

THE DECLARATION ABOUT PATIENTS' RIGHTS IN RUSSIA

This Declaration about patients' rights in Russia was developed on the basis of the:

- Constitution of the Russian Federation;
- Laws of the Russian Federation;
- Declaration on the promotion of patients' rights in Europe (passed by the European Consultation on the Rights of Patients, Amsterdam, the Netherlands, March, 1994);
- European Charter of Patients' Rights (developed by a working group of representatives of EU member states, the project discussed in Rome on 7 Sept. 2002 under the auspices of the Initiative Active Citizenship Network and European Charter of Patients Right);
- Charter of Fundamental Rights of the European Union¹;
- Theory and practice in healthcare, medical assistance and protection of patients' rights in Russia –

And, consequently, it was approved at the First All-Russian Patients' Congress on 28 May 2010 in Moscow.

Preamble

In despite of the constitutional rights of patients in Russia and those defined by law, there are different barriers for many patients to access the essential medical assistance, which results in their health worsening, getting disabled and premature mortality. We cannot put up with that the rights ensured by law are not observed keeping in mind that Russia is keen to build a constitutional and socially responsible state, which follows from Article 7 of the Constitution of the Russian Federation. The government and society must find mechanisms of cooperation and mutual understanding that will make it possible to solve the problems of both particular persons and big communities. These mechanisms must include steadfast adherence to the rights, which can be ensured by open dialogue only that aims, in particular, at the observation of citizens' rights for health and medical assistance with the most effective usage of healthcare resources.

This Declaration is based on the Russian legislation and takes into account the most contemporary global achievements as far as patients' rights are concerned. The fourteen fundamental rights are acknowledged in Europe, and these rights are for: diseases prevention, accessibility of medical assistance, information, informed consent and refusal, free choice, individual life and confidentiality, respect for patient's time, meeting standards, security, innovations, excluding pain and sufferings, tailored treatment, complaints and compensation. These fourteen should be augmented with two more: the rights of the patient's family members and the right of a patient for protection.

This Declaration expresses a consolidated opinion of the civil society about the necessity to take measures to create more sophisticated mechanisms to realize patients' rights, to improve legal norms and mechanisms to protect rights. Maximum openness must become the basis for these processes. Neither decision, which is able to affect the healthcare system, must be passed without public hearings.

The Declaration addresses the civil society, government institutions and all those involved in protecting or realizing these rights. Realizing the Declaration provisions must become a priority of any group of active citizens, who deal with the issues of patients' rights, but it also calls upon medical professionals and healthcare managers, legislators, government and law-enforcement bodies.

¹ On 30 March 2010, the European Parliament, European Council and EU Commission passed the Charter of Fundamental Rights of the European Union (2010/C 83/02 document published in the Official EU bulletin #83, 2010).

The First All-Russian Congress of patients and patient societies considers it significant to pass this Declaration about patients' rights in Russia to ensure the government observes the norms of the Declaration and to conform the policy and legislation to the norms.

Part 1. Rights of patients

1.1. Right to prevention measures

Each person has the right to set up conditions to maintain a healthy lifestyle, to take necessary and timely measures in order to prevent and early diagnose diseases.

The healthcare system must do all to stop diseases developing, but once developed, they must be eliminated at the earliest possible stage. Healthcare facilities must follow this objective, while concurrently raising public awareness, providing free-of-charge sessions for various vulnerable communities, ensuring accessible scientific findings and technological innovations for all citizens.

The state must be responsible for the policy it pursues, where it pertains to the relevance of preventive measures, together with objective assessment of risks balancing in the prevention campaign and of the real danger of emerging and/or spreading of the disease for the society and each individual.

1.2. Right to accessible medical assistance

Each person has the right to accessible medical assistance, which is required for maintaining his/her health. Each person has the right to the required, timely and secure treatment*.

Each person has the right to ambulance, emergency, in-patient treatment aid, rehabilitation, and care.

