

22188

ACT 41/2002 of 14 November 2002, basic regulating Act on the autonomy of the patient and on the rights and obligations in matters of clinical information and documentation.

JUAN CARLOS I

KING OF SPAIN

To all those who might see and understand this Act.
Know ye, that the General Parliament has approved and I come to sanction the following Act.

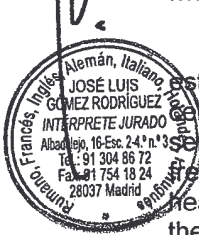
STATEMENT OF MOTIVES

The importance which the rights of patients have as a basic axis of clinical-care relations is highlighted by noting the interest that has been shown in them by virtually all international organisations with powers in this field. Since the end of the Second World War, organisations such as the United Nations, UNESCO or the World Health Organisation, or more recently the European Union or the Council of Europe, among many others, have issued declarations or in some cases have passed legal regulations on general or specific aspects related to this question. In this regard, mention needs to be made of the importance of the Universal Declaration of Human Rights, of 1948, which has been the obligatory point of reference for all constitutional texts subsequently passed, or, within the more strictly health field, the Declaration on promotion of the rights of patients in Europe, pronounced in 1994 by the Regional Office for Europe of the World Health Organisation, apart from the many international declarations of greater or less scope and influence that have referred to those questions.

Recently, mention can be made of the special relevance of the Convention of the Council of Europe for the protection of human rights and the dignity of the human being with regard to the applications of biology and medicine (Convention on the rights of man and biomedicine), signed on 4 April 1997, which came into force in Spain on 1 January 2000. This Convention is a fundamental initiative: indeed, unlike the different international declarations that have preceded it, it is the first international instrument of a binding legal nature for the countries that are signatories to it. Its special value lies in the fact that it establishes a common framework for the protection of human rights and human dignity in the application of biology and medicine. The Convention explicitly deals with, in detail and thoroughly, the need to acknowledge the rights of patients, among which are highlighted the right to information, informed consent, and intimacy of information relating to the health of persons, pursuing the scope of a harmonisation of the legislations of various countries in these fields; in this regard, it is absolutely advisable to bear the Convention in mind when it comes to tackling the challenge of regulating questions of such importance.

Nevertheless, it needs to be said that the regulation of the right to protection of health, contained in section 43 of the 1978 Constitution, from the point of view of questions that are most strictly tied to the condition of subjects of rights of user persons of health services, in other words, the materialisation of the rights relating to clinical information and individual autonomy of patients in relation to their health, has been the object of a basic regulation at the State level, by means of the General Health Act 14/1986, of 25 April 1986.

Moreover, this Act, in spite of the fact that it basically focused its attention on the establishment and ordering of the health system from the organisational point of view, devotes certain provisions to this question, notable among which is the wish to humanise the health services. So, it maintains the utmost respect for the dignity of the person and of individual freedom, on the one hand, and on the other, it declares that the health organisation must permit health to be guaranteed as an inalienable right of the population by means of the structure of the National Health System, which must be assured under conditions of scrupulous respect for personal intimacy and individual freedom of the user, guaranteeing the confidentiality of the



information relating to the health services that are provided and without any kind of discrimination.

On the basis of those premises, the present Act completes the provisions of the General Health Act announced as general principles. In this regard, it strengthens and grants special treatment to the right to autonomy of the patient. In particular, deserving special mention is the regulation on prior instructions which, in accordance with the criteria set down in the Oviedo Convention, contemplate the wishes of the patient expressed beforehand within the scope of informed consent. Likewise, the Act deals in depth with everything to do with the clinical documentation generated in care centres, in particular underlining the consideration and the materialisation of the rights of users in this aspect.

In September 1997, as part of the development of a collaboration agreement between the General Council of the Judiciary and the Ministry of Health and Consumption, a joint seminar was held on clinical information and documentation, in which the main regulating and judicial aspects of the subject were discussed. At the same time, a group of experts was set up who were placed in charge of drawing up guidelines for the future development of this subject. On 26 November 1997 this group signed a report which has been taken into account in producing the fundamental principles of this Act.

