

**CITIZENS' CHARTER OF  
RIGHTS AND DUTIES  
WITH REGARD TO HEALTH  
AND HEALTH CARE**

*July 24, 2001*

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## **I. INTRODUCTION**

## 1. The rights and duties of citizens that use the national health system

The rights and duties of the citizens that use the health-care system are based on article 43 of the Constitution, which recognises the right to health protection, and entrusts public authorities with the organisation and monitoring of public health through preventive measures and by providing the necessary services. There is also provision for the law to establish the rights and duties of everyone.

Developing this provision, article 10 of Law 14/1986, of April 25, the General Health Law (BOE [*Official State Gazette*] no. 102, of April 29 ), establishes citizens' rights regarding the different public health administrations; similarly, it determines which of these rights can and must be exercised with regard to private health-care services, respecting their specific economic system.

As far as duties are concerned, article 11 of the aforementioned Law establishes the obligations of the citizen vis-à-vis the health system institutions and organisations.

## 2. Background

The Department of Health and Social Security, by virtue of the accreditation Order of April 25, 1983 (DOGC no. 325, of May 4), which regulated the accreditation of health-care centres in Catalonia, established, as a mandatory standard for centres and services that wished to secure accreditation, their obligations to deliver, on admission of patients, a text detailing the rights and duties of patients. These rights and duties were included in the actual accreditation standard.

The publication of this accreditation Order gave rise to the constitution of a group of experts who drafted a document containing the rights of patients that use hospitals, to facilitate correct and objective interpretation.

This document was published in 1984 via the brief treatise *Rights of patients who use hospitals*, published by the Department of Health and Social Security. Since then, it has become a basic document for reflection and study by users and health professionals, centres, institutions and organisations of the health sector.

A new accreditation Order was published on July 10, 1991 which regulates the accreditation of hospital centres (DOGC no.1477, of August 7), now in force, which establishes, as a requirement for accreditation, evaluation of the degree of compliance of the rights detailed in the aforementioned brief treatise. The aforementioned Order details the list of rights in terms practically identical to those of the brief treatise. It also establishes that all patients attended to at a hospital must have access to the aforementioned brief treatise.

Since then, an ensemble of initiatives emerging from the health regions, centres and sometimes from some insurance companies, have completed and afforded continuity to the provisions of the Order.

### **3. Justification**

As has already been made clear, the concern for observing the rights of the patients has been present for some time in Catalan health-care institutions and organisations; but in any case the rapid evolution that must take place in the question the rights renders it necessary to conduct a revision of the legal framework and the application of the rights and duties of users, adapting them

to the present, bringing in newer areas and aspects (the genetic constitution of the individual, research, etc.).

This evolution can be seen in all the countries with a similar level of development, and is closely related to the increase in needs, the demand for a higher quality of life and a commitment by health system the professionals to provide a more satisfactory response to patients' demands.

At the moment it is impossible to predict the evolution of the relationship that will arise among between the different agents of the health world, but probably the insurance system will make it possible to have a relationship of mixed commitment with shared responsibility between doctors, insurers and patient.

Regardless of what form this relationship takes, it will be necessary to establish mechanisms that make for a more effective respect for rights, their degree of demands and the inclusion of aspects rendered necessary by the advance of society, the explosion of the different biomedical disciplines and the connection between health care and research.

Similarly, and parallel to this, citizens will have increasingly more information and responsibility for their health and undoubtedly more power of decision in this regard. Therefore, the demand for compliance with their duties will also increase.

To pre-empt this new situation, and with a view to catering to other questions posed at present, the Department of Health and Social Security wishes to renew the spirit of the charter of rights of 1984 and draw up a new document which, based on the existing one, and bringing in the latest breakthroughs in the different areas, will make it possible to reflect more deeply on and promote actions geared towards making further progress in respect for the dignity of the individual and improvement of health-care quality.

#### **4. Writing of the document**

The group that started to write this document began by conducting an exhaustive revision of existing models of charters in our environment, of the documents of countries that have signed the same conventions and which have a similar model of society, as well as others with less developed regulations, where Charters of rights allow for several interpretations that sometimes give rise to conflicts of interests.

International conventions, laws and other standards were used to approach all the areas that the new charter of rights and duties aims to cover; or in other words, the areas and traits which in an overall way impact health care provided to users and their health.

Once these areas had been determined and defined, an exhaustive search was run on all legislation, international conventions, codes of conduct, declarations of organisations and international institutions which address different aspects related to the rights and duties of patients.

Specific mention must be made of the Universal Declaration of Human Rights of 1948, due to its import in this area; the Declaration for the promotion of the rights of the patients in Europe of 1994, and the Convention on biomedicine and human rights of the Council of Europe for the protection of human rights and the dignity of human beings with regard to the application of biology and medicine, the recently approved Charter of Fundamental Rights of the European Union, published in the DOCE of 18.12.2000, series C no. 364/1.

Law 21/2000, of December 29 on the right to health-related information and the autonomy of the patient and Clinical Documentation (DOGC no. 3303, of January 11, 2001) were also taken into account in the writing of this document.

Other documents taken into account include the provisions which, with regard to users, are included in the report by the sub-commission to make progress in the consolidation of the national health system by studying the measures necessary to guarantee a stable financial framework and to modernise the health system, maintaining the systems of universalisation and equity of access (*Boletín Oficial de las Cortes Generales* of November 17, series D, no. 205).

Finally, it must also be pointed out that the writing of this Charter also complied with an ensemble of recommendations submitted by the Ombudsman to the Department of Health and Social Security over the last few years, including, amongst others, access to health care, waiting time, the guarantee of privacy and the use of assisted reproduction techniques to prevent gender-related hereditary diseases.

