

CHART

S

EUROPE

PART

THE

THE

THE

THE

THE



Active Citizenship Network

Via Flaminia 53 – 00196 Rome (Italy)

Tel +39 06 36 71 83 76 – fax +39 06 36 71 83 33

www.activecitizenship.net • info@activecitizenship.net

This material has been made possible by an unrestricted educational grant from Merck Sharp & Dohme.



EUROPEAN CHARTER of PATIENTS' RIGHTS

ACTIVE CITIZENSHIP NETWORK





EUROPEAN CHARTER of PATIENTS' RIGHTS



*a*CTIVE CITIZENSHIP NETWORK

P R E A M B L E

Despite their differences, national health systems in European Union countries place the same rights of patients, consumers, users, family members, weak populations and ordinary people at risk. Despite solemn declarations on the “European Social Model” (the right to universal access to health care), several constraints call the reality of this right into question.

As European citizens, we do not accept that rights can be affirmed in theory, but then denied in practice, because of financial limits. Financial constraints, however justified, cannot legitimise denying or compromising patients’ rights. We do not accept that these rights can be established by law, but then left not respected, asserted in electoral programmes, but then forgotten after the arrival of a new government.

The Charter of Fundamental Rights of the European union is the basis of the declaration of the fourteen concrete patients’ rights currently at risk: the right to preventive measures, access, information, consent, free choice, privacy and confidentiality, respect of patients’ time, observance of quality standards, safety, innovation, avoidance of unnecessary suffering and pain and personalised treatment, and the right to complain and to receive compensation. These rights are also linked to several international declarations and recommendations, issued by both the WHO and the Council of Europe. They regard organisational standards and technical parameters, as well as professional patterns and behaviour.

Each of the national health systems of the EU countries manifests quite different realities with respect to patients’ rights. Some systems may have patients’ rights charters, specific laws, administrative regulations, charters of services, bodies such as ombudspersons, procedures like alternative dispute resolution, etc. Others may have none of these. In any case, the present Charter can reinforce the degree of protection of patients/citizens’ rights in the different national contexts, and can be a tool for the harmonisation of national health systems that favours citizens’ and patients’ rights. This is of the utmost importance, especially because of the freedom of movement within the EU and the enlargement process.

The Charter is submitted for consideration by civil society, national and EU institutions, and everyone who is able to contribute, by actions and omissions, to the protection or the undermining of these rights. Because of its connection to the present European reality, and to trends in health care, the Charter may be submitted to future reviews and will evolve over time.

The implementation of the Charter shall be primarily entrusted to those active citizenship organisations working on patients’ rights at national level. It will also require the commitment of health care professionals, as well as managers, governments, legislatures and administrative bodies.

Part One: Fundamental Rights

1. The EU Charter of Fundamental Rights

- The Charter of Fundamental Rights, which will represent the first “brick” in the European constitution, is the main reference point of the present Charter. It affirms a series of inalienable, universal rights, which EU organs and Member States cannot limit, and individuals cannot waive. These rights transcend citizenship, attaching to a person as such. They exist even when national laws do not provide for their protection; the general articulation of these rights is enough to empower persons to claim that they be translated into concrete procedures and guarantees. According to Article 51, national laws will have to conform to the Nice Charter, but this shall not override national constitutions, which will be applied when they guarantee a higher level of protection (Article 53).

In conclusion, the particular rights set forth in the Nice Charter are to be interpreted extensively, so that an appeal to the related general principles may cover any gaps in the individual provisions.

- Article 35 of the Charter provides for a right to health protection as the “*right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices*”.

Article 35 specifies that the Union must guarantee “*a high level of protection of human health,*” meaning health as both an individual and social good, as well as health care. This formula sets a guiding standard for the national governments: do not stop at the floor of the “minimum guaranteed standards” but aim for the highest level, notwithstanding differences in the capacity of the various systems to provide services.

- In addition to Article 35, the Charter of Fundamental Rights contains many provisions that refer either directly or indirectly to patients’ rights, and are worth recalling: the inviolability of human dignity (article 1) and the right to life (article 2); the right to the integrity of the person (article 3); the right to security (article 6); the right to the protection of personal data (article 8); the right to non-discrimination (article 21); the right to cultural, religious and linguistic diversity (article 22); the rights of the child (article 24); the rights of the elderly (article 25); the right to fair and just working conditions (article 31); the right to social security and social assistance (article 34); the right to environmental protection (article 37); the right to consumer protection (article 38); the freedom of movement and of residence (article 45).

2. Other international references

The fourteen rights illustrated below are also linked to other international documents and declarations, emanating in particular from the WHO and the Council of Europe.

As regards the WHO, the most relevant documents are the following:

- The Declaration on the Promotion of Patients' Rights in Europe, endorsed in Amsterdam in 1994;
- The Ljubljana Charter on Reforming Health Care, endorsed in 1996;
- The Jakarta Declaration on Health Promotion into the 21st Century, endorsed in 1997.