The healthcare system must provide for equal accessibility of medical assistance for all citizens (including those in prison) without any discrimination on the ground of solvency, place of residence, disease type, legal competence, time of the patient's recourse to medical assistance or on the ground of any other reason.

The government must remove barriers to medical assistance in the form of paid services at governmental and municipal institutions, the obligatory producing of a policy of Compulsory Medical Insurance (OMS), the registration at the place of residence of a patient and other conditions that restrict the constitutional right of citizens to free-of-charge medical assistance at governmental and municipal healthcare institutions.

Provision of essential pharmaceuticals must be free.

A person who suffers from a rare disease has the same right to essential treatment and pharmaceuticals as people with frequent diseases.

1.3. Right to information

Each person has the right to accessible information concerning his/her condition, healthcare and healthcare system potentials to use, various methods, means, technologies, procedures and standards used in medical practice. This information must be based on the findings of relevant research and technological innovations.

* Accessible medical assistance includes three major dimensions: temporary accessibility (timeliness of rendering assistance), accessibility within reach (assistance is closest possible to the patient's place of residence), and material accessibility (reducing, or compensating for, the costs burden of a patient to cover expenses of the healthcare system).

Organizations and healthcare professionals are obliged to give full information to patients about their rights.

Authorities, organizations and healthcare professionals must provide a patient with necessary information as required or, on his/her request, in the course of realizing the patient's rights. In doing so, the religious, ethnic, and language features of the patient must be taken into consideration.

Information may not be given to a patient rudely or as an act of grace. A patient has the right to be treated with respect and humanely.

Information in writing must not substitute for live communication between a doctor and a patient. Information may not be imposed on a person against his/her will.

Healthcare organization and medical personnel must communicate with a patient in a language, which he/she understands and in a way that is clear to the individual with no medical education background according to his/her capabilities.

The healthcare system must make the information easily accessible, remove bureaucracy barriers as far as the accessibility of the information is concerned, provide educational sessions and inform healthcare organizations and their personnel, make and distribute information materials.

Each patient has the right to have a look at all medical records related to his/her condition, as well as photocopy those documents, ask questions and have explanations to render the records explicable, and request getting rid of mistakes as they appear.

Each patient must be encouraged to sign medical documents to confirm he/she has familiarized him/herself with the records of the doctor, and/or given consent (or, disagreement) to the medical interventions offered.

Each patient of a hospital / in-patient clinic has the right to continuing and sound information.

Each person has the right to a direct access to information with regard to research activities, capabilities of pharmaceutical therapy and technological innovations. This kind of information can be made available from public or private sources provided it meets the criteria of authenticity, reliability and transparency.

1.4. Right to informed consent and to refusing medical intervention

Each person has the right to access all information to help participate in full in making decisions that have to do with his/her health and precede medical assistance measures. Accessing such information is a condition for making medical interventions of any method, including those of participation in scientific research.

Healthcare facility and medical staff are obliged as required, or on patient's request, to inform him/her in detail on the treatment suggested and associated risks and complications, side effects, alternative diagnostics and ways of treatment as well as their pros and cons, on possible changes in treatment planning during the treatment course (as well as in the course of an operation, with complications developed, other adverse untoward reactions).

The informing must be carried out timely (with interventions planned ahead, no later than 24 hours before the treatment itself) so that the patient is able to actively participate in decisions on therapies with regard to his/her health.

A patient has the right to depute a representative in an oral or written statement well in advance or at the time of getting the information and making a decision about interventions.

In all circumstances, when, following the informing, consent is given by a representative, legal representative or family member, the patient should be involved if possible in decision-making, where he/she is concerned directly, whether this is an under-age or adult who has limitations to understand information and make decisions.

It is inadmissible to extract organs of a person without his/her life-time consent given to extraction.

A patient's consent should be given based on these principles only.

A patient has the right to refuse suggested interventions, as well as to change his mind in the course of diagnostics and treatment, and to refuse continuing it. The patient must be informed on the refusal consequences. The patient's refusal must not be the reason to discriminate against him/her when seeking further medical assistance.