Once the different rights were established for each area, a way to make them more patent was sought, with specific situations for compliance given.

In a second phase, the document was enhanced via the different inputs and nuances provided by the different sectors and collectives representing society, professional and users. This consensus-driven effort aims to match contents to current needs in health policies and to the new scientific and technological advances of the different levels of health care, respecting convergent sensitivities and interests.

## **5. Distinguishing traits**

This document provides for the rights and duties applicable to all health care services, regardless of their level and who the legal provider is.

### **- Primary, specialised and social-health care**

On comparing the different charters of patient rights and duties from all over the world, it transpires that there is a major preponderance of charters of rights for hospital users; however, charters that refer to the users of other public health services appear progressively.

This document refers the whole health care process and to the ensemble of health care services, extending the scope of previous charters which only referred to the hospital setting. Thus, reference is made to primary, specialised and social-health care, while health promotion, disease prevention and the process of healing and rehabilitation are also addressed.

### **- Public and private areas**

Most rights apply to all areas of health care and are important in the citizen-health system relationship, be it a private or public system. Other rights refer only to public health care services, and mainly those related to the catalogue of public services.

## **- Dignity and ethics**

The rights that may be regarded as being related to the dignity of the individual (the autonomy of the patient, information, privacy and confidentiality, etc.) are complemented by others, as users of an insurance system and receivers of a service: choice of professional, possibility of a second opinion, etc.

Sections added include those pertaining to all aspects and guarantees, advances derived from knowledge of the genetic constitution of the individual and related to research, particularly those provided for by the Convention on biomedicine and human rights of the Council of Europe for the protection of the human rights and the dignity of human beings with regard to the application of biology and medicine, ratified by the Spanish Parliament and published in the BOE [*Official State Gazette*] of October 20, 1999, and which became effective on January 1, 2000.

## **6. Contents of the charter of rights and duties**

This proposal contains an ensemble of areas that help to systematise the rights and duties of the citizens that use the services.

It must be made clear that respect for dignity, human personality and the autonomy of the patient configure a core of rights that afford meaning to the others, which express the embodiment of the rights of the individual with regard to the different areas in which they are applied.

In this regard, the right to equality and non-discrimination is seen as a basic right, without which nothing else would make sense. The very concept of rights presumes that all people have them, with no type of discrimination.

The main groups of rights, which are developed in section II, are outlined below.

### **- Rights related to the equality and non-discrimination of the individual**

According to the Constitution, all people are equal before the Law and cannot be discriminated against for any reason of birth, race, gender, religion, opinion or any other personal or social condition or circumstances. In the health area, it must be understood that these causes of non-discrimination are complemented by those provided in the corresponding international conventions that have been ratified by the Spanish State.

However, there is a concept of positive discrimination when these differences or distinctions between persons stem from the need to protect the more vulnerable.

In a setting of limited available resources and means, the need to prioritise health care requires the integration and evaluation of the demands and the interests of the population at large. In this context, the criteria that must guide priority in access to health care services are: the seriousness of health problems, the efficacy of the treatments proposed and, respecting the distinguishing traits of the more vulnerable groups, equal access.

### **- Rights related to the autonomy of the patient**

It must be presumed that all individuals are able, a priori, to receive information and give their free and informed consent in any health-care action proposed, unless they lack this capacity. It is up to doctors and nursing professionals to provide all the information required, clearly and adapted to the characteristics of the patients, so that they can use their freedom of judgement and decision voluntarily.

**- Rights related to privacy and confidentiality**

Every person has the right to the confidentiality of their health data. They also have the right to access to such data being prevented, unless the data is subject to the legislation in force.

The centres will have to take the relevant measures to guarantee these rights and to do so draft - as applicable - protocolised standards and procedures to guarantee that any such access is legitimate.

**- Rights related to the genetic constitution of the individual**

In view of the progress of new techniques and investigation into genetics and reproduction, all individuals have the right to establish a group of guarantees, to prevent ethically acceptable limits from being overstepped and their basic rights from being violated.

**- Rights related to scientific research and experimentation**

The patient's participation in scientific experimentation in the areas of radiology and medicine must be secured freely, based on good clinical practices, and comply with the different international conventions and other legal provisions that guarantee the protection of human beings.

Human rights in the areas of experimentation are established in different international conventions and include mainly the right not to be exposed to disproportionate risks and the right to a private life and to proper treatment. The following are also inherent: respect for the free determination of each person,

free choice to participate in a study, to be informed on research being carried out on him and to cease to participate when he deems fitting.

**- Rights related to prevention and promotion of the health**

This area comprises an ensemble of relative rights in the measures that make it possible to reduce the probability of the appearance of a complaint or a disease, interrupt it or moderate the progression thereof, based on a range of interventions of proven efficacy, which have been accepted by health professionals and the citizens.

**- Rights related to health-care information and access to clinical documentation**

The patient has the right to know all information obtained about his health. He also has the right to have, in term that are understandable to him, suitable information on his health and health-care process (including the terms of risks/benefits, as a consequence of the treatment/non-treatment). Nevertheless, the wish of a person not to be informed must also be respected, if he does not want to, and/or if he so declares expressly.

**- Rights related to access to health care**

The Health Services and the health-care apparatuses must be organised as efficiently as possible so that the health care can be provided as soon as possible according to pre-established criteria of equity, availability of resources, type of condition, priority of emergency and waiting time.

**- Rights related to the information on the Health Services and the participation of users**

It includes the rights pertaining to general information on the health services and to epidemiological information, those pertaining to civic and social participation in the health system, and the right to submit complaints and suggestions, as applicable.