The attention granted to these matters at the time by the General Health Act implied a notable advance as reflected by, among others, its sections 9, 10 and 61. Nevertheless, the right to information, as a right of the citizen when he or she demands health attention, has in recent years been the object of various qualifications and extensions by Acts and provisions of various types and ranks, revealing the need for a reform and updating of the regulation considered in the General Health Act. So, Organic Act 15/1999, of 13 December 1999, on Personal Data Protection classifies data relating to the health of citizens as specially protected data, and it establishes a particularly rigorous system for its obtaining, custody and possible transfer. This defence of confidentiality had already been defended by the Community Directive 95/46, of 24 October 1995, in which, as well as reaffirming the defence of the rights and freedoms of European citizens, especially with regard to their intimacy relating to information concerning their health, it noted the presence of other general interests such as epidemiological studies, situations of serious risk for the health of a collective group, and clinical research and tests which, when included in regulations having the rank of an Act, can justify a motivated exception to the rights of the patient. So, a Community conception of the right to health was thus manifested in which, together with the specific interest of each individual, as the recipient par excellence of the information relating to health, other agents and juridical goods also appeared referring to public health, which had to be considered, with the necessary relevance in an advanced democratic society. Along these lines, the Council of Europe, in its Recommendation of 13 February 1997, relating to the protection of medical data, after affirming that it should be gathered and processed with the consent of the concerned party, stated that the information can be restricted if so provided by an Act and it constitutes a necessary measure for reasons of general interest.

All these circumstances made it advisable to undertake an adaptation of the General Health Act with the objective of clarifying the legal situation and the rights and obligations of health professionals, of citizens and of health institutions. The aim is, within the field of clinical information and documentation, to offer the same guarantees for all citizens of the State, thereby strengthening the protection of health acknowledged by the Constitution.

CHAPTER I

General principles

Section 1. *Scope of application*

The object of this Act is the regulation of the rights and obligations of patients, users and professionals, as well as of public and private health centres and services, in matters of patient autonomy and of clinical information and documentation.

Section 2. *Basic principles*



1. The dignity of the human person, respect for the autonomy of his or her wishes and for their intimacy, shall guide all activities aimed at obtaining, using, filing, safeguarding and transferring clinical information and documentation.

2. All actions in the field of health in general require the prior consent of patients or users. The consent, which must be obtained after the patient has received proper information, shall be granted in writing in the situations provided for in Law.

3. The patient or user has the right to freely decide among the available clinical options, after having obtained received proper information.

4. All patients or users have the right to refuse treatment, except in the cases determined in Law. Their refusal of treatment shall be stated in writing.

5. Patients or users have the duty to provide data on their physical state or on their health in a manner that is faithful and truthful, and also to collaborate in its obtaining, specially when necessary for reasons of public interest or on account of health care.

6. Any professional intervening in the care activity is obliged not only to undertake the correct rendering of his or her techniques but also to comply with the duties of clinical information and documentation, and to respect the decisions freely and voluntarily adopted by the patient.

7. The person who prepares or has access to clinical information and documentation is obliged to maintain due confidentiality.

Section 3. *Legal definitions*

For the purposes of this Act, the following definitions are understood:

Health centre: the organised collection of professionals, facilities and technical means performing activities and rendering services for caring for the health of patients and users.

Medical certificate: the written declaration from a doctor attesting to the state of health of a person at a particular moment.

Informed consent: the free, voluntary and conscious conformity of a patient, stated in the full use of his or her faculties after having received proper information, so that an action can be undertaken affecting his or her health.

Clinical documentation: the support of any kind or class containing a set of data and information of a caring nature.

Clinical history: the set of documents containing the data, assessments and information of whatsoever nature on the situation and the clinical evolution of a patient during the course of the care process.

Clinical information: any data, no matter what its form, class or type, permitting knowledge to be acquired or expanded concerning the physical state and health of a person, or the manner of preserving it, looking after it, improving it or retrieving it.

Medical discharge report: the document issued by the doctor in charge of a health centre on completion of the care process for a patient, containing data on that patient, a summary of his or her clinical history, the care activity carried out, the diagnosis and the therapeutic recommendations.

Intervention in the health field: all actions carried out with preventive, diagnostic, therapeutic, rehabilitating or investigative ends.

Free choice: the power of the patient or user to freely and voluntarily choose among various doctors or among care centres, under the terms and conditions established by the competent health services in each case.