As regards the Council of Europe, one must recall in particular the 1997 Convention on Human Rights and Biomedicine, as well as Recommendation Rec(2000)5 for the development of institutions for citizen and patient participation in the decision-making process affecting health care.

All these documents consider citizens' health care rights to derive from fundamental rights and they form, therefore, part of the same process as the present Charter.

Part Two: Fourteen Rights of the Patient

This part proposes the proclamation of fourteen patients' rights, which together seek to render the fundamental rights recalled above concrete, applicable and appropriate to the current transitory situation in the health services. These rights all aim to guarantee a "high level of human health protection" (Article 35 of the Charter of Fundamental Rights), to assure the high quality of services provided by the various national health services. They must be protected throughout the entire territory of the European Union.

With regard to the fourteen patients' rights, some preliminary statements are called for:

- The definition of rights implies that both citizens and health care stakeholders assume their own responsibilities. Rights are indeed correlated with both duties and responsibilities.
- The Charter applies to all individuals, recognising the fact that differences, such as age, gender, religion, socio-economic status and literacy etc., may influence individual health care needs.
- The Charter does not intend to take sides on ethical issues.
- The Charter defines rights as they are valid in contemporary European health systems. It shall therefore be reviewed and modified to allow for their evolution, and the development of scientific knowledge and technology.
- The fourteen rights are an embodiment of fundamental rights and, as such, they must be recognised and respected independently of financial, economic or political constraints, taking the criteria of the appropriateness of care into consideration.
- Respect for these rights implies the fulfilment of both technical / organisational requirements, and behavioural/professional patterns. They therefore require a global reform of the ways national health systems operate.
- Each article of the Charter refers to a right and defines and illustrates it, without claiming to foresee all possible situations.

1-Right to Preventive Measures

Every individual has the right to a proper service in order to prevent illness.

The health services have the duty to pursue this end by raising people's awareness, guaranteeing health procedures at regular intervals free of charge for various groups of the population at risk, and making the results of scientific research and technological innovation available to all.

2-Right of Access

Every individual has the right of access to the health services that his or her health needs require. The health services must guarantee equal access to everyone, without discriminating on the basis of financial resources, place of residence, kind of illness or time of access to services.

An individual requiring treatment, but unable to sustain the costs, has the right to be served free of charge.

Each individual has the right to adequate services, independently of whether he or she has been admitted to a small or large hospital or clinic.

Each individual, even without a required residence permit, has the right to urgent or essential outpatient and inpatient care.

An individual suffering from a rare disease has the same right to the necessary treatments and medication as someone with a more common disease.

3-Right to Information

Every individual has the right to access to all kind of information regarding their state of health, the health services and how to use them, and all that scientific research and technological innovation makes available.

Health care services, providers and professionals have to provide patient-tailored information, particularly taking into account the religious, ethnic or linguistic specificities of the patient.

The health services have the duty to make all information easily accessible, removing bureaucratic obstacles, educating health care providers, preparing and distributing informational materials.

A patient has the right of direct access to his or her clinical file and medical records, to photocopy them, to ask questions about their contents and to obtain the correction of any errors they might contain.

A hospital patient has the right to information which is continuous and thorough; this might be guaranteed by a "tutor".

Every individual has the right of direct access to information on scientific research, pharmaceutical care and technological innovations. This information can come from either public or private sources, provided that it meets the criteria of accuracy, reliability and transparency.

4-Right to Consent

Every individual has the right of access to all information that might enable him or her to actively participate in the decisions regarding his or her health; this information is a prerequisite for any procedure and treatment, including the participation in scientific research.

Health care providers and professionals must give the patient all information relative to a treatment or an operation to be undergone, including the associated risks and discomforts, side-effects and alternatives. This information must be given with enough advance time (at least 24 hours notice) to enable the patient to actively participate in the therapeutic choices regarding his or her state of health.

Health care providers and professionals must use a language known to the patient and communicate in a way that is comprehensible to persons without a technical background.

In all circumstances which provide for a legal representative to give the informed consent, the patient, whether a minor or an adult unable to understand or to will, must still be as involved as possible in the decisions regarding him or her.

The informed consent of a patient must be procured on this basis.

A patient has the right to refuse a treatment or a medical intervention and to change his or her mind during the treatment, refusing its continuation.

A patient has the right to refuse information about his or her health status.

5-Right to Free Choice

Each individual has the right to freely choose from among different treatment procedures and providers on the basis of adequate information.

The patient has the right to decide which diagnostic exams and therapies to undergo, and which primary care doctor, specialist or hospital to use. The health services have the duty to guarantee this right, providing patients with information on the various centres and doctors able to provide a certain treatment, and on the results of their activity. They must remove any kind of obstacle limiting exercise of this right.