All the centres will have a charter of rights and duties, which will inform of the patient's legally established rights. The centre will also provide clear information on the conditions of the user's relationship with the health system, on the way he accesses this system, on the catalogue of services and its service portfolio.

**- Rights related to health-care quality**

This section includes the different rights geared towards guaranteeing that the health services work properly throughout the whole health-care process, and includes: professional qualification, treating patients with respect, coordination between health-care levels and integral health care.

### **Duties of the citizens with regard to health care services**

In the areas of health and health care, the citizen is becoming an increasingly more active subject who is responsible for his health and who has to fulfil a series of duties.

Participation, information and the responsibility of the citizen with regard to the health system and the health value, is progressively becoming a quality parameter of this system and a condition for its sustainability.

The convergence of the citizens' exercise of their rights and of the general interests leads to a conception of rights which is not possible without the reference to duty.

Thus, citizens that use the Health Services have rights, but also duties, which must be known by citizens and health professionals alike.

## **7. Strategies for compliance with the citizens' charter of rights and duties with regard to health and health-care services by the Administration and organisations**

For respect for the rights of citizens to be fully accomplished, the health-care centres and apparatuses of the health network must work properly. Making sure that resources match the needs of the users and are properly organised and boosting awareness of this charter by professionals is the responsibility of each and every one of the service providers, be they public or private. In the final analysis, the Department of Health and Social Security, as the ultimate guarantor of the quality of the services provided to citizens, must facilitate the necessary instruments for effective compliance with the provisions of this Charter.

In view of the programmatic nature of the document, the Department of Health and Social Security will promote initiatives for the implementation of standards, as well as the measures needed for the rights and duties of this Charter to be enforced, including follow-up and evaluation.

Generally speaking, these measures, which will be developed jointly with the agencies and organisations of the health area, include:

- The drafting of a an awareness-raising plan to dynamise organisations with a view to engaging all professionals, leading actors in the health system, in this question, promoting measures to foster and respect the principles of the Charter.
- The drafting of a dissemination plan targeting the citizens, with measures that boost awareness of the Charter of rights and duties, with particular emphasis on the different educational levels.

- The drafting of a plan to assess the degree of awareness of and respect for the rights and duties, addressing aspects of major import in greater depth.
- Fostering the adaptation of charters of rights for specific groups (mental health, the elderly, children, people deprived of their freedom, etc.) complementing this document.

## **II. RIGHTS OF THE CITIZEN WITH REGARD TO HEALTH AND HEALTH CARE**

## **1. RIGHTS RELATED TO THE EQUALITY AND NON-DISCRIMINATION OF THE INDIVIDUAL**

### **1.1. Right to health care and to health services**

Citizens have the right to enjoy health care and health services and the corresponding services, either individually or collectively, as provided for by the law.

### **1.2. The right to exercise the rights acknowledged in this charter without discrimination**

The use of the rights and the freedoms recognised in this Charter must be guaranteed without any type of discrimination, such as gender, race, colour, language, religion, political or other opinions, national or social origin, belonging to a national minority, property, birth, genetic heritage, disease or any other condition.

### **1.3. Rights of the more vulnerable groups in specific health situations**

Children, the elderly, the mentally ill, people with chronic and crippling diseases, and those belonging to specific groups recognised as a health risk, have rights, taking the available media and resources into account, to specific actions and programmes.

The public authorities will ensure that the rights and duties of this Charter are observed and enforced, so that the rights to equality and non-discrimination are implemented efficaciously.



## 2. RIGHTS RELATED TO THE AUTONOMY OF THE INDIVIDUAL

### 2.1. The rights to be informed first, to be able to subsequently give (*informed consent*) for the performance of any diagnostic or therapeutic procedure

*Informed consent* means the acceptance of a procedure by a patient after the latter has been furnished suitable information and in time enough to be able to participate freely in the decision (risk, benefits, side effects of the procedure, alternative procedures, etc.).

In any case the patient may withdraw his consent totally freely at any time.

Situations of exception in which *informed consent* will not be required:

- When the operation entails a risk to public health.
- When the emergency renders further delay impossible through the threat of irreversible lesions or possible death.

Situations of surrogate consent:

- When the patient, according to the criteria of the physicians in charge of his health care, is not able to understand the information due to a physical or mental condition that renders it impossible for him to understand his situation, the consent will have to be secured from his relatives, representatives or persons in some way related to him.
- In cases of legal incapacity. The guardian needs legal authorisation to apply medical treatments to the incapacitated person which basically

may constitute a serious threat to the patient's life or physical or mental integrity. If the immediacy of the application of this treatment rendered it impossible to obtain this authorisation, this will be reported to the court or board of guardianship within a term of twenty-four hours at the most.

- In the case of individuals confined for psychic disorders, the relatives or the interested party must secure legal authorisation to apply medical treatments to the incapacitated person which basically may constitute a serious threat to the patient's life or physical or mental integrity. If the immediacy of the application of this treatment rendered it impossible to obtain this authorisation, this will be reported to the court or board of guardianship within a term of twenty-four hours at the most.

This consent must be given in writing for surgery, invasive diagnostic procedures and generally speaking) when procedures involving known and foreseeable risks and drawbacks that may impact the health of the patient, or the foetus, in the case of a pregnant woman, are to be performed.

In all cases in which a patient has given his written *informed consent* he will be entitled to be provided with a copy of the signed document.

## **2.2. Right of the patient to choose between the different therapeutic options and to refuse the medical or health actions proposed.**

The patient has the right to choose freely between the options proposed by the physicians in charge of him and to refuse diagnostic tests and/or treatments if he does not agree with them.

