(7) In the case of married or cohabiting couples, the written consent of both partners is required.

(8) In the case of single women, their request and written consent is sufficient.

(9) Any information of the heterosexual couple, related to the treatment of infertility through the application of in vitro fertilization methods, constitutes a medical secret and will not be transmitted to other people without the couple's consent.

(10) In the case of oocytes and embryos left unused after the in vitro fertilization program, patients have the right to decide:

a) their cryopreservation for further use in their own medically assisted reproduction projects;

b) refusal of their further use and, respectively, their destruction;

c) donating them to another couple in order to get pregnant.

[Art.11 para.(10) in the wording of LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

Article 12. Donation of sexual cells and embryos

(1) The donation of sex cells and embryos must be based on the principles of voluntary informed consent, confidentiality and anonymity of the donor and the recipient (except in the case of harvesting from a person close to the recipient), altruism of the donor and solidarity between the donor and the recipient.

(2) Sperm donors can be men of reproductive age (not less than 18 years and not more than 45 years old) who, following medical examinations, biological and genetic tests, psychological evaluation and andrological examination, have were confirmed to be physically and mentally healthy and to have normal spermogram parameters.

(3) Oocyte donors can be women of reproductive age (not less than 18 years and not more than 36 years old) who, following medical examinations, biological and genetic tests, psychological evaluation and gynecological examination, have were confirmed to be physically and mentally healthy and to have normal ovarian reserve parameters.

(4) Donors of embryos or oocytes for another medically assisted reproductive couple can also be patients of the in vitro fertilization program who, through a free decision and informed consent, accept to donate supernumerary embryos or supernumerary oocytes (oocyte sharing) or to donate the gametes or embryos left over from their own reproductive treatment after the decision to end their own reproductive/paternal project.

(5) A gamete or embryo donor cannot be a person who:

a) does not have full exercise capacity;

b) is kept under arrest, is in a penitentiary or an accommodation center for foreigners;

c) is subject to the measure of isolation, quarantine or is subject to treatment for hospitalized patients;

d) is deprived of parental rights;

e) is not able to evaluate the act of donation or its consequences;

f) is forcibly hospitalized.

(6) Sex cell donation can be anonymous or non-anonymous. Non-anonymous donors of sex cells can be relatives of patients up to the 2nd degree (for women - female relatives, for men - male relatives), as well as people related to them through a special condition (friends, friends).

(7) The independent approval commission monitors and controls the correctness and legality of the non-anonymous (unrelated) oocyte donation procedure, and also authorizes oocyte donation in the situations provided for in this article.

(8) In the case of anonymous donation of gametes and/or embryos, the confidentiality and preservation of the anonymity of the donor and the recipient(s) who used donated gametes and/or embryos for medically assisted reproduction must be guaranteed.

(9) In exceptional circumstances, which involve a certain danger to the life or health of the child/children born with the help of medically assisted reproduction technologies using anonymously donated gametes or embryos, in accordance with the criminal procedural law, the identity of the donor may be disclosed provided that such disclosure is essential to avoid the danger or to achieve the intended legal purpose.

(10) Donation of oocytes from an anonymous donor must be limited to six cycles of ovarian stimulation with oocyte sampling, and a break of at least 3 months will be made between donation cycles.

(11) Gametes from a donor are used only for medically assisted reproduction of a limited number of children. The maximum number of live births that have been conceived with the gametes of an anonymous donor must not exceed three.

(12) Donors of sex cells and embryos assume no commitments and are absolved of parental responsibility towards the future child. They do not have the right to request the disclosure of data about the child or its parents.

(13) The medical criteria for donor selection are established by the National Council for Medically Assisted Reproduction.

(14) The donation of sex cells and/or embryos can be carried out based on voluntary consent and will be completed in the form of an informed consent, signed by the donor(s), which will include:

a) the purpose(s) for which the cells and/or embryos will be used - for reproductive purposes, within the medically assisted reproduction programs, to obtain pregnancies in people with fertility problems;

b) the specific instructions for destruction, if the cells and/or embryos are not used for the purpose for which the consent was obtained;

c) description of the particularities of the medical procedure to be performed;

d) information on potential risks, side effects and possible complications;

e) the legal consequences of the donation.

