

Law 2/2010, dated 8th April, on Personal Rights and Guarantees to die in dignity¹.

BOJA number 88. Seville, 7 May 2010.

THE PRESIDENT OF THE REGIONAL GOVERNMENT OF ANDALUSIA, LET IT HEREBY BE KNOWN TO ALL

That the Andalusian Parliament has approved, and I, on behalf of the King of Spain and by the authority invested in me by the Constitution and the Statute of Autonomy for Andalusia, hereby enact and order the following to be made public:

ACT ON PERSONAL RIGHTS AND GUARANTEES TO DIE IN DIGNITY

PREAMBLE

I

Article 149.1.16 of the Spanish Constitution vests in the State sole responsibility for setting the framework and general co-ordination of healthcare provision.

Article 55.1 of the Statute of Autonomy for Andalusia grants the Autonomous Community exclusive responsibilities for the organisation, internal management, evaluation, inspection and control of healthcare facilities and services, without prejudice to the provisions of the foregoing Constitution.

Likewise, articles 55.2 of the Statute of Autonomy for Andalusia stipulates that the Autonomous Community of Andalusia has shared responsibilities on health matters affecting the Community and in particular, over the management and implementation of measures for preserving, protecting and promoting public health in all spheres.

The Statute of Autonomy for Andalusia, article 20.1, acknowledges the right of citizens to issue an advance health directive or living will, which should be respected in accordance with this Act. Furthermore, paragraph two of the aforementioned article 20 states that all persons

¹ I, Alison Turner Hanover, Sworn translator of English, duly authorised by the Spanish Ministry of Foreign Affairs and registered at the Civil Governor's Office in Málaga, hereby state that a document (Ley de la Muerte Digna, BOJA) drafted in Spanish has been handed to me for translation into English. The translation of this document entails 17 pages and is, to the best of my knowledge and understanding, a faithful version of the original.

shall have the right to receive adequate pain management and comprehensive palliative care, and are entitled to full dignity in death. The right to receive palliative care is repeated in article 22.2.i) of the Statute of Autonomy. Although pain management forms an integral part of comprehensive palliative care, the Statute of Autonomy for Andalusia attaches particular importance to such treatment, and, consequently, this right is further developed in this Act in particular.

Article 38 of the Statute of Autonomy for Andalusia establishes that the ban on discrimination contained in article 14 and the rights duly recognised in Chapter II shall be binding on all public authorities in Andalusia and, depending on the nature of each right, on private persons; these shall be interpreted in such a way as to ensure full effectiveness. Parliament shall approve the appropriate laws for enactment, which shall respect, in all cases, the substance thereof set forth in the Statute for Autonomy, and shall lay down the benefits and services attached, where appropriate, to the exercise of said rights.

In the regulatory scope of the Autonomous Community of Andalusia, paragraphs 3 and 11 of article 2 of Act 2/1998, dated 15th June, on Health in Andalusia, stipulates that initiatives on health protection should be based on the principles of the “integral concept of health” and the “continuing improvement in service quality, with particular attention to personalised care and the comfort of patients and their family members”.

II

End of life issues have gained great prominence in today's society. Firstly, advances both in medicine and related sciences have made it possible for life to be prolonged or basic functions maintained to an extent considered impossible only a few years ago. This, coupled with an ageing population and the subsequent increase in the number of people suffering from chronic illness, has meant that more and more people suffering from degenerative or irreversible diseases reach a terminal stage in which the underlying disease cannot be cured, their life expectancy is limited, and they and their families are subject to intense personal and shared suffering, frequently against a backdrop of intensive healthcare of a highly technical nature. Secondly, the growing importance given to personal autonomy has had a profound effect on the doctor-patient relationship, which must now adapt to the individuality of the patient. In a democratic society, respect for the freedom of choice and autonomy of an individual must be upheld during illness and at the end of life.

Article 5 of the European Council Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine) signed in Oviedo on 4th April 1997, states that a health intervention may only be performed once the person concerned has given their free and informed consent. Likewise, article 5 of the Universal Declaration on Bioethics and Human Rights, approved by the General Conference of UNESCO on 19th October 2005, stipulates that the autonomy of persons to make decisions must be respected.