The patient has the right to choose between different therapeutic options and/or to refuse medical treatment, even life-sustaining treatment. The informed consent will be obtained according to the provisions of section 2.1 and the same exceptions will be applicable.

Under no circumstances can the patient be refused any care, treatment and support he needs, and alternative treatments must be offered if necessary, if they are available in the centre, or else the patient will be given advice on how to obtain this suitable resource before he is discharged.

## **2.3. The right of the minor to be consulted so that his opinion will be regarded as a determining factor, depending on his age and his degree of maturity, in decisions pertaining to interventions that may be taken on his health**

When the minor is not competent enough - intellectually or emotionally - to understand the scope of the operation for his health, the consent must be given by his representative after his opinion has been heard, as the case may be, if he is over 12 years old. In the other cases, and particularly in cases of emancipated minors and adolescents above the age of sixteen, the minor has to give his consent personally.

#### **2.4. Every individual has the right to die according to their concept of dignity**

Every individual has the right to live through the process they are affected by until death, with dignity. The patient has the right to reject any treatment geared towards prolonging his life when he believes that a therapy or operation may reduce his quality of life to such an extent that it is incompatible with his conception of the dignity of the individual, and thus avoid the so-called therapeutic obstinacy.

All people have the right to be able to access palliative comfort treatment and in particular pain alleviation treatment that must be provided in the most ideal possible setting (home, hospital, etc.).

When the patient is in hospital, every effort must be made to accommodate his relatives in a suitable social context that is conducive to privacy and eventually mourning.

If the patient death in the hospital, special attention must be provided to the relatives and the people who are close to the patient to provide them with suitable aid and guidance at that time.

The corresponding procedure and actions cannot contravene the law.

#### **2.5. Rights for advance directives formalised by the relevant document to be observed**

In the advance directive document, an adult with sufficient capacity, and of his own free will, issues the instructions to be taken into account when he is in a situation in which the prevailing circumstances render it impossible for him to

personally express his own will, in accordance with the legally established requirements and effects.

Advance directives or actions with provisions that are contrary to the law or good clinical practices cannot be entertained, or those that do not exactly match the eventuality provided for by the individual when he made the advance directive. In these cases, the relevant note must be made in the clinical history of the patient.

### **3. RIGHTS RELATED TO PRIVACY AND CONFIDENTIALITY**

#### **3.1. The right to decide who may be present during health-care procedures**

Barring professionals who by dint of their responsibility absolutely must be present, this right refers to the possibility of limiting the presence of investigators, students or other professionals who are not directly caring or treating the patient. The presence of relatives or close persons, must be agree by patient wishes, except in cases where any such presence is incompatible or unadvisable in view of the nature of the treatment.

In partum, access of the father, or as applicable, other relatives appointed by the mother, should be facilitated so that he/they can be present.

These considerations are particularly important in the case of minors and any patients with reduced autonomy: the elderly, the mentally ill, etc.

#### **3.2. The rights to preserve the privacy of a patient's body in the presence of others**

This means that any care given should preserve the basic aspects of privacy: hygiene, visits, care, explorations, etc., the provision of single-person changing rooms and limiting of access by professionals and other users, whether or not they are relatives, if they are not directly involved in care-giving. In the case of hospitalised patients, this means the right to have a reserved physical space in the room guaranteeing a certain intimacy.

### **3.3. The right to be attended to in a setting that guarantees privacy, dignity, autonomy and safety of the individual**

In the case of hospitalisation, the patient has the right to continue to maintain his relationship with the outside and the people he is related to, depending on the framework and the organisational regulations of the centres and services.

Living habits should also be respected, dealing compatibility with health-care needs, with the rights of other patients and with the regulations of the health care centre.

The patient has the right to freedom and confidentiality of correspondence and communication.

The patient has the right to receive health care in health care centres and health establishments that strive to guarantee safety standards related to safety environment and facilities where patients are attended to.

### **3.4. The right to freedom of ideology, religion and worship**

The person has the right to have his moral and cultural values respected, as well as his religious and philosophical convictions. Any practices derived therefrom must be compatible with medical practice and care and must be respectful of the health centre's regulations.

In the situation of hospitalisation, the right to refuse or receive spiritual aid must be respected, regardless of belief.

### **3.5. The right to confidentiality of information**

This right means that any patient information is subject to strict confidentiality and must respect the patient's right to privacy.

This is particularly important in data that may be more or less sensitive,: Patient identification and patient history, beliefs, genetic inheritance, adoption, infectious diseases, being a victim of ill-treatment, etc. In this regard, it must be remembered that data may only be accessed by health professionals engaged directly in patient care, and that it cannot be provided to other professionals or relatives/related persons without authorisation by the patient. It must also be remembered that the right to confidentiality is not absolute and that different exceptions are recognised, including the following:

- When maintaining confidentiality may constitute a relevant danger or prejudice for another person.
  
- When the actual patient authorises the divulgence of information to third parties, although this does not oblige the professional to furnish it.
  
- When maintaining confidentiality may jeopardise the actual patient, which is particularly important in the case of abuse.

### **3.6. The right to access personal data obtained in health care**

This is the right to know personal information and data in files and records, be they automated or not, and which were obtained during health care.

Without prejudice to the provisions established for the clinical history in section 7.3. of this document, the patient has the right to access, change and cancel data, as provided for by the law. Similarly, he has the right to know any safety measures and which persons and/or organisations/institutions may access these data and which guarantee the confidentiality thereof.

### **3.7. The right for his consent to be requested before the conduct and dissemination of iconographic records**

The patient has the right to give his consent prior to the conduct and dissemination of iconographic records that identify him (photos, videos, etc.) and to have the reasons for the conduct thereof and the scope of dissemination explained to him.