(15) Consent/agreement for the donation of gametes and/or embryos can be revoked at any time as long as they are available on the date of revocation.

(16) In the case of embryo donation, the partners of the donor couple from which the gametes originate and which generated the embryo, as well as the oocyte donor, in the case of oocyte sharing, must be considered non-partner donors and must comply with the general examination criteria medical and testing for non-partner donation.

(17) The use of gametes from an anonymous donor is prohibited in the case of persons related up to the 3rd degree. Compliance with the quality of the medical act in the case of the use of gametes from an anonymous donor is entirely the strict responsibility of the public or private medical service provider.

[Art.12 in the redaction of LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

Article 12 [1] . Providing allowances to donors
of sperm, oocytes and embryos

(1) The act of donating reproductive cells (sperm, oocytes) and embryos is voluntary and unpaid.

(2) Donors of reproductive cells (sperm, oocytes) and embryos may receive compensation to cover expenses and inconveniences related to the donation procedure, examinations and related medical treatments, loss of income and other justified expenses caused by the act of donation. The compensation offered to donors of reproductive cells and embryos is paid by patients who request the donation procedure only through the medical institution that provides such services.

(3) The donation contract is concluded in authentic form and confidentially between the donor and the public or private medical service provider or tissue and/or cell bank authorized for this type of activity.

(4) Any advertising or promotion activity carried out by the public or private medical service provider, as well as by the authorized tissue and/or cell bank, which encourages the donation of human reproductive tissues and cells must respect the altruism of the donation and in under no circumstances can the donation be encouraged by offering profit or economic benefits.

[Art.12 [1] introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

Article 13. Cryopreservation and transport
sex cells, embryos
and reproductive tissues

(1) Persons who benefit from medically assisted reproduction programs have the right to cryopreservation of sex cells (spermatozoa, oocytes), embryos, as well as male and female reproductive tissues (testicular tissue, ovarian tissue) in the public or private medical and sanitary

institution , as well as in the tissue and/or cell bank, authorized and accredited for this type of activity.

(2) In the case of men, fertility preservation can be applied:

a) in case of illness and treatments that could seriously affect sperm quality, for men of reproductive age and minor boys;

b) for the cryopreservation of donor sperm or of men participating in medically assisted reproduction programs;

c) in the case of delayed reproduction, for men of reproductive age, at their request.

(3) Cryopreservation of sperm obtained from the husband/partner or from the donor can be carried out both for artificial insemination and for in vitro fertilization.

(4) In the case of women of reproductive age, fertility preservation may be applied:

a) before treatments that foresee risks of loss of reproductive function;

b) in the case of delayed reproduction, at the request of the beneficiaries.

(5) Fertility conservation in minors is carried out with the consent of the guardianship authority or the minor's legal representatives, before treatment that foresees risks of loss of reproductive function.

(6) Cryopreservation of embryos can be applied in case of obtaining a surplus of oocytes/embryos within the in vitro fertilization program.

(7) Cryopreservation of sex cells and embryos is carried out based on the patient's written informed consent, which contains information regarding:

a) the purpose(s) for which the sex cells and/or embryos are used (personal reproductive purpose, donation) and all specific instructions for destruction if the cells and/or embryos are not used for the purpose for which consent was obtained;

b) the cryopreservation method, data on the conditions and terms of preservation of sex cells and/or embryos.

(8) If the infertility treatment is performed with gametes or cryopreserved embryos, the consent of the spouses/partners for their thawing must be obtained for each treatment.

(9) The criteria and conditions for cryopreservation, transport and thawing of sex cells, embryos and reproductive tissues are established by the National Council for Medically Assisted Reproduction.