1.5. Right to free choice

Each person has the right to freely choose among different methods of diagnostics, treatment and rehabilitation. A patient has the right to freely choose among healthcare facilities and his/her attending doctor.

Based on recommendations and explanations the doctor gives, a patient has the right to choose, what diagnostic examinations and prevention measures, courses of treatment or rehabilitation will be used to treat him/her.

The healthcare system is obliged to guarantee this right, that is, to inform patients on various facilities and physicians involved in carrying out certain interventions of medical assistance and their results.

Healthcare facilities and physicians must not hinder exercising this right. The heads of healthcare facilities are obliged to assist a patient in exercising his/her right to choose a doctor.

When choosing a mode of treatment, a physician or healthcare facility, a patient has the right to have, at least, the opinion of another doctor (a 'second opinion'), as well as he/she has the right to a council of physicians. The healthcare facility must ensure exercising this right.

The information with regard to healthcare facilities must be accessible including the comparative analysis of quality markers among establishments of one type, when possible (ratings). Likewise, the information on qualifications and results of the medical staff work must be accessible.

1.6. Right to protect private life and confidentiality issues

Each person has the right to the confidentiality of personal data including the information of a fact seeking medical assistance, his/her health status, diagnosis and recommended diagnostic and therapeutic methods, as well as to protection of private life during examinations, visits to doctors and in the course of treatment on the whole.

All data and information regarding an individual's health status and medical arrangements, which he/she has undergone, and other records obtained during examinations and treatment should be considered as personal data and, accordingly, protected.

Communication and treatment must develop in appropriately confidential circumstances and in the presence of persons who are absolutely necessary. The patient must agree to the presence of other persons or intercede for them to be present.

Medical secrecy as a term must be understood as a limitation to the right of the very patient to information.

1.7. Right to respect patient's time

Each person has the right to get appropriate treatment without delay and within prescribed time. This right is exercised with regard to any stage of treatment. Untimely rendered medical assistance should be considered as a failure to render medical assistance.

Based on standards and in accordance with the urgency of a case, the healthcare system is obliged to identify the waiting time within which the necessary medical assistance must be rendered.

The standards for rendering medical assistance in development must include time parameters: optimal time point to start rendering medical assistance and requirements for its continuation.

The healthcare system must ensure for each patient a timely access to assistance that he/she requires, and in the event of a waiting list in place it must ensure this patient is entered in the list immediately with the information about the entrance delivered to the patient.

Each patient has the right to familiarize him/herself with the waiting list on demand and provided personal data protection norms are maintained.

If the healthcare system is unable to render assistance within the necessary prescribed time, the government must ensure access to alternative services of comparable quality. In doing so, all expenses of the patient must be compensated within acceptable terms without resorting to the court system.

Physicians must give enough time to their patients for, including but not limited to, informing.

1.8. Right to adherence to standards

Each person has the right to access quality medical assistance based on adherence to standards of quality medical assistance and conditions to render it. The standards must stipulate the level of medical assistance quality that ensures the highest possible cure or prevention of a disease.

The right to quality medical assistance requires that healthcare facilities and professionals should ensure an adequate level of professional interventions, comfort (services) and human treatment. This provides for exact formulating and keeping standards of quality, which must be approved using the processes of public consultations among all stakeholders, regularly re-examined and re-assessed for bringing in balance with the modern standard of scientific knowledge and technology development.

1.9. Right to safety

Each person has the right to medical assistance that is safe for his/her life and health without any harm to the health as a result of shortcomings of medical assistance, deficiencies of healthcare activities and mistakes, and to the right to access medical assistance that meets quality standards.

To guarantee this right, healthcare facilities must constantly control and confirm that medical equipment is fully operational, while the operating personnel have a good training. Healthcare system professionals must take responsibility in full for the proper safety of all methods of medical assistance technologies.

Physicians must be able to prevent possible mistakes through continuous improvement and keeping track of precedents, where the government provides essential conditions including dignified salaries and position of a physician in the society. The medical staff, who itemize risks and drawbacks for their superiors and/or colleagues, must be protected from any negative impacts.