## **4. RIGHTS RELATED TO THE GENETIC CONSTITUTION OF THE INDIVIDUAL**

### **4.1. The right to confidentiality of information of his genome and that it not be used for any type of discrimination**

Every person must have the guaranteed right to the confidentiality of information on his genome, and that this information will not be used for any type of individual and collective discrimination. The genomic data records will be configured and the necessary mechanisms implemented to guarantee confidentiality of genomic information.

### **4.2. The right to enjoy the advantages of new genetic technologies in the current legal framework**

- In the conduct of genomic tests, when they are indicated, to identify individuals that are carriers of genes responsible for a disease or else to detect predisposition to the development of a disease. These tests may only be performed with medical or medical research finalities, in the framework of a suitable genetic council, and always with the individual's informed consent.
- In the intervention on the human genome, with preventive, diagnostic and therapeutic ends.

Only interventions geared towards modifying the human genome for preventive, diagnostic or therapeutic reasons, and when there is no intention of changing the descendent genome, may be carried out.

- To use assisted reproduction techniques to prevent gender-related hereditary diseases.

Interventions whose objective is to create a human being genetically identical to another, either alive or dead, are prohibited. Genetically identical human being means one who shares the same genetic nuclear load.

## **5. RIGHTS RELATED TO SCIENTIFIC RESEARCH AND EXPERIMENTATION**

**5.1. The right to know whether the prognostic, diagnostic and therapeutic procedures applied to a patient may be used for a teaching or research project which under no circumstances may involve an additional hazard for his health. In any event, prior written authorisation by the patient, and acceptance by the researcher and the management of the corresponding health centre will be required**

Persons may participate in research and experimentation studies under the following conditions:

1. When there is no alternative method in the experiment with human beings of comparable efficacy.
2. When the risks to the individual are not disproportionate to the potential benefits of the experiment.
3. When the project of the experiment has been approved by a competent authority (Clinical Investigation Ethical Committee or other interdisciplinary committees in no way related to the experimentation), after an independent study has been conducted on its scientific relevance, including an evaluation of the importance of the object of the

experiment, as well as a multidisciplinary study addressing the ethical issue. Clinical trials must have the relevant authorisation from the Ministry of Health.

4. When the person has been informed on the rights and the guarantees established by that Law for the protection of individuals participating in experiments, the identity of the person in charge and the source of funding.
5. When the person gives his free, express, specific and written consent as established in section 2.1. and 2.2. of this document, to participate in the experiment, and may withdraw his consent at any time.
6. When the person knows that he has the right to remain anonymous if the results are published. If this anonymity cannot be maintained in the publication, the patient's signed consent will be required.
7. He must be able to access the findings of the investigation in which he participated, in the form of any ensuing publications and understandable summaries.

When a person is not capacitated to give his consent freely, he may only participate in an experiment when:

- a) The conditions listed in points 1, 2, 3 and 4 of the previous section are met.
- b) The envisaged results of the experiment entail a real and direct benefit for his health.

- c) The experiment cannot be performed with comparable efficacy in persons who can give their consent.
- d) A written and specific authorisation has been provided by the individual's representative, or by a legally appointed authority or institution.
- e) The person does not overtly reject the experiment.

In exceptional cases, experiments that do not entail a direct benefit for the individual's health may be authorised if criteria 1, 3, 4 and 5 are met, and furthermore:

- f) If the experimentation seeks a significant improvement in scientific knowledge that may make it possible to obtain, within a given period of time, benefits for the person who is participating in the experiment or for others with similar diseases and disorders.
- g) If the experiment only involves a minimum risk or inconvenience to the individual.

**5.2. The patient has the right to access and use preparations of tissues or biological samples from a biopsy or extraction to be able to seek a second professional opinion or to continue with the care in a different health centre**

This implies the existence of a system of custody of biological samples to ensure that accessibility thereto is properly regulated and documented.

Whenever tissues or biological samples from a biopsy, extraction or donation are kept, the patient has the right to be informed of this and to authorise any use to be made of them.

When the patient does not authorise the use of tissues or biological samples from a biopsy or extraction they must be disposed of as health waste.

## **6. RIGHTS RELATED TO THE PREVENTION OF DISEASE AND THE PROMOTION AND PROTECTION OF HEALTH**

**6.1. Citizens have the right to have suitable knowledge of the health problems that entail a health risk for the community, and that such information will be disseminated in comprehensible, real and suitable terms for health protection**

Citizens have the right to have suitable knowledge of the hazards related to the environment, food, drinking water and individual behaviour that represent a risk to health affecting the community, and that such information will be disseminated in comprehensible, real and suitable terms for health protection

This information must be sufficient, understandable, suitable and must include the factors, situations and causes of risk for health, including general epidemiological information regarding the most common health problems, with a view to promoting the improvement of healthy behaviours and habits, both individual and collective.

**6.2. The right to enjoy a quality environment**

This right must make it possible for current and future generations to lead a dignified and healthy life with well-being.

**6.3. The right to consume safe food and drinking water**

**6.4. The right to know the plans, actions and the services available in matters of prevention, promotion and protection of health, and to know how to use them**

**6.5. The right to receive preventive health care within the framework of the regular physicians attentions or treatments**

Health professionals should provide these services, along with information on the activities that are to be performed and their objective, always making sure that preventive practices entail no additional risk to the individual.

**6.6. The right to reject preventive actions proposed in situations that do not entail any risk to third parties, without prejudice to the provisions of public health standards or regulations**

When the person to whom preventive actions are proposed in situations that do not entail any risk to third parties rejects them, this rejection will be recorded in the clinical history or, as applicable, in the corresponding document.