The exercise of this right is particularly important in Andalusia's multicultural and diverse society, where different beliefs, values and preferences regarding dying and individual approach to death exist side by side. All these deserve equal respect and their exercise must

be guaranteed, provided this does not contravene the provisions of national law. Both Act 14/1986, dated 25th April, on General Health, and Act 2/1998, dated 15th June, on Health in Andalusia, have recognised and regulated a patient's right to individual autonomy with regard to their health status. The importance of the latter led to a more specific regulation, that of Act 41/2002, dated 14th November, providing the regulatory basis for patient autonomy, rights and obligations with respect to clinical information and documentation. Nevertheless, the growing frequency of complex situations related to a patient's capacity to take decisions regarding their own life, and the decision whether or not to apply certain treatments which have been the subject of broad social debate, illustrate the wisdom of specifically regulating the rights associated with the end of life process in order to safeguard the dignity of terminally ill and dying patients, to respect their autonomy and to guarantee full exercise of their rights.

In the framework of provisions contained in the Statute of Autonomy for Andalusia, the texts laid down in articles 20 and 22.2 of the Statute of Autonomy are hereby implemented in the present Act, and take into consideration the recommendations issued by the Andalusian Region's Health Ethics and Research Commission at their ordinary general meeting held on 25th June 2008, regarding the ethical substance of a future law regulating dignity in death.

All human beings aspire to live in dignity. The legal system attempts to both define and protect this aspiration. However, death also forms part of life. Dying is the final act in the personal biography of each human being, and cannot be held separate from it. Therefore, the imperative of living in dignity includes death. Living in dignity requires dying with dignity.

The right to live in dignity cannot be curtailed by an undignified death. It is, therefore, the duty of the legal system to define and protect the ideal of dying in dignity.

There has been broad debate in recent years on the specific scope of this ideal, and the rights stemming from it, not only in Spain and in the Autonomous Region of Andalusia, but worldwide. Nevertheless, a fairly consolidated ethical and legal consensus can be said to exist on some of the issues and rights surrounding the "good death" ideal, on which the articles of this Act have a bearing.

One of the most widely accepted key issues contained in the ideal of dying with dignity is the right of patients to receive comprehensive quality palliative care. This has already been established by Recommendation 1418/1999 of the Parliamentary Assembly of the European Council, on "Protection of the human rights and dignity of the terminally ill and the dying", These Recommendations were taken into consideration when drawing up the National Plan for Palliative Care, the Andalusian Plan for Palliative Care 2008-2012, and in the motion put forward by the Spanish Parliament's Health Commission. Recommendation 24/2003 of the European Council, on "The organisation of palliative care" recommends that legislative measures be taken to establish a coherent framework for palliative care. Our Statute of Autonomy, in articles 20 and 22, grants this idea the status of a right within the Autonomous Community of Andalusia. However, no ethical and legal consensus has yet been reached on certain situations, such as allowing a sufferer to request help from another person to put an end to his or her life.

On this point, reference must be made to the highly relevant term “euthanasia”. Etymologically speaking, euthanasia means “good death”, and in this etymological sense, provides a perfect summary of the ideal of dying in dignity. Nevertheless, this term has acquired numerous emotional interpretations and attachments that have rendered it imprecise and in need of a new definition. Adjectives such as “active”, “passive”, “direct”, “indirect”, “voluntary” or “involuntary” have been introduced to clarify the different meanings attached to the term. This has only added to the existing confusion in the minds of citizens, healthcare professionals, the media, and even experts in bioethics and law. In an attempt to define the meaning of the word euthanasia, the term is increasingly used merely to describe actions that: a) cause the death of patients, that is, directly and intentionally by means of a single, immediate cause-effect relationship, b) are carried out at the express and informed request, repeated over time, of competent patients, c) are carried out in a context of suffering considered unacceptable by the patient due to an incurable disease that has not been successfully mitigated by other means, for example, by palliative care, and d) are performed by healthcare professionals who know the patient personally and who have a significant clinical relationship with him/her.

In light of these criteria, no actions should be labelled “euthanasia” unless they fall into the preceding categories. The term does not appear in the current Criminal Code; however, article 143.4 of said Code does include mention of the situation for a form of aided or induced suicide, by means of an exceptional sub-category. This Law does not include the regulation of “euthanasia”.