The government must take effective measures to regulate on the government level in the sphere of the turnover of pharmaceuticals, medical engineering and products of medical use for the purpose of ensuring the quality safety of medical assistance.

The government must take timely and adequate measures towards excluding pharmaceuticals, methods and technologies from the turnover lacking proved effectiveness and safety. The government must take drastic measures as applied to violators in the area of patient safety.

The government must not permit circulations of untrustworthy information that mislead patients with regard to the properties of products and services as the case is with biologically active supplements and various pseudo-medical equipment and items.

1.10. Right to innovations

Each person has the right to access innovation methods for diagnostics and treatment regardless of economic or financial consideration.

The government must stimulate and support biomedical research provided it is in line with legal and ethical fundamental principles of the society.

The rights of patients, who participate in a clinical trial, must be observed in accordance with international ethical rules regardless of the type and level of the clinical trial.

Trial results should be distributed and put into practice in a decent way while making new technologies accessible within shortest possible terms.

1.11. Right to eliminate pain and sufferings

Each person has the right to that all possible measures should be taken to prevent sufferings and pain during each period of his/her disease development.

To this end, the healthcare system is obliged to take all meaningful measures including palliative care, and to make the patient's access to it easier.

The government must organize an effective system to provide in-patients with painkilling medicines they need.

1.12. Right to individual therapy

Each person has the right to planning of diagnostic and therapeutic procedures, which would be consistent with his/her personal needs in the best possible way. Standards must permit the physician to make well-grounded individual prescriptions.

For this purpose, the healthcare system must ensure that treatment planning is flexible and, if possible, tailored to a person, while economic criteria should enjoy no priority to the right for essential medical assistance.

1.13. Right to complaints and claims

Each person has the right to file a claim or make it known, as well as to the right to get a reply to it.

The healthcare system must ensure this right is realized, and, in doing so the government must inform patients about their rights through specialized organizations and enable them to identify violations and file complaints appropriately.

Healthcare authorities and facilities must reply to any complaints and claims in detail and within a period of time adequate for the situation, but not longer than the term established by the law. In the event of danger posed to the health and life of a person, the reply must be given without delay.

Claims can be filed with the support of independent voluntary establishments, organizations or experts.

A patient or his/her family and legal representative, in the event of his/her death, has/have the right to carry out an independent medical expertise if the quality of medical assistance is doubted and the health or life of a person is harmed, which has resulted in the background of, or from, a medical intervention. The government must ensure this right is realized.

1.14. Right to compensation for harm

Each person has the right to an appropriate and sufficiently prompt compensation for the harm one has suffered if commission or omission of an act of medical assistance or of a health professional has caused a property or moral harm.

Healthcare facilities must guarantee compensation regardless of the condition severity degree and the cause of the harm (ranging from unreasonably long time to wait to a violation of medical assistance standards), including cases when it is impossible to identify exactly who of those having rendered medical assistance is responsible for the harm in the long run.

In the event of a harm to the health or life of a citizen while rendering medical assistance, the person who did it must compensate for the harm, if it is unproven that his/her acts agreed with the requirements of the law, normative acts, the agreement provisions, and, in the absence of these, with normally placed demands, and if there are reasons to believe that the unveiled discrepancy has to do with the harm in question as the only cause or one of the causes.

In the event of a harm to the health or life of a citizen when having recourse for medical assistance, while the person responsible for rendering the medical assistance did not commit all acts to conform to the requirements of the law, normative acts, the agreement provisions, and, in the absence of these, to normally placed demands (or, omitted acts), the person who did it compensates for the harm, if there are reasons to believe that committing certain acts may have prevented the harm under consideration.

1.15. Rights of patient's family members

The rights of patient's family members (espouse, parents, children), in their essence, aim at the fullest and safest realization of patients' rights, therefore they are a part of the latter.