A patient who does not have trust in his or her doctor has the right to designate another one.

6-Right to Privacy and Confidentiality

Every individual has the right to the confidentiality of personal information, including information regarding his or her state of health and potential diagnostic or therapeutic procedures, as well as the protection of his or her privacy during the performance of diagnostic exams, specialist visits, and medical/surgical treatments in general.

All the data and information relative to an individual's state of health, and to the medical/surgical treatments to which he or she is subjected, must be considered private, and as such, adequately protected.

Personal privacy must be respected, even in the course of medical/surgical treatments (diagnostic exams, specialist visits, medications, etc.), which must take place in an appropriate environment and in the presence of only those who absolutely need to be there (unless the patient has explicitly given consent or made a request).

7-Right to Respect of Patients' Time

Each individual has the right to receive necessary treatment within a swift and predetermined period of time. This right applies at each phase of the treatment.

The health services have the duty to fix waiting times within which certain services must be provided, on the basis of specific standards and depending on the degree of urgency of the case.

The health services must guarantee each individual access to services, ensuring immediate sign-up in the case of waiting lists.

Every individual that so requests has the right to consult the waiting lists, within the bounds of respect for privacy norms.

Whenever the health services are unable to provide services within the predetermined maximum times, the possibility to seek alternative services of comparable quality must be guaranteed, and any costs borne by the patient must be reimbursed within a reasonable time.

Doctors must devote adequate time to their patients, including the time dedicated to providing information.

8-Right to the Observance of Quality Standards

Each individual has the right of access to high quality health services on the basis of the specification and observance of precise standards.

The right to quality health services requires that health care institutions and professionals provide satisfactory levels of technical performance, comfort and human relations. This implies the specification, and the observance, of precise quality standards, fixed by means of a public and consultative procedure and periodically reviewed and assessed.

9-Right to Safety

Each individual has the right to be free from harm caused by the poor functioning of health services, medical malpractice and errors, and the right of access to health services and treatments that meet high safety standards.

To guarantee this right, hospitals and health services must continuously monitor risk factors and ensure that electronic medical devices are properly maintained and operators are properly trained.

All health professionals must be fully responsible for the safety of all phases and elements of a medical treatment.

Medical doctors must be able to prevent the risk of errors by monitoring precedents and receiving continuous training.

Health care staff that report existing risks to their superiors and/or peers must be protected from possible adverse consequences.

10-Right to Innovation

Each individual has the right of access to innovative procedures, including diagnostic procedures, according to international standards and independently of economic or financial considerations.

The health services have the duty to promote and sustain research in the biomedical field, paying particular attention to rare diseases.

Research results must be adequately disseminated.

11-Right to Avoid Unnecessary Suffering and Pain

Each individual has the right to avoid as much suffering and pain as possible, in each phase of his or her illness.

The health services must commit themselves to taking all measures useful to this end, like providing palliative treatments and simplifying patients' access to them.

12-Right to Personalized Treatment

Each individual has the right to diagnostic or therapeutic programmes tailored as much as possible to his or her personal needs.

The health services must guarantee, to this end, flexible programmes, oriented as much as possible to the individual, making sure that the criteria of economic sustainability does not prevail over the right to health care.

13-Right to Complain

Each individual has the right to complain whenever he or she has suffered a harm and the right to receive a response or other feedback.

The health services ought to guarantee the exercise of this right, providing (with the help of third parties) patients with information about their rights, enabling them to recognise violations and to formalise their complaint.

A complaint must be followed up by an exhaustive written response by the health service authorities within a fixed period of time.

The complaints must be made through standard procedures and facilitated by independent bodies and/or citizens' organizations and cannot prejudice the patients' right to take legal action or pursue alternative dispute resolution.

14-Right to Compensation

Each individual has the right to receive sufficient compensation within a reasonably short time whenever he or she has suffered physical or moral and psychological harm caused by a health service treatment.

The health services must guarantee compensation, whatever the gravity of the harm and its cause (from an excessive wait to a case of malpractice), even when the ultimate responsibility cannot be absolutely determined.

Part Three: Rights of Active Citizenship

The rights set forth in the Charter refer to the “individual” rather than the “citizen” insofar as fundamental rights override the criteria of citizenship, as noted in the first part. Nevertheless, each individual who acts to protect his or her own rights and/or the rights of others performs an act of “active citizenship.” This section thus employs the term “citizens” to refer to active persons working in the territory of the European Union.

In order to promote and verify the implementation of the above stated patients’ rights, some citizens’ rights must be proclaimed. They mainly regard different groups of organized citizens (patients, consumers, advocacy groups, advice-givers, self-help groups, voluntary and grassroots organisations, etc.) that have the unique role of supporting and empowering individuals in the protection of their own rights. These rights are pegged to the rights of civic association, contained in article 12, section 1, of the Charter of Fundamental Rights.