Doctor in charge: the professional who is in charge of coordinating the information and the health care of the patient or of the user, with the nature of being the main intermediary of that patient or user in everything to do with their attention and information during the care process, notwithstanding the obligations of other professionals participating in care actions.

Patient: the person who requires health care and is subjected to professional attendance for the maintenance or recovery of his or her health.

Health service: the care unit with its own organisation, provided with technical and personnel resources qualified for carrying out health activities.

User: the person who uses the health services for education and promotion of health, prevention of illnesses and health information.

CHAPTER II

The right to health information

Section 4. *Right to information on care*

1. On the occasion of any action in the field of their health, patients have the right to know all the information on it, apart from the situations for which the Law makes an exception. Also, all persons have the right that their wish not to be informed should be respected. The information which, as a general rule, shall be provided verbally with a note of this being made in the clinical history, consists of at least the purpose and the nature of each intervention, their risks and their consequences.

2. The clinical information forms part of all care actions, it shall be truthful, it shall be communicated to the patient in a way that is comprehensible and suited to his or her needs and it shall help the patient to take decisions in accordance with their own free will.

3. The doctor in charge of patients guarantees to them that he or she shall comply with their right of information. Professionals attending to them during the care process or who apply a specific technique or procedure shall also be responsible for informing them.

Section 5. *Holder of the right to information on care*

1. The holder of the right to information is the patient. Persons connected to him or her shall also be informed, for reasons of relationship or de facto reasons, to the degree that the patient permits this expressly or tacitly.

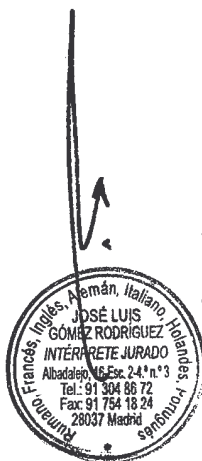
2. The patient shall be informed, including in cases of incapacity, in a manner suited to his or her possibilities of comprehension, complying with the duty to also inform his or her legal representative.

3. When, in the opinion of the doctor caring for him or her, the patient lacks the capacity for understanding the information on account of his or her physical or mental state, the information shall be conveyed to persons tied to the patient by virtue of relationship or de facto reasons.

4. The right to health information of patients can be limited by the accredited existence of a state of therapeutic necessity. Therapeutic necessity shall be understood as being the power of the doctor to act professionally without previously informing the patient concerning whom, for objective reasons, the knowledge of his own situation could seriously harm his health. In such an event, the doctor shall leave a reasoned note of the circumstances in the clinical history and he shall inform persons tied to the patient by virtue of relationship or de facto reasons of his decision.

Section 6. *Right to epidemiological information*

Citizens have the right to know about health problems of the collective group when they imply a risk for public health or for their own individual health, and the right to this information



being made known in terms that are truthful, comprehensible and suitable for the protection of health, in accordance with that set down in Law.

CHAPTER III

The right to intimacy

Section 7. *The right to intimacy*

1. All persons have the right that the confidential nature of the data referring to their health should be respected, and that no one can gain access to it without prior authorisation as provided for in law.

2. Health centres shall adopt the appropriate measures for guaranteeing the rights referred to in the previous paragraph and, when appropriate, they shall draw up the rules and procedures of protocol guaranteeing legal access to the data of patients.

CHAPTER IV

Respect for the patient's autonomy

Section 8. *Informed consent*

1. All actions in the field of the health of a patient need the free and voluntary consent of the affected party once he or she has assessed the options proper to the case after received the information provided for in section 4.

2. The consent shall be verbal as a general rule. Nevertheless, it shall be given in writing in the following cases: surgical operation, invasive diagnostic and therapeutic procedures and, in general, application of procedures involving risks and inconveniences having notable and foreseeable negative repercussions on the health of the patient.

3. Written consent from the patient shall be necessary for each of the actions specified in the previous paragraph of this section, safeguarding the possibility of the incorporation of annexes and other data of a general nature, and the patient shall have sufficient information on the application procedure and on its risks.

4. All patients or users have the right to be warned regarding the possibility of using the prognostic, diagnostic and therapeutic procedures that might be applied to them in a teaching or research project, which shall in no case be able to entail any additional risk for their health.