If the patient has not appointed a representative, while medical assistance being rendered to the patient with his/her inability to explicitly express his/her will on the impendent intervention, or, on the other hand, if it is deemed that the patient does not perceive information adequately, the person who renders medical assistance struggles duly to find out the will of, at least, one family member or legal representative, provided the time to find it out does not threaten the patient's health or life. While finding it out, the family member or legal representative of the patient is authorized in the case of the patient as much as the patient himself/herself is.

In the event of contradictory opinions among family members or legal representatives of the patient with regard to the impendent intervention, the physician has the right to choose which oncoming treatment option is to apply, while keeping patient's interests in mind.

Family members and legal representatives of the patient have the right to be with him/her in any medical facility at all times provided this does not disturb other patients and the patient has not forbidden them to stay near.

In the event of patient's death, his/her family members and legal representatives have the right to familiarize themselves with the originals and have copies of all medical documents, including the results of the postmortem and medico-legal examinations.

1.16. Right to protection

Each patient has the right to protect his/her rights and freedoms in all possible legal ways.

In accordance with Article 45 of the Constitution of the Russian Federation, the protection of rights and freedoms of a human and citizen in the Russian Federation is guaranteed.

To administer guarantees, the government must have institutions, mechanisms and tools to protect, including:

- the patients' rights commissioner in Russia for the President of Russia, whose objective is to inform patients on their rights, the right to demand copies of medical documents with consent of the patient or his/her family members or legal representatives, legal consultation

for patients and their relatives and friends, complaint and application handling, organizing pre-trial examinations, referring to law-enforcement bodies and to the court, encouraging the system of patients' rights commissioners in medical facilities;

- healthcare prosecutor's office – a specialized prosecutor's office in the area of healthcare and medical assistance;
- patients societies which should have the rights no less than those of societies for protecting the rights of consumers in Russia;
- the institution for independent medical investigation;
- insurance medical companies having powers for pre-trial compensations to a patient for a harm inflicted to his/her health and life while rendering medical assistance;
- unified judicial practice based on recommendations of the Supreme Court of Russia to courts as for investigating cases that require compensation for moral and material harm inflicted upon the health and life of a patient while rendering medical assistance, as well as for identifying regulations and amounts of compensation;
- assignment of the postmortem examination department onto the authority of [the Russian Federal Service on Surveillance in Healthcare and Social Development;
- assignment of medico-legal facilities onto the authority of the Ministry of Justice of the Russian Federation or the Prosecutor's Office of the Russian Federation;
- free of charge for a citizen (family members and a legal representative in case of the citizen's death), carrying out medico-legal investigation on application or complaint, as well as carrying out an independent legal expertise on application, complaint or at the suit in connection with drawbacks in medical assistance, violations of citizens' rights while rendering medical assistance and/or harm inflicted, and ensuring this in any subject of the Russian Federation with a possibility of depersonalization of medical documents under expert examination.

Part II. Rights of citizens for activity

Rights of citizens for activity

Rights contained in this Declaration belong not to 'citizens' but to 'people' (individuals), inasmuch as basic rights, enumerated in Part I, have nothing to do with the concept of citizenship. Nevertheless, each person who acts to protect his/her rights or the rights of other persons is 'an active citizen of the state'. Therefore, the term 'citizen' is used in this part.

In order to promote the above-mentioned patients' rights and to control they are observed, certain civil rights must be in use. Mostly, they are associated with various organized groups of citizens (patients, consumers, as well as foundations, consulting agencies, self-help groups, volunteering organizations, etc), which play a unique part of supporting and encouraging particular individuals in protecting their rights. These rights are linked to the right to the freedom to run activities at voluntary organizations and are provided in Article 30 in the Constitution of the Russian Federation.

2.1. Right to activities in public interests

Citizens, as private individuals and members of associations, have the right to actively protect the rights for medical assistance of both private individuals and groups of them.

The duties of authorities and other stakeholders include those to support and encourage such activities.