[Art.13 in the redaction of LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

Chapter IV
INSURANCE OF RIGHTS IN THE FIELD REPRODUCTIVE HEALTH

Article 14. State policy in the field of reproductive health protection

(1) State policy in the field of reproductive health protection is oriented towards:

a) formation of a conscious and responsible attitude of the population towards sexual-reproductive health;

b) preventing unwanted pregnancy and reducing the number of abortions;

c) prophylaxis of sexually transmitted infections and HIV/AIDS infection;

d) the correct and extensive use of methods of contraception and protection of the reproductive function;

e) ensuring the birth of healthy and desirable children;

f) supporting families with children and couples planning their pregnancy;

g) development of quality reproductive health protection services;

h) the effective training of governmental, non-governmental and private institutions, the mass media in the defense and realization of reproductive rights as safely as possible;

i) propagation of knowledge in the field of sexual and reproductive education of the population;

j) supporting scientific research in the field of reproductive health;

k) university and postgraduate training of specialists in the field of reproductive health protection and in the field of reproductive rights according to international standards.

(2) The Government approves national programs whose objective is to protect reproductive health.

(3) Local public administration authorities have the right to develop and implement programs regarding the protection of reproductive health in the territory.

Article 15. Provision of protection services
of reproductive health

Reproductive health protection services can be provided by public and/or private medical service providers, authorized and accredited for this type of activity, in the manner established by legislation."

10. Article 16 is supplemented with paragraphs (3)–(5) with the following content:

"(3) The National Council for Medically Assisted Reproduction is a collegial, permanent and consultative body, whose purposes are:

a) counseling and guidance regarding medically assisted reproduction activities;

b) contributing to the development of the normative framework and standards in the field of medically assisted reproduction;

c) updating and disseminating scientific and technical knowledge in the field of medically assisted reproduction;

d) assisting the Ministry of Health in examining complaints in the field of medically assisted reproduction;

e) consulting the competent authorities regarding the development and application of regulations regarding medically assisted reproduction.

(4) The National Council for Medically Assisted Reproduction includes representatives of:

a) Ministry of Health;

b) Gynecology and Obstetrics Commission within the Ministry of Health;

c) Andrology and Sexual Medicine Commission within the Ministry of Health;

d) Ministry of Internal Affairs;

e) Transplantation Agency;

f) the National Agency for Public Health;

g) scientific communities and professional associations in the field of medically assisted reproduction, medical genetics and bioethics.

(5) The National Council for Medically Assisted Reproduction is established under the Ministry of Health and operates based on a regulation approved by the ministry.

[Art.15 in the redaction of LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

Article 16. Coordination of reproductive health protection services

(1) All human reproductive health protection activities are organized and coordinated by the Ministry of Health.

(2) For the coordination and supervision of the activity of medically assisted human reproduction, a committee is established within the Ministry of Health, whose duties are established by order of the Minister of Health.

Article 17. Training of personnel in the field of reproductive health

(1) The persons who provide reproductive health protection services must have special training in this field.

(2) The training of specialists in the field of reproduction rights is carried out according to the legislation in force, in accordance with the state programs, elaborated and approved in the established manner.

(3) Medical staff of public and/or private medical service providers and tissue and/or cell banks, who are directly involved in the activities of donation, sampling, control, processing, preservation, storage, distribution and use in humans of reproductive tissues and cells, must have the necessary qualifications to perform these tasks and receive appropriate continuing professional training.

[Art.17 para.(3) introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

Article 18. Accreditation, authorization and inspection

(1) Public and/or private medical service providers who provide medically assisted reproduction services operate on the basis of:

a) the operating sanitary authorization, issued by the National Agency for Public Health;

b) the accreditation certificate, issued by the National Health Evaluation and Accreditation Council;

c) The Regulation on the application of medically assisted technologies, approved by the National Council for Medically Assisted Reproduction after its coordination with the Ministry of Health;

d) authorizing the activities of donation, sampling, control, processing, conservation, storage, distribution and human use of reproductive tissues and cells, according to Law no. 42/2008 on the transplantation of human organs, tissues and cells.

(2) Control over the quality of the activities of donation, sampling, control, processing, preservation, storage, distribution and human use of reproductive tissues and cells in the field of medically assisted reproduction is carried out by the Transplantation Agency and is maintained through a control system of quality and testing of all activities carried out by public and/or private medical service providers.