Refusal of treatment, limitation of measures for life support and palliative sedation should not, however, be regarded as acts of euthanasia. These actions never deliberately seek to end the life of the patient, but instead to relieve or prevent suffering while the patient’s autonomy is fully respected and to ensure a humane approach to death. Accepting the right of a patient to refuse a particular healthcare intervention simply shows full respect for his/her personal autonomy, for an individual's freedom to manage their own life and accept the consequences of the decisions they take. When examining a request to withdraw mechanical ventilation, the Andalusian Advisory Council, supported this decision in Decision number 90/2007 by considering that “... the request is protected by the right to refuse treatment and the right [of the patient] to live in dignity...” and that “... healthcare professionals are required to act accordingly to respect the right of the patient to refuse the life support measures implemented...”. Inappropriate use of life support measures, i.e. when they only serve to artificially maintain the patient biologically alive but with no real possibility of a full recovery of his/her own life, goes against the dignity of human life. As a result, the decision not to initiate or to withdraw measures provides full respect for such dignity. A further example of respect for human dignity is to provide those terminally ill patients who freely wish to do so the possibility of approaching death without suffering, in peace. None of these practices can be considered contrary to ethical conduct based on the idea of dignity and respect for the Universal Declaration of Human Rights. Indeed, they should be considered as both sound clinical practice and as professional conduct that is fully compliant with prevailing laws.

In recent years several cases concerning refusal of treatment, limitation of life support measures or palliative sedation have given rise to debate in society both within Andalusia and nationwide. These debates have raised certain doubts regarding the ethical and lawful nature

of the actions taken by professionals. This Act seeks to make a decisive contribution towards legal certainty, for both citizens and healthcare professionals, regarding the actions included herein.

III

Another of the widely accepted key issues contained in the ideal of dying with dignity is a person's right to draft a written document in which they express their wishes and preferences if a situation arises where they cannot decide for themselves, and by means of said document to designate the person who will take decisions in their stead. This right has been regulated in the Autonomous Community of Andalusia by Act 5/2003, dated 9th October, on advance healthcare directives. Article 20 of the current Statute of Autonomy for Andalusia legally reinforces this right held by Andalusian citizens, and declares the expressions “living will” and “advanced healthcare directive” to be synonymous.

Following years of legal development, during which a significant number of Andalusian citizens have made use of this right, the approval of the Statute of Autonomy and the Act provides an excellent framework to bring up to date the legal regulations governing this important aspect of the ideal of dying with dignity.

As stipulated at the end of its Preamble, Act 5/2003, dated 9th October, “seeks to fill a void and enhance the healthcare care provided to Andalusian citizens, fully respecting their freedom and, in addition, providing healthcare professionals facing extreme clinical situations with legal safeguards. There can be no doubt that these goals will contribute towards general welfare and respect for individual freedom, as well as help build a fairer and more supportive society”.

We can safely say that since then the Act has amply met these goals.

Experience gained to date has shown that this legislative framework can be further improved. From the standpoint of the principle of individual free will, there are two main channels or instruments to ensure dignity at the end of life, namely the individual's right to clinical information, to informed consent, and to take decisions; and the right of the individual to prepare their advance healthcare directive, and for this directive to be implemented. Both rights share the same premise - the principle of free will - although in the case of informed consent, the patient declares their wishes in person, that is, at the time the need for medical treatment arises, while, in the case of advance healthcare directives, the patient's consent is given in advance should the need arise.

From this perspective, one of the conceptual changes introduced in article 9.5 of Title 11 of this text is to build the scope of an “individual's life values” into the advance healthcare directive, together with the possibility of granting citizens greater access to advance healthcare directives. If, in Act 5/2003, dated 9th October, it was incumbent on officials attached to the Regional Ministry of Health responsible for the register to verify the capacity and formal requirements of the directive, under this Law, this duty is taken over by officials authorised by the Regional Ministry of Health, thus making it possible for advance healthcare directives to be issued anywhere within the Autonomous Community of Andalusia, and facilitating access to the Advance Healthcare Directive Register for citizens.

Another issue that has emerged is the need to improve access to advance healthcare directives for professionals involved in delivering healthcare. If Act 5/2003, dated 9th October, referred to the "healthcare professionals in charge of the procedure" as being required to consult the Register to ascertain the existence of an advance healthcare directive, the scope of this responsibility has now been extended to include healthcare personnel responsible for the delivery of care, thus enhancing the efficacy of such directives. Furthermore, advance directives should be systematically entered into a patient's clinical record so this information is readily accessible for healthcare professionals.