5. The patient shall be freely able to revoke their consent in writing at any moment.

Section 9. *Limits on informed consent and consent by representation*

1. Waiver by the patient concerning the reception of information is limited by the interest of the health of the patient him or herself, of third parties, of the collective group or by the therapeutic demands of the case. When the patient expressly states his or her wish not to be informed, that wish shall be respected with the waiver being set down on record in a document, notwithstanding the obtaining of his or her prior consent to the intervention.

2. Doctors shall be able to carry out essential clinical interventions in favour of the patient's health, without any need to have his or her consent, in the following cases:

a) When there exists a risk for public health on account of the health reasons set down by Law. In all cases, once the pertinent measures have been adopted pursuant to the provisions of Organic Act 3/1986, the judicial authorities shall be notified within a maximum period of 24 hours whenever they have provided for the obligatory internment of persons.

b) When there exists an immediate serious risk for the physical or mental integrity of the patient and it is not possible to obtain his or her authorisation, in which case, and when the



circumstances so permit, his or her relatives or persons with de facto ties to the patient shall be consulted.

3. Consent by representation shall be granted in the following situations:

a) When the patient is not capable of taking decisions in the opinion of the doctor in charge of the case, or his or her physical or mental state does not permit the patient to take charge of the situation. If the patient lacks a legal representative, the consent shall be granted by virtue of relationship or de facto reasons.

b) When the patient is legally disqualified.

c) When the patient is a minor and is neither intellectually nor emotionally capable of understanding the scope of the intervention. In this case, the consent shall be given by the legal representative of the minor after having heard the opinion of the latter if he or she is over the age of twelve. In the case of minors who are neither incapable nor disqualified, but emancipated or over the age of sixteen, consent may not be given by the representative. Nevertheless, in the case of action entailing serious risk, in the opinion of the doctor, the parents shall be informed and their opinion shall be taken into account for taking the appropriate decision.

4. The voluntary interruption of pregnancy, the practice of clinical tests and the practice of human assisted reproduction techniques are governed by that set down in general on the majority of age and by the special provisions having application.

5. The granting of consent by representation shall be suited to the circumstances and proportional to the needs which have to be attended to, at all times in favour of the patient and with respect to his or her personal dignity. The patient shall participate in the decision taking during the course of the health process, to the degree that this is possible.

Section 10. *Conditions of information and consent in writing*

1. The doctor shall, before obtaining the patient's written consent, provide him or her with the following basic information:

a) The relevant or important consequences which the intervention originates with regard to safety.

b) The risks related to the personal or professional circumstances of the patient.

c) The probable risks under normal conditions, in accordance with the experience and state of the science or directly related to the type of intervention.

d) The contraindications.

2) The doctor in charge must in each case consider the fact that the more doubtful the outcome of an intervention, the greater the need for prior written consent from the patient.

Section 11. *Prior instructions*

1. By means of the document of prior instructions, a person who is of age, capable and free, states his or her wishes in advance, with the aim that those wishes shall be obeyed at the moment in which a situation is reached in which circumstances the patient is not capable of personally expressing them with regard to the care and treatment of his or her health or, in the event of death, with regard to the destination of their body or their organs thereof. The executor of the document can furthermore designate a representative so that, if the case arises, he or she can act as an intermediary of the patient with the doctor or the medical team in order to ensure that the prior instructions are obeyed.

2. Each health service shall regulate the proper procedure so that, if the situation arises, obeisance of the prior instructions of each person is guaranteed, said instructions having at all times to be set down in writing.

3. Prior instructions that are contrary to the legal code, or to "lex artis", shall not be applied, nor shall those which fail to correspond to the supposition of fact which the interested party was considering at the moment of stating them. The clinical history of the patient shall contain a reasoned record of the notes related to these considerations.



4. The prior instructions shall be able to be freely revoked at any moment with a written record of this being left.

5. With the aim of ensuring efficacy throughout national territory of the prior instructions stated by patients and formalised in accordance with the provisions of legislation of the respective Autonomous Regions, a National Register of prior instructions shall be set up within the Ministry of Health and Consumption, which shall be governed by the rules that are defined in regulations, with prior agreement of the Inter-territorial Council of the National Health System.

Section 12. *Information in the National Health System*

1. In addition to the rights acknowledged in the above sections, patients and users of the National Health System shall have the right to receive information on available services and care units, their quality and the requisites concerning access to them.