1. Right to perform general interest activities

Citizens, whether individuals or members of an association, have the right, rooted in the principle of subsidiarity, to perform general interest activities for the protection of health care rights; there is a concomitant duty on the part of the authorities and all relevant actors to favour and encourage such activity.

2. Right to perform advocacy activities

Citizens have the right to perform activities for the protection of rights in the area of health care, and in particular:

- The right to the free circulation of persons and information in public and private health services, within the bounds of respect for privacy rights;
- The right to carry out auditing and verification activities in order to measure the effective respect for the rights of citizens in the health care system;
- The right to perform activities to prevent violation of rights in the field of health care;
- The right to directly intervene in situations of violation or inadequate protection of rights;
- The right to submit information and proposals, and the consequent obligation, on the part of the authorities responsible for the administration of public and private health services, to consider them and reply;
- The right to public dialogue with public and private health authorities.

3. Right to participate in policy-making in the area of health

Citizens have the right to participate in the definition, implementation and evaluation of public policies relating to the protection of health care rights, on the basis of the following principles:

- The principle of bilateral communication with regard to agenda setting, or, in other words, the ongoing exchange of information among citizens and institutions in the definition of the agenda;
- The principle of consultation in the two phases of policy planning and decision, with the obligation on the part of institutions to listen to the proposals of citizens' organisations, to give feedback on these proposals, to consult them before taking each decision, and to justify their decisions if they differ from the opinions expressed;
- The principle of partnership in implementation activities, which means that all partners (citizens, institutions and other private or corporate partners) are fully responsible and operate with equal dignity;
- The principle of shared evaluation, which implies that the outcomes of the activities of the civic organisations ought to be considered as tools for evaluating public policies.

Part Four: Guidelines For Implementing The Charter

The dissemination and application of the contents of this Charter will have to be carried out at many different levels, particularly at the European, national and local levels.

Information and Education

As a means of informing and educating citizens and health care workers, the Charter may be promoted in hospitals, the specialised media and other health care institutions and organisations. The Charter may also be promoted in the schools, universities and all other places where questions regarding the construction of the “Europe of Rights” are addressed. Special attention should be devoted to training and educational activities for doctors, nurses and other health care stakeholders.

Support

Support for and subscription to the Charter could be gathered from health care stakeholders and citizens’ organisations. The special commitments of those health services and professionals that subscribe to the Charter should be defined.

Monitoring

The Charter may also be used as a means of monitoring the state of patients’ rights in Europe by civic organisations, the information media and independent authorities, with the use of appropriate tools. A periodic report could be published to further awareness of the situation and outline new objectives.

Protection

The Charter may be used to launch activities for the protection of patients’ rights, conceived as prevention as well as actions to restore rights that have been violated. Such activities may be pursued by active citizenship organisations, by institutions and bodies like ombudspersons, ethical committees or Alternative Dispute Resolution commissions, justices of the peace, as well as by the courts. Institutions, procedures and tools coming from the “European legal space” should be employed to this end.



Dialogue

A dialogue among the stakeholders can be pursued on the basis of the Charter's contents, in order to work out policies and programmes for the protection of patients' rights. Such a dialogue would take place among governmental authorities, public and private companies involved in health care, as well as professional associations and labour unions.

Budgeting

In relation to the patients' rights contained in this Charter, quotas, representing a percentage of the health budget to set aside for the resolution of specific situations (for example, waiting lists), or for the protection of those in particularly critical situations (like the mentally ill), could be set and applied. The respect for such quotas, or the degree of deviation from them, could be verified by annual reporting.

Legislation

The Charter rights may be incorporated into national and European laws and regulations in full or in part, to make the goal of protecting patients' rights an ordinary part of public policies, notwithstanding the immediate implementation of such rights in light of the European Union Charter of Fundamental Rights.

The Charter was drafted by Active Citizenship Network in collaboration with 12 citizens' organizations.

It was presented for the first time during the Conference "The Future Patient" held the 14 - 15 November 2002 in Brussels.

Organizations that participated in the drafting of the Charter

APOVITA, Portugal

Cittadinanzattiva, Italy

Confederacion de Consumidores y usuarios (CECU), Spain

Danish Consumer Council, Denmark;

Deutsche Gesellschaft für Versicherte und Patienten e. V. (DGVPV), Germany

Fédération Belge contre le Cancer, Belgium

International Neurotrauma Research Organization, Austria

Irish Patients Association Ltd, Ireland

KE.PKA, Greece

Nederlandse Patiënten Consumenten Federatie (NPCF), The Netherlands

The Patients Association, UK

Vereniging Samenwerkende Ouder- en Patiëntenorganisaties (VSOP),
The Netherlands