## **7. RIGHTS RELATED TO HEALTH-CARE INFORMATION AND ACCESS TO CLINICAL DOCUMENTATION**

### **7.1. The right to receive information on health-care process and health condition**

The patient has the right to know all information obtained about his health and to have, in terms that are understandable to him, suitable and true information on his health and health-care process, including diagnosis, risk/benefits, the consequences of treatment and non-treatment and whenever possible prognosis. Nevertheless, the wish of a patient not to be informed must also be respected

The information will be provided in a understandable language that is for him, taking his personal, cultural, linguistic and educational characteristics, etc., into account. At the same time, he will be helped to understand the information so that it will afford him the elements of judgements he needs to take any necessary decisions on matters affecting his interests.

Health professionals must ask their patients who they wish to be informed. The related persons must be informed to the extent permitted by the patient, either expressly or tacitly.

Minors or patients who are not competent to understand the information will be informed according to their degree of understanding, as will their representatives, relatives or related persons.

## **7.2. User's rights for his clinical history to be comprehensive and include all the information on his health condition and clinical and health care and treatments in different health episodes**

The clinical history, integrated and unique, must include all the information on the patient's health condition and the clinical and health treatments and care corresponding to the different health episodes. This information must be true and updated, and must include the identification data pertaining to the patient and health care, clinical and health care and social data, as the case may be.

Technical resources permitting, the Department of Health and Social Security will promote mechanisms for the shared use of clinical histories so that patients attended to in different centres will not have to undergo repeat examinations and procedures, and the health-care services will have access to all available clinical information.

## **7.3. The user's rights to access the documentation on his clinical history**

The patient has the right to access the documentation on his clinical history and to obtain a copy of any data contained in it.

Health **care** centres must regulate the procedure for guaranteeing access. The patient also has the right to know this procedure.

Patients' right to access the documentation of their clinical history must never jeopardise any third party rights to the confidentiality of their own data, if such data are included in this documentation, or the rights of the professionals who have to participate in the making thereof. The latter may invoke confidentiality of their comments, opinions or subjective annotations.

This right may be exercised by representation, provided that it is duly accredited.

In the case of deceased patients, access to the clinical history will be facilitated to heirs, unless expressly prohibited by the patient.

Other relatives and related persons may access the relevant health data if there is a serious risk for their health or if so established by a summons.

#### **7.4. The right to have written information on the health-care process and health condition**

The user has the right to written information in understandable terms, be it a hospital discharge or outpatient or emergency report. This also includes medical certificates accrediting health condition in the cases established by legal provision or standard.

## **8. RIGHTS RELATED TO ACCESS TO HEALTH CARE**

### **8.1. The right of access to public health care services**

Within the framework of the public system, the citizen has the right to access quality health care in his place of residence and to have an integrated offer of reference services.

### **8.2. The right to choose professional and health centre**

The users and patients of the public health care services are entitled to have their preferences in terms of health professionals and health centres must respect, in primary, specialised and social-health care, in the terms and conditions established, and depending on availability in the public health care network.

The insurer will offer guidance to users and patients that wish to exercise this right, furnishing the data needed to access the services.

The professionals chosen will be their main interlocutors and in charge of the process, along with the health-care team, and will integrate the information pertaining to the patient's process

### **8.3. The right to have access to necessary medicines, health, products, and health accessories**

The users have the right to obtain medicines, health, products, and health accessories needed to promote, maintain or re-establish their health in the terms provided for by the law.

The health professionals must inform the patient, in understandable language, on the correct use of health products, expected effects, possible adverse effects, possible interactions with other medicinal products or food and, if necessary, of existing alternatives, so as to promote the rational use of medicinal products.

#### **8.4. The right to be attended to within a time suited to the pathological condition and according to equity-based criteria**

The health services and health-care apparatuses must be organised as efficiently as possible so that the patient can be attended to as promptly as possible, and according to criteria of equity, suitability and availability of resources, type of condition, emergency priority, a reasonable pre-established waiting time guaranteeing continuity of health-care.

The patient has the right to stay in a hospital or health establishment during his health-care process by medical criteria, depending on the patient condition.

#### **8.5. Right to request a second opinion**

When the patient wishes to seek complementary or alternative information on diagnosis and therapeutic recommendations of major individual import, he has the right to seek the opinion of a second professional, as provided for by the law.

## **9. RIGHTS RELATED TO GENERAL INFORMATION ON THE HEALTH-CARE SERVICES AND THE PARTICIPATION OF USERS**

### **9.1. The right to the availability of the charter of rights and duties in all health centres**

All health and social-health centres, services and establishments must provide the citizens' Charter of rights and duties with regard to health and health care services as a framework for the relationship between the centre and the users.

### **9.2. The right to receive general information and information on services**

The user has the right to be informed on services and requirements for the use thereof, the centre's operating standards, access procedures and useful information, as well as to comparative health information on the technology available, health-care results and waiting lists, amongst others.

Furthermore, he is entitled to receive economic information pertaining to definite and foreseeable expenses incurred in the health care, and to be informed of other ways of obtaining complementary information.

### **9.3. The right to know the services covered by insurance**

The user has the right to know what services are covered by insurance, be it public or private, the conditions in which they will be rendered, as well as any limited clauses and complaint channels in the event of conflict.

### **9.4. The right to know and identify the professionals providing the health care**

The user has the right to know the name and the qualification of the health professionals providing the health care and (for) personnel must be identified clearly and visibly.

### **9.5. The right to make complaints and suggestions**

The user has the right to know and use procedures for submitting suggestions and complaints. They must be evaluated and have a writing answered , within a suitable deadline, in accordance with legally established terms and conditions.