2. The health services shall, in their health centres and services, provide a guide or notice of the services specifying the rights and obligations of users, the benefits that are available, the care characteristics of the centre or service, and their endowment of personnel, facilities and technical means. All users shall be provided with information on participation guides and on suggestions and claims.

3. Each health service shall regulate the procedures and systems for guaranteeing the effective compliance with the provisions of this section.

Section 13. *Right to information for the choice of doctor and centre*

Users and patients of the National Health System, both in primary care and in specialised, shall have the right to the corresponding prior information for choosing a doctor, and likewise a centre, pursuant to the terms and conditions established by the competent health services.

CHAPTER V

The clinical history

Section 14. *Definition and filing of the clinical history*

1. The clinical history comprises the set of documents relating to the care processes of each patient, with the identification of the doctors and other professionals who have intervened in them, with the aim of obtaining the maximum possible integration of the clinical documentation of each patient, at least within the scope of each centre.

2. Each centre shall file the clinical histories of its patients, whether they be on paper, audiovisual, computing or other support, in such a way that their security, their correct conservation and the recovery of the information are guaranteed.

3. The health authorities shall establish the mechanisms guaranteeing the authenticity of the contents of the clinical history and of the changes made to it, along with the possibility of its future reproduction.

4. The Autonomous Regions shall approve the necessary provisions so that the health centres can adopt the appropriate technical and organisational measures for filing and protecting the clinical histories and prevent their destruction or their accidental loss.

Section 15. *Content of the clinical history of each patient*

1. The clinical history shall incorporate the information that is considered important for the true and updated knowledge of the patient's state of health. All patients or users have the right to have set down on record, in writing or on the most suitable technical support, the information obtained in all their care processes carried out by the health service both within the field of primary care and in that of specialised care.



2. The primary aim of the clinical history shall be to facilitate health care, leaving a record of all data which, according to medical opinion, permit the true and updated knowledge of the state of health. The minimum content of the clinical history shall be the following:

- a) Documentation relating to the clinical-statistical sheet.
- b) Authorisation for admission.
- c) The urgency report.
- d) The anamnesis and the physical examination.
- e) The evolution.
- f) The medical orders.
- g) The inter-consultation sheet.
- h) The reports on complementary examinations.
- i) The informed consent.
- j) The anaesthesia report.
- k) The operating theatre report or the birth register.
- l) The pathological anatomy report.
- m) The evolution and planning of nursing care.
- n) The therapeutic application of nursing.
- ñ) The constants graph.
- o) The clinical discharge report.

Paragraphs b), c), i), j), k), l) ñ) and o) shall only be required in filling in the clinical history in the event of hospitalisation process or when this is so provided.

3. The filling in of the clinical history, in aspects related to the direct care of the patient, shall be the responsibility of the professionals intervening in that care.

4. The clinical history shall be kept according to the criteria of unity and integration, in each care institution at least, in order to facilitate the best and most appropriate knowledge by doctors of the data on a particular patient in each care process.

Section 16. *Uses of the clinical history*

1. The clinical history is an instrument fundamentally intended for guaranteeing suitable care for the patient. The care professionals of the centre carrying out the diagnosis or treatment of the patient have access to the clinical history of the latter as a fundamental instrument for his or her adequate care.

2. Each centre shall establish the methods that at all times allow access to the clinical history of the patient by the professionals looking after them.

3. Access to the clinical history for judicial, epidemiological, public health, research or teaching purposes is governed by the provisions of Organic Act 15/1999, on Personal Data Protection, and in the General Health Act 14/1986, and other rules of application in each case. Access to the clinical history with these ends makes it obligatory to keep data on the personal identification of the patient separate from the clinical-care data, in such a way that anonymity can, as a general rule, be assured, unless the actual patient has given his or her consent not to separate them. An exception is made of cases of investigation by the judicial authority in which unification of the identifying data with the clinical-care data is considered essential, in which case the provisions of the judges and courts in the corresponding process shall be abided by. Access to the data and documents of the clinical history is strictly limited to the ends specified in each case.

4. The administration and managerial personnel of health centres may only access data in the clinical history in relation to their own tasks.

5. Duly accredited health personnel who perform the duties of inspection, evaluation, accreditation and planning have access to the clinical histories in compliance with the tasks concerning the checking of the quality of care, respect for the rights of the patient or any other obligation of the centre in relation to patients and users, or the actual health authority itself.

6. Personnel accessing data from the clinical history in the performance of their tasks are subject to the duty of secrecy.



7. The Autonomous Regions shall regulate the procedure so that a record is kept of access to the clinical history and its use.

Section 17. *The conservation of clinical documentation*

1. The health centres have the obligation to conserve the clinical documentation under conditions that guarantee its correct maintenance and security, though not necessarily on the original support, for the due care of the patient during the appropriate length of time in each case and for a minimum five years starting from the date of discharge from each care process.

2. The clinical documentation shall also be conserved for judicial effects in accordance with the existing legislation. It shall likewise be conserved when there exist reasons of epidemiology, research or organisation and functioning of the National Health System,. Its treatment shall be done in such a way that the identification of the persons affected is as far as possible avoided.

3. Health professionals have the duty to cooperate in the creation and maintenance of an ordered and sequential clinical documenting of the care process of patients.

4. The management of the clinical history by centres with hospitalised patients, or by those centres that attend to a sufficient number of patients under any other category of care, according to the criterion of the health services, shall be done via the admissions and clinical documentation unit, which is in charge of combining the clinical histories into a single archive. The custody of those clinical histories shall come under the responsibility of the management of the health centre.

5. The health professionals who develop their activity on an individual basis are responsible for the management and custody of the care documentation they generate.

6. Having application to the clinical documentation are the technical measures on security established by the legislation regulating the conservation of files containing data of a personal nature and, in general, by Organic Act 15/1999, on Personal Data Protection.

Section 18. *Rights of access to the clinical history*

1. The patient has the right of access, with the reservations stated in paragraph 3 of this section, to the documentation on the clinical history and to obtain a copy of the data appearing therein. Health centres shall regulate the procedure guaranteeing the observance of these rights.

2. The right of access by the patient to the clinical history can also be exercised by duly accredited representation.

3. The right of the patient to access to the documentation on the clinical history cannot be exercised to the prejudice of the right of third parties to confidentiality of the data noted therein and gathered in the therapeutic interest of the patient, nor to the prejudice of the right of professionals taking part in its preparation, who can oppose the right of access on the grounds of confidentiality of their subjective notes.

4. Health centres and doctors practising on an individual basis shall only facilitate access to the clinical history of deceased patients for persons who are tied to them by virtue of relationship or for de facto reasons, unless the deceased has expressly prohibited this and this is so accredited. In whatsoever case, access by a third party to the clinical history on account of a risk to his or her own health shall be limited to the pertinent data. Information affecting the intimacy of the deceased or the subjective notes of the professionals shall not be facilitated, nor shall any information prejudicial to third parties.

Section 19. *Rights related to the custody of the clinical history*

The patient has the right to the health centres establishing a mechanism of active and custody of clinical histories. Said custody shall permit the gathering, integration,



recovery and communication of the information subject to the principle of confidentiality, in accordance with that set down by section 16 of this Act.

CHAPTER VI

Discharge report and other clinical documentation

Section 20. *Discharge report*

Any patient, relative or person tied to them, as the case might be, shall, once the care process has concluded, have the right to receive from the health centre or service a discharge report with the minimum contents defined by section 3. The characteristics, requisites and conditions of discharge reports shall be determined on a regulatory basis by the regional health authorities.

Section 21. *Discharge of the patient*

1. In the event of not accepting the prescribed treatment, it shall be proposed to the patient or user that they sign the voluntary discharge papers. If they do not sign them, the management of the health centre shall, at the proposal of the doctor in charge, be able to propose forcible discharge under the conditions regulated by Law. The fact of not accepting the prescribed treatment shall not give rise to forcible discharge when there exist alternative treatments, even if they are of a palliative nature, so long as they are provided by the health centre and the patient accepts receiving them. This circumstance shall be duly documented.

2. In the event that the patient does not accept the discharge, the management of the centre shall hear the patient, after checking the corresponding clinical report, and if the patient persists in his or her refusal, the management shall inform the judge so that he can uphold or overturn the decision.

Section 22. *Issuing of medical certificates*

Any patient or user has the right to be issued with certificates accrediting their state of health. These shall be free when so established by a legal or regulatory provision.

Section 23. *Professional obligations on technical, statistics and administrative information*

In addition to the obligations stated on the subject of clinical information, health professionals also have the duty to fill in protocols, registers, reports, statistics and other documentation of a caring or administrative nature having to do with the clinical processes in which they intervene, and which are required of them by the corresponding health centres or services and the health authorities, including those related to medical research and epidemiological information.

Additional provision one. *Nature of basic legislation*

This Act has the condition of being basic, in conformity with that established in section 149.1.1st and 16th of the Constitution.

The State and the Autonomous Regions shall, within the scope of their respective competencies, adopt the necessary measures for the effectiveness of this Act.

Additional provision two. *Supplementary application*

The rules of this Act relating to information on care, information for the exercise of the freedom of choice of the doctor and of the centre, the informed consent of the patient and clinical documentation shall be of supplementary application in medical research projects, in the processes of removal and transplanting of organs, in those of application of assisted human reproduction techniques and in those lacking any special regulation.

Additional provision three. *Coordination of the clinical histories*



The Ministry of Health and Consumption, in coordination and with the collaboration of the Autonomous Regions having competence in the matter, shall, with the participation of all interested parties, promote the introduction of a system of compatibility which, heeding the evolution and availability of the technical resources, and the diversity of systems and types of clinical histories, shall allow its use by the care centres of Spain attending to the same patient, avoiding a situation in which patients who are attended to in different centres are subjected to unnecessarily repeated examinations and procedures.

Additional provision four. Needs associated with handicap

The State and the Autonomous Regions shall, within the scope of their respective competencies, issue the required provisions for guaranteeing that patients or users with special needs, associated with a handicap, have the rights in matters of autonomy, information and clinical documentation that are regulated in this Act.

Additional provision five. Information and documentation on medicines and health products

The information, documentation and publicity relating to medicines and health products, as well as the system of prescriptions and the corresponding prescription orders, shall be regulated by their specific rules, notwithstanding the application of the rules established in this Act in terms of the prescription and use of medicines or health products during the care processes.

Additional provision six. Sanctioning system

Infringements of the provisions of this Act are subject to the sanctioning system provided for in Title 1, Chapter VI, of the General Health Act 14/1986, notwithstanding the civil or criminal liability and professional or statutory liability as appropriate in law.

Sole transitory provision. Discharge report

The discharge report shall be governed by the provisions contained in the Order of the Ministry of Health, of 6 September 1984, until the provisions contained in section 20 of this Act have been legally developed.

Sole repealing provision. General repeal and repeal of specific provisions

Provisions of equal or lesser rank which oppose those provided for in this Act, and specifically section 10, paragraphs 5, 6, 8, 9 and 11, section 11, paragraph 4, and section 61 of the General Health Act 14/1986 are repealed

Sole final provision. Entry into force

This Act shall enter into force in a period of six months starting from the day following its publication in the "Official State Gazette".

Therefore,
I order all Spaniards, individuals and authorities, to observe this Act and cause it to be observed.

Madrid, 14 November 2002.

JUAN CARLOS R.

The President of the Government
JOSÉ MARÍA AZNAR LÓPEZ



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The information, documentation and publicity relating to medicines and health products, as well as the system of prescriptions and the corresponding prescription orders, shall be regulated by their specific rules, notwithstanding the application of the rules established in this Act in terms of the prescription and use of medicines or health products during the care processes.

Additional provision six. Sanctioning system

Infringements of the provisions of this Act are subject to the sanctioning system provided for in Title 1, Chapter VI, of the General Health Act 14/1986, notwithstanding the civil or criminal liability and professional or statutory liability as appropriate in law.

Sole transitory provision. Discharge report

The discharge report shall be governed by the provisions contained in the Order of the Ministry of Health, of 6 September 1984, until the provisions contained in section 20 of this Act have been legally developed.

Sole repealing provision. General repeal and repeal of specific provisions

Provisions of equal or lesser rank which oppose those provided for in this Act, and specifically section 10, paragraphs 5, 6, 8, 9 and 11, section 11, paragraph 4, and section 61 of the General Health Act 14/1986 are repealed

Sole final provision. Entry into force

This Act shall enter into force in a period of six months starting from the day following its publication in the "Official State Gazette".

Therefore,
I order all Spaniards, individuals and authorities, to observe this Act and cause it to be observed.

Madrid, 14 November 2002.

JUAN CARLOS R.

The President of the Government
JOSÉ MARÍA AZNAR LÓPEZ