A further new feature is the express regulation of the duties of healthcare professionals with regard to advance directives or living wills; such professionals are required to inform patients and their relatives of such directives, ascertain whether a living will has already been drawn up, and if so, to consult the Advance Healthcare Directive Register to ascertain the substance thereof, and to respect the values and instructions contained in the document.

A further major aspect of the reforms made to the previous regulation is the definition of the duties of the representative appointed by the individual granting the living will.

Article 3 of Act 5/2003, dated 9th October, describes this duty as that of standing in for the patient for the purpose of granting informed consent. However, practical experience has shown that the main problems of interpreting an advance healthcare directive and the role of the representative occur in unforeseen clinical situations - let us recall that this instrument can be used by both those suffering from a terminal illness, as well as by others who simply anticipate their wishes for any future situations that may arise - it being albeit impossible to foresee each and every one of these situations. Furthermore, in many living wills the signees simply express their values and appoint a representative, without specifying any particular instructions or clinical situations. For all these reasons, it is felt advisable to specify in more detail both the powers of the representative and the interpretive criteria he/she should apply. Thus, on the assumption that the latter will consistently act in the best interests of the person they represent, with full respect for their personal dignity, the Act dictates that in the case of clinical situations not explicitly provided for in the directive, both the life values described in the directive and the presumed wishes of the patient had they been capable of deciding for themselves at that time must be taken into consideration.

IV

For the purpose of effectively ensuring full dignity in death, this Act not only stipulates and implements the rights of the terminally ill and dying, but also determines the duties of the healthcare personnel caring for the patient at the end of his/her life, and lays down a number of obligations for both public and private healthcare institutions, intended to guarantee patients' rights.

In so doing, the Act regulates the duties of the healthcare professionals charged with caring for the dying, with regard both to the information on their case, which must be recorded in the patient's clinical record, and to respecting the patient's preferences, whether these are

expressed by means of informed consent, or in the form of a living will; for this latter case, minimum criteria for evaluating the *de facto* in capacity of the patient are therein established.

Particular attention has been paid to the duties of professionals with regard to limiting life support measures in order to avoid so-called over-zealous prolongation of life or therapeutic obstinacy, and to determine the procedure to be followed to withdraw or abstain from implementing these measures in consensus with the care team and maintaining whatever treatment may be necessary to ensure the comfort of the dying person.

In this Act, healthcare institutions and facilities come to the forefront as guarantors of the exercise of rights, and are subject to a set of obligations to provide these services. In this respect, facilities and institutions must enable family members to accompany the patient and guarantee appropriate care, including pain management, together with advice and fair, quality palliative care either at healthcare facilities or in the patient's own home.

Likewise, they will provide support for the family of the terminally ill patient, including bereavement counselling and a private room for cases where healthcare is provided in a hospital setting.

Finally, all healthcare facilities and institutions will have access to a Healthcare Ethics Committee to advise them whenever clinical decisions raise ethical conflicts.

Final provision number one amends article 6, paragraph 1, letters h and ñ of Act 1/1998, dated 15th June, on Health in Andalusia, concerning the rights of patients, pursuant to the provisions of Act 41/2002, dated 14th November, which provides the regulatory basis for patient autonomy, rights and obligations with respect to clinical information and documentation. In the present legal text, patients are granted the right to information, while the general obligation to provide this in writing, as laid down in Act 2/1998, dated 15th June, has now been removed.

Finally, final provision number two amends some specific aspects of Act 5/2003, dated 9th October, on advance healthcare directives, relating to articles 3, 6 and 9.2. The power to verify the requirements that determine the validity of the living will is extended to include public officials authorised by the Regional Ministry of Health for this purpose; access to the same is extended to include the healthcare professionals involved in the process; and inclusion of the living will in the clinical record becomes mandatory.

TITLE 1

GENERAL PROVISIONS

Article 1. Purpose.

The purpose of this Act is to regulate the exercise of individual rights of the terminally ill and dying, the duties of the healthcare personnel caring for such patients, and the guarantees that healthcare institutions are obliged to provide for these cases.

Article 2. Aims.

This Act aims to:

- a) protect the dignity of the individual at the end of his/her life.
- b) guarantee the autonomy of patients and respect for their wishes at the end of life, including those declared in advance through their living will.

Article 3. Scope.