2.2. Right to activity on representation of patients' interests

Citizens and organizations involved in protecting rights and interests of patients have the right to activity on protecting rights for healthcare and medical assistance, in particular:

- a. right to free movement for people and information within the healthcare system to the extent, which is allowed by respect for privacy;
- b. right to control the observation of citizens' rights in the healthcare in practice through control and inspecting measures;
- c. right to activity to prevent violation of rights or insufficient protection of rights;
- d. right to directly intervene if having rights violated or insufficiently protected;
- e. right to transfer information and proposals and the consequent duty for healthcare management bodies, to consider and respond to them;
- f. right to an open discussion with the management bodies of state and private healthcare;
- g. right to activities in the area of providing patients with information.

2.3. Right to participate in making policy in the healthcare area

Citizens have the right to participate in making, reforming and assessing government political measures having to do with protecting rights for healthcare and medical assistance in accordance with the principles as follows:

- a. principle of bilateral interaction between citizens or associations of them and bodies of government and municipal management when making perspective plans by means of engagement in boards of supervisors (trustees) at medical facilities;
- b. principle of obligatoriness for public hearings and consultations at the stages of planning and making decisions with authorities liable to defer to proposals of voluntary organizations and other stakeholders, who have a right to express their view with regard to impendent decisions. Authorities are obliged to explain their decisions that deviate from the view expressed by discussion participants;
- c. principle of keeping partner relationships, which means that all discussion participants are fully responsible and equal in proceedings;
- d. principle of a joint assessment, which means that all views expressed by voluntary organizations are considered as a significant part of the tool in assessing government political measures.

Part III

Recommendations for implementing the Declaration

Dissemination and application of this Declaration contents must be implemented on all levels: all-Russian level, levels of Russian subjects, and municipal formations.

Information and training activities

To inform and provide training for citizens and health professionals, the Declaration should be presented in media sources, medical facilities, schools, universities and in all other establishments where issues of civil society, constitutional state, citizens and patients' rights protection and so on are discussed. In doing so, special attention should be given to training and educational functions for physicians, medical profession, low grade medical workers and other health professionals.

Support

Agitation to support and acknowledge the Declaration is allowed among healthcare professionals and voluntary organizations. Meanwhile, healthcare organizations and

professionals that work in the healthcare system and have acknowledged the Declaration should enjoy exclusive preferences set up for them.

Supervision

The Declaration can be used by groups of citizens, media sources and independent bodies as a basis to assess and supervise the situation around patients' rights in Russia. Regular reports can also be published in order to raise public sensitivity to patients' rights and to identify new tasks.

Protection

This Declaration can be used to push actions for protecting patients' rights, the violation of which must be prevented, as well as for restoring the rights, which have been outraged. Such measures can be taken by voluntary organizations, institutions or commissions/committees such as, for instance, patients' rights commissioners, committees for ethics, commissions for alternative clarification of disputes, lay magistrates or magistrate's courts, healthcare prosecutor's office. For this purpose, it is necessary to use institutions/organizations, procedures and tools of the 'Russian sphere of law'.

Dialogue

On the basis of the Declaration, it is possible to have a conversation among stakeholders in order to develop programmes and measures to protect the rights of patients. Such a dialogue should take place between voluntary organizations, government authorities, municipal and private healthcare organizations as well as professional establishments and trade unions.

Assignment of the budget

Realization of the rights in full that are mentioned in this Declaration is not necessarily associated always with budgetary expenditures.

The government must identify the range of rights, which must be supported at the expense of the government or municipal budget, meanwhile, for realization of the remaining part of the range of rights more in full, the government must create other conditions to realize them.

The government must fund medical assistance with the help of the most effective means able to achieve the best effect in treatment with the budget rationally used.

The government must also fund programmes and mechanisms to protect patients' rights.

Legislation

The rights stated in the Declaration can be, partially or in full, entered in Russian legislative and normative legal acts in order to make protection and realization of patients' rights an obligatory part of the government policy.

Together with voluntary organizations and other stakeholders, the government is to develop and adopt legislation about the rights of patients and their protection taking into consideration the provisions of this Declaration.