### **9.6. The right to participation in community health institutions and organs and the social organisations in the terms established by the law and conditions.**

**9.7. The right to use information and communication technology to the extent that such technology has been implemented and developed in the health network**

The users have the right for health care services to use available information technology to ensure that the time required by users in access, formalities and receipt of information is cut to the minimum possible. It is presumed that this access will depend on the development of these systems in the health care network and with the guarantees of confidentiality and safety provided for by the legislation in force.

## **10. RIGHTS RELATED TO HEALTH-CARE QUALITY**

### **10.1. The right to humane and scientific health-care quality**

Health professionals must provide health care according to ethical guidelines and standards of action, behaviour, respect for human dignity, and taking the live styles and beliefs of each person into account. This health care, based on current scientific knowledge, will be adapted to the needs and characteristics of each person and in the case of disease will be adapted to the seriousness and medical and social complexity involved.

### **10.2. The right to ascertain the level of quality of health centres**

To this end, the patient has the right to ascertain the Quality Assurance mechanisms in place in a health centre, as well as the institutions and organisations that endorse it. The patient also has the right to know health-care results achieved as measured by indicators.

### **10.3. The right to receive continual and integral health care**

All patients have specific rights in this area:

- The right to have, in primary health care, a physician in charge of integrating his health-care process and the care given over time, as well as a refereed professional nurse

- The right to receive health care that includes measures of prevention, diagnosis, treatment and rehabilitation.
- The right for there to be mechanisms of operation and coordination between the different levels, entities, centres and professionals involved in his care, in order to guarantee the quality thereof.

### **III. DUTIES OF THE CITIZENS WITH REGARD TO HEALTH AND HEALTH CARE**

In the areas of health and health care, the citizen-user is becoming an increasingly more active subject who is responsible for his health and must fulfil a series of duties.

The participation, information and responsibility of the citizen with regard to the health system and the health asset is progressively becoming a quality parameter of this system and a condition for its sustainability.

The convergence of the citizens' exercise of their rights and of the general interests leads to a conception of rights which is not possible without the reference to duty.

Thus, the citizens that use the health services have rights; but they also have duties, which must be known by citizens and health professionals alike.

**1. The duty to look after their health and be responsible for/with it. This duty must particularly be demanded when the health of other people may be placed at risk or jeopardised.**

The citizen has the duty to take care of his health and be actively responsible for it. Community life means that this duty is enforceable, particularly in cases when the health of other people may be placed at risk or jeopardised. Health has both an individual and social aspect that configure the corresponding areas of individual and collective responsibility.

**2. They must make use of the resources, services and rights according to their health needs and depending on availability in the health system, with a view to facilitating access by all citizens to health care in conditions of effective equality.**

The current health system is based, among other principles, on equal access to services. Enhancement and effective compliance with the principles of equity requires, in progressive fashion, that use of resources target the satisfaction of health needs, so that the aforementioned use of resources will be as efficient as possible, avoiding undiligent, irresponsible or abusive behaviour.

Similarly, the citizen has the obligation to comply with the standards that regulate access to the recognised rights.

**3. The duty to comply with the general health-specific provisions which are common to the whole population, as well as specific provisions determined by the health services.**

The citizen is bound to comply with the general health-specific provisions common to the whole population, as well as specific provisions determined by the health services, without prejudice to the exercise of the right to free choice between therapeutic options and to decline proposed medical treatment or health care actions, according to the terms established by the law.

**4. The duty to respect and comply with health measures adopted for the prevention of risk, the protection of health or the fight against threats to public health, such as smoking, alcoholism and traffic accidents, or transmittable diseases that can be prevented by vaccinations or other preventive measures, as well as collaboration in the accomplishment of these ends.**

Health is an asset to individuals and society, of which citizens are part, which the public authorities must recognise and promote and establish the legal standards, responsibilities and public actions necessary to guarantee respect and a high level of protection. In the bosom of advanced societies, both the prevention of health and public health risks and situations pertaining to the protection and promotion of health means that citizens are required to behave

actively in these areas of action and establish measures that must be fulfilled for the sake of community health objectives.

**5. The duty to act responsibly in the use of the health services offered by the health care system, mainly pharmaceutical, complementary, job disability and social.**

The correct and suitable use of resources and services offered by the health system is a duty of all citizens. In a scenario of limited resources, the demand for resources to be used properly and in accordance with needs is a principle of justice that must contribute to the effective equity of the health system and its future sustainability. The responsible use of resources and services of the health system, based on reasons of social solidarity and economic efficacy in the allocation of resources is an objective to be shared by everyone.

**6. The duty to responsibly use and enjoy health care services in accordance with the corresponding standards.**

Citizens must be respectful and make due use of health care facilities and services so as to make sure they are duly conserved and can operate properly, taking into account general standards of use and any rules and regulations established by health care centres and services

**7. The duty to respect the rules and regulations established in each centre, as well as the personal and professional dignity of the personnel employed.**

Citizens must respect and collaborate in compliance with the rules and regulations established by the health care institutions and services.

The exercise of habits, customs and lifestyles of the individual must be compatible and respect the rules and regulations and instructions established by the health services and centres which are necessary for their operation and organisation.

Similarly, the personnel of the health centres and institutions, other patients and relatives or companions must be treated with due respect and dignity.

**8. The citizen must provide, truthfully, his identification data and any data pertaining to his physical condition or health needed for the health-care process or for reasons of the general interest.**

Within the limits required by the respect for the right to privacy and confidentiality of personal data, the citizen is obliged to furnish, truthfully, any data he has on his family and personal background, physical condition and any other data that may be required to facilitate the health care process or for the general interest.