(3) In order to guarantee the quality and safety of reproductive cells and/or tissues to be used for medically assisted reproduction technologies, the Transplantation Agency has the right to organize inspections and implement appropriate control measures regarding:

a) the activities of donation, sampling, control, processing, preservation, storage, transport and delivery of tissues or cells, including the procedures and activities carried out in accordance with this law;

b) the documents or registers that are kept in accordance with this law;

c) cases of serious adverse reactions and effects.

(4) The quality control of the activities of donation, sampling, control, processing, conservation, storage, distribution and human use of tissues and reproductive cells is carried out in compliance with the provisions of Law no. 133/2011 on the protection of personal data.

[Art.18 in the redaction of LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

Article 19. Monitoring of protection services
of reproductive health and reproduction
medically assisted

(1) Public and/or private medical service providers at district, municipal and national level prepare annual reports on reproductive health, which are presented to the Ministry of Health.

(2) The monitoring of the activities of donation, sampling, control, processing, preservation, storage, distribution and human use of reproductive tissues and cells, carried out by public and/or private medical service providers, including for medically assisted reproduction, is carried out by Transplant Agency.

(3) Public and/or private medical service providers, tissue and/or cell banks, as well as legal entities carrying out activities of sampling, transport and delivery of tissues and/or reproductive cells are required to submit reports on to the activities of donation, sampling, control, processing, conservation, storage, distribution and human use of reproductive tissues and cells, in the manner established by the Ministry of Health.

[Art.19 in the redaction of LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

Article 19 [1] . Authorization of import, export
and cross-border movements
of tissues and/or cells
reproductive

(1) The import and/or export of reproductive tissues and/or cells is necessary to satisfy the request of a reproductive couple or a single woman for medically assisted reproduction, or the request of a person whose reproductive tissues or cells are stored for the purpose of medically assisted reproduction or in order to preserve and restore fertility.

(2) Only tissue and/or cell banks authorized for medically assisted reproduction activities have the right to carry out import and/or export activities of reproductive tissues and/or cells.

(3) The authorization to import or export reproductive tissues and/or cells is issued by the Transplantation Agency at the request of public and/or private medical service providers or tissue and/or cell banks authorized for this type of activity.

(4) Frozen genetic material (oocytes, sperm, embryos, reproductive tissue), at the request of patients, can be transported from one clinic/tissue and/or cell bank to another clinic/tissue and/or cell bank , located both on the territory of the Republic of Moldova and outside it.

[Art.19 [1] introduced by LP339 of 08.12.22, MO440-444/30.12.22 art.809; in force 01.01.23]

Article 20. Funding

(1) The activity of public institutions/organizations that provide reproductive health protection services is financed within the limits of the means allocated from the budgets of all levels.

(2) Reproductive health protection services are financed from the state budget, from the budget of the mandatory medical assistance insurance fund and, as the case may be, from personal contributions, donations and sponsorships.

(3) Couples in which both partners are medically insured and meet the medical criteria established by the Ministry of Health will benefit from in vitro fertilization as part of the mandatory medical assistance insurance within the limits of the available financial means, according to the normative acts approved by the Government.

Article 21. Responsibilities

Legal entities and natural persons that ensure the realization of rights in the field of reproductive health bear the responsibility established by the legislation in force.

Article 22. Sanctions

Non-compliance with the provisions of this law attracts, as the case may be, disciplinary, contraventional or criminal liability, according to the law.

Chapter V
FINAL AND TRANSITIONAL PROVISIONS

Article 23.

(1) This law enters into force 30 days after its publication.

(2) On the date of entry into force of this law, any other provisions to the contrary shall be repealed.

(3) Ministry of Health:

a) within 6 months from the date of entry into force of this law, will develop a special regulation for the provision of services in the field of medically assisted human reproduction;

b) within 3 months from the date of entry into force of this law, in collaboration with the Ministry of Education and the Ministry of Justice, will develop the rules for the application of this law.

PARLIAMENT PRESIDENT Marian LUPU

Chisinau, June 15, 2012.
No. 138.