This Act shall be applicable within the territory of the Autonomous Community of Andalusia, to the dying or those faced with decisions related to the end of life, to the personnel involved in providing healthcare for such patients, and to the healthcare facilities, services and organisations, both public and private, and insurance companies, operating in Andalusia.

Article 4. Basic principles.

The basic principles on which this Act is founded are:

- a) The guarantee of full respect for an individual's dignity at the end of life.
- b) The promotion of an individual's freedom, autonomy and wishes, in accordance with their wishes, preferences, beliefs or values, and the preservation of their privacy and confidentiality.
- c) The guarantee that an individual's decision to refuse treatment, or the withdrawal thereof, will not be detrimental to the level of comprehensive care and the individual's right to full dignity at death.
- d) The guarantee of each individual's right to receive comprehensive palliative care and appropriate pain management at death.
- e) Effective equality and absence of discrimination in an individual's access to healthcare services at the end of life.

Article 5. Definitions.

For the purpose of this Act, the following definitions will prevail:

- a) Quality of life: Individual satisfaction with objective living conditions based on personal values and beliefs.
- b) Informed consent: In accordance with the provisions contained in article 3 of Act 41/2002, dated 14th November, providing the regulatory basis for patient autonomy and rights and obligations with respect to clinical information and documentation, informed consent is "a patient's freely granted, voluntary and conscious acceptance, stated in full possession of their faculties after having received relevant information, for an action that will affect their health to be initiated".
- c) Palliative care: Organised set of health interventions comprehensively devised to improve the quality of life of patients and their families faced with problems associated with a terminal illness by preventing and relieving suffering, and the identification, assessment and management of pain and other physical and/or mental symptoms.

d) Advance healthcare directive: In accordance with the provisions of article 2 of Act 5/2003, dated 9th October, on advance healthcare directives, it is the declaration, made to be entered into the Advance Healthcare Directive Register, written by a capable person, who deliberately and freely expresses the options and instructions that must be observed in the context of the care they may receive in the event of clinical circumstances arising under which they are unable to express their wishes in person.

e) Health intervention: In accordance with the provisions of article 3 of Act 41/2002, dated 14th November, this refers to “any action performed for preventive, diagnostic, therapeutic, rehabilitation or research purposes”.

f) Limitation of therapeutic efforts: Withdrawal of, or failure to initiate, a life support measure or any other kind of intervention that would be futile in the opinion of the health professionals involved, given the poor prognosis of the person in terms of length and quality of future life, and which would only contribute to prolonging a clinical situation devoid of any reasonable expectations of improvement.

g) Life support measure: Healthcare intervention intended to maintain an individual's vital signs, irrespective of whether or not such intervention has any therapeutic effect on the underlying disease or biological process posing the threat to the individual's life.

h) Attendant physician: In accordance with the provisions of article 3 of Act 41/2002, dated 14th November, this refers to “the professional responsible for organising the information and care of the patient or user, acting as the main interlocutor with the patient on all matters relating to their care and information during the care process, without prejudice to the duties of other professionals participating in treatment strategies”.

i) Therapeutic obstinacy: Situation in which life support or other interventions are initiated or maintained in a terminally ill or dying patient affected by a serious and irreversible disease, when these are of no clinical use and only serve to prolong biological life with no real possibility of improvement or recovery in the patient and, accordingly, are subject to limitations.

j) Dying persons: Individuals who have a terminal illness or are close to death.

k) Representative: Person of legal age, capable of giving consent on behalf of another, having been assigned this duty in an advance healthcare directive or pursuant to prevailing legal provisions, if no such directive exists.

l) Palliative sedation: Administration of drugs in the dosage and combination required to diminish an individual's consciousness during terminal illness or death in order to provide appropriate relief of one or more refractory symptoms, subject to explicit informed consent under the terms of the Law.

m) Refractory symptom: That which fails to respond to adequate treatment and can only be controlled by reducing the patient's level of consciousness.

n) Death throes: Stage which gradually leads to death, clinically manifested by severe physical deterioration, extreme weakness, cognitive disorders and impaired consciousness, difficulty to relate and ingest, and with a life expectancy spanning a few days.

ñ) Situation of *de facto* incapacity: Situation in which individuals fail to understand and have no will to govern their own life independently, without a court order of incapacitation necessarily being issued.

o) Terminal status: Existence of an advanced, incurable and progressive disease with no reasonable possibility of responding to specific treatment, with a limited life expectancy, and during which intense and changing symptoms can arise that require specific palliative care.

p) Living will: synonymous with advance healthcare directive.

q) Life values: Set of values and beliefs held by an individual that lend meaning to his/her life and on which their decisions and preferences regarding disease and death are based.

TITLE II

RIGHTS OF THE INDIVIDUAL AT THE END OF LIFE

Article 6. Right to health information.

1. The dying or those confronted with decisions relating to end of life issues, are entitled to receive information under the terms of articles 4 and 5 of Act 41/2002, dated 14th November.

2. When, in spite of having been explicitly offered health information by the healthcare professionals involved in patient care, the patient voluntarily and freely refuses such information, their decision shall be respected, they will be informed of the importance thereof, and they will be asked to appoint a person willing to receive the information and to take decisions in their stead.

Article 7. Right to take decisions and to give informed consent.

1. The dying or those confronted with decisions relating end of life issues, are entitled to take decisions regarding care interventions affecting them.

2. Without prejudice to the provisions contained in Article 11, any intervention in this regard requires prior, voluntary and freely given consent from patients after receiving and assessing the information stipulated in article 6.

3. Consent shall generally be given verbally, and shall in any event be stated on the clinical record, without prejudice to the provisions contained in article 8.2 of Act 41/2002, dated 14th November.

Article 8. Right to refuse an intervention, or to have an intervention withdrawn.

1. All individuals are entitled to refuse an intervention put forward by healthcare professionals following a process of information and decision, even though doing so may endanger their life. Said refusal must be recorded in writing. If the patient is unable to sign, the refusal shall be signed by another person acting as witness at their behest, recording their name and the reason why the person refusing the proposed intervention is prevented from signing. All the foregoing must be recorded in writing in the clinical record.

2. Likewise, patients are entitled to revoke their informed consent granted for a specific intervention. This will unfailingly result in the withdrawal of the said intervention, even though doing so may endanger their life, without prejudice to the provisions of article 6.1.ñ of Act 2/1998, dated 15th June, on Health in Andalusia.

3. Withdrawal of informed consent must be made in writing. If the person is unable to sign, another person acting as witness at their behest will sign in their stead, recording their name

and the reasons preventing the person withdrawing their informed consent from signing. The foregoing must be recorded in writing in the clinical record.

Article 9. Right to draw up an advance healthcare directive.

1. Without prejudice to the provisions contained in article 11.1 of Act 41/2002, dated 14th November, all individuals are entitled to draw up their advance healthcare directive under the conditions established in Act 5/2003, dated 9th October, and other applicable regulations.

2. Once recorded in the Andalusian Advance Healthcare Directives Register, the advance directive or living will shall be entered into the appropriate clinical record under legally stipulated conditions which shall, in all cases, include the procedures for providing access to advance instructions given by patients from other Autonomous Communities and registered in the National Advance Directives Register in accordance with the provisions of Royal Decree 124/2007, dated 2nd February, regulating the National Advance Directives Register and the corresponding computer generated personal data file.

3. Likewise, the advance directive recorded on the Andalusian Advance Healthcare Directive Register shall be entered into the national register of advance instructions under the terms established by Royal Decree 124/2007.

4. When the advance healthcare directive includes the appointment of a representative, this person shall always act in the best interest of the person they represent and shall respect their dignity. They shall, in all events, ensure that the instructions laid down by the person they represent are duly implemented.

5. In order to estimate the person's wishes if they were at that time in a fit state to decide, the representative shall take into consideration the values or opinions declared in the directive when taking decisions for clinical situations not explicitly described therein.

6. The interested party may determine the functions of the person chosen to represent them, and the latter must abide by these at all times.

Article 10. Rights of incapacitated persons with regard to information, decisions and informed consent.

1. When the person receiving care is deemed by their physician to be incapacitated *de facto*, the responsibility of receiving information, giving consent and, where appropriate, choosing a private residence to receive the comprehensive palliative care referred to in article 12.2, shall, in descending order, fall on the person specifically appointed for this purpose in the advance healthcare directive, the person acting as legal representative, the spouse or domestic partner, closest family members, and within this group, the oldest, without prejudice to any ruling by the competent judicial authority pursuant to procedural law.

2. In the case of legally incapacitated patients, the provisions of the incapacitation ruling will apply, provided this includes no express ban or limitation on receiving information and giving informed consent. In this situation, the physician in charge shall assess the real capacity of such patients, under the terms established in article 20.

3. Incapacitation shall not prevent patients from being informed and taking part in the decision making process, to the extent they are able to discern.

4. The rights of incapacitated patients shall always be exercised in their best interests, ensuring respect for their personal dignity. The wishes of patients shall always be interpreted

on the basis of both previously stated wishes, and those they would presumably have expressed had they been able to do so.

Article II. Rights of patients who are minors.

1. All patients who are minors shall be entitled to receive information concerning their illness and proposed healthcare interventions in a manner adapted to their ability to comprehend. They are also entitled to be heard, provided they are at least twelve years of age, pursuant to the provisions of article 9.3.c of Act 41/2002, dated 14th November.

2. When patients who are minors are not able either intellectually or emotionally to understand the extent of the proposed healthcare intervention, the persons acting as their legal representatives shall be empowered to give informed consent, in accordance with the provisions article 9.3.c of Act 41/2002, dated 14th November.

3. Emancipated minors, or those who are sixteen years of age or older, shall provide their own informed consent, although their parents or legal representatives shall be informed and their opinion taken into consideration when the corresponding final decision is taken, pursuant to the provisions of article 9.3.c of Act 41/2002, dated 14th November. Likewise, emancipated minors, or those who are sixteen years of age or older, are entitled to revoke their informed consent and refuse the intervention proposed by healthcare professionals, under the terms of article 8.

4. In any event, care processes for minors shall respect their particular needs and comply with the provisions of prevailing regulations.

Article 12. The right of patients to receive comprehensive palliative care and to choose a private residence where such care shall be delivered.

1. All terminally ill or dying individuals are entitled to top quality, comprehensive palliative care.

2. Terminally ill or dying patients, if they so wish, are entitled to receive the palliative care they require at the private residence of their choice in the Autonomous Community of Andalusia, provided there is no contraindication.

Article 13. The right of patients to pain management.

Patients are entitled to receive the best treatment to prevent and relieve pain, including sedation if pain is refractory to specific treatment.

Article 14. The right of patients to receive palliative sedation:

Terminally ill or dying patients are entitled to receive palliative sedation as and when required.

Article 15. Right to personal and family privacy and confidentiality.

Dying patients are entitled to personal and family privacy and to the protection of all data related to their healthcare.

Article 16. Right to receive support.

Under the terms of article 23, and provided that care is delivered in a hospital setting, dying patients are entitled to:

- a) Family support, if they so wish.
- b) Receive the last rites, in line with their beliefs and convictions, when they so request.

TITLE III

DUTIES OF HEALTHCARE PERSONNEL CARING FOR DYING PATIENTS

Article 17. Duties with respect to clinical information.

1. The attendant physician for each patient must guarantee compliance with the right to information established in article 6.
2. Other healthcare personnel attendant on patients during their care process, or those involved in delivering specific treatment, are also required to provide these patients with clinical information in accordance with their level of responsibility and participation in the care process.
3. The professionals referred to in paragraphs 1 and 2 above shall record on the clinical record that the patient was provided with and understood such information.

Article 18. Duties regarding clinical decisions.

1. Before proposing a healthcare intervention for a dying patient, the attendant physician must ensure that such an intervention is clinically indicated, bringing to bear their clinical judgement based on the latest scientific developments, on the available scientific evidence, on their own professional expertise, on their experience and on the clinical status, severity and prognosis of the person in question. Should they, in their professional judgement, conclude that a healthcare intervention is required, this shall be put to the patient for their free and voluntary consent. The patient may then either accept the proposed intervention, freely choose between the available clinical options, or refuse it, under the terms established in this Act and in Act 41/2002, dated 14th November.
2. All medical professionals involved in the care of patients are required to respect the values, beliefs and preferences of their patients with regard to their clinical decisions, under the terms established in this Act, in Act 41/2002, dated 14th November and in Act 5/2003, dated 9th October, and in their corresponding implementing regulations. Moreover, they must abstain from imposing procedural criteria based on their own beliefs or personal, moral, religious or philosophical convictions.

Article 19. Duties regarding advance healthcare directives.

1. All medical professionals are required on request of the interested party to provide information about the right to draw up an advance healthcare directive.

2. If the patient is incapacitated, professionals should proceed according to the provisions of article 9.2 of Act 5