**9. The duty to sign the relevant document if he refuses to any health action proposed - particularly in the case of diagnostic tests, preventive action and treatment of especial relevance for the patient's health. This document will clearly express that the patient was duly informed of the possible consequences, and that he rejected the procedures advised.**

In the exercise of his autonomy, the patient, once he has the information he needs to grant his consent, may refuse a diagnostic test, preventive action, treatment and even request to be discharged from hospital. Once he is in possession of suitable and sufficient information reveals the consequences and the risks that may arise from his decision, the patient is under the obligation to record his choice in writing, if it is different to the proposed health care action.

**10. The patient is obliged to accept discharge once the health-care process the centre or the unit can offer is complete. If for different reasons there were a divergence of criteria on the patient's part, his opinion will be heard by means of reasonable channels of dialogue and with due tolerance and, once these channels have been exhausted, and should the situation so require, the centre or the unit will have to look for the resources needed to provide him with suitable care.**

Once the health care that the centre or unit can offer the patient has been completed, and taking into account health-care complexity and the different hospital levels of the system, the patient has the duty to accept discharge. Should the situation so require, the centre or the unit will have to look for the resources needed to provide him with suitable care.

**The Department of Health and Social Security would like to thank the following persons for their collaboration in the writing of this document:**

**Francesc Abel**, Instituto Borja de Bioética; **Josep Arnau**, Dirección General de Recursos Sanitarios (DSSS); **Montserrat Artigas**, División de Atención al Cliente y Calidad (SCS); **Lluís Balaguer**, ABS La Llacuna; **Maria Josep Borràs**, Asesoría Jurídica (DSSS); **Marco A. Broggi**, Hospital Universitario Germans Trias i Pujol; **Esther Busquets**, Dirección General de Recursos Sanitarios (DSSS); **Maria Casado**, Observatorio de Bioética y Derecho; **Jaume Duran**, Dirección General de Recursos Sanitarios (DSSS); **Oriol Duch**, Dirección de Atención Primaria Girona (ICS); **Norma Garriga**, Servicio de Calidad Asistencial y Acreditación (DSSS); **Pilar González**, Dirección de Atención Primaria Baix Llobregat Centro (ICS); **Pau Hernando**, Consorcio Sanitario del Parc Taulí; **Glòria Jodar**, Atención al Usuario, DAP Baix Llobregat Litoral (ICS); **Albert Jovell**, Fundación Josep Laporte; **Rafael Lledó**, Hospital Clínico y Provincial de Barcelona; **Eduard Mata**, Dirección General de Salud Pública (DSSS); **M. Virtudes Pacheco**, Hospital de la Santa Creu i de Sant Pau; **Mercè Peris**, Instituto Catalán de Oncología; **Eugeni Sedano**, Dirección General de Recursos Sanitarios (DSSS); **Núria Terribas**, Instituto Borja de Bioética.

**Similarly, the Department of Health and Social Security is grateful to the following organisations for their inputs and considerations:**

Asociación Catalana de Establecimientos Sanitarios (**ACES**), Federación Catalana Pro Personas con Retraso Mental (**APPS**), Colegio de Biólogos de Cataluña (**CBC**), Consejo de Colegios de Médicos de Cataluña (**CCMC**), Consorcio Hospitalario de Cataluña (**CHC**), Confederación Obrera de Cataluña (**CONC**), Colegio Oficial de Psicólogos de Cataluña (**COPC**), Coordinadora de Usuarios de la Sanidad (**COSO**), Federación de Mutualidades de Previsión Social de Cataluña (**FMPSC**), Instituto Catalán de la Salud (**ICS**), Sociedad Española de Atención al Usuario de la Sanidad (**SEAUS**), Sociedad de Salud Pública de Cataluña y Baleares (**SSPCIB**), Unión de Consumidores de Cataluña (**UCC-UCE**), Unión Catalana de Entidades Aseguradoras y Reaseguradoras (**UCEAC**), Unión Catalana de Hospitales (**UCH**), Consejo de Colegios de Diplomados en Enfermería de Cataluña (**CCDIC**).

Special thanks are due to the **Bioethics Committee of Catalonia** for its member's assessment the writing of this document:

**Eugeni Sedano, Francesc Abel, Rogeli Armengol, Josep Ballester, Josep M. Bertran, Mercè Boada, Margarita Boladeras, M. Josep Borràs, Marc Antoni Broggi, Esther Busquets, Montserrat Busquets, Josep M. Busquets, Joaquim Calaf, Salvador Cardús, Victòria Camps, Maria Casado, Pau Ferrer, Xavier Foz, Pau Hernando, Josep M. Martínez Carretero, Màrius Morlans, Rafael de Oleza, Joan Padrós, Josep M. Payà, Joan Maria Pons, Josep Enric Rebés, Lluís Revert, Joan Viñas,**

and the members of the **Advisory Board of the Department of Health and Social Security:**

**Francesc Abel, Mercè Boada, Francesc Domènech, Rafael Esteban, Carlos Ferrandiz, Gonçal Foz, Guillem López, Ramon Massaguer, Ciril Rozman, Montserrat Tejedor, Manuel Trias, Joan Uriach.**

The writing of this document was coordinated by: **Josep Ramon Arisa**, Asesoría Jurídica (SCS) and **Josep M. Busquets**, Dirección General de Recursos Sanitarios (DSSS).

Thanks to **Raquel Enrich**, Asesoría Jurídica (SCS) and **Cristina Sabaté**, Dirección General de Recursos Sanitarios (DSSS) for their administrative support in writing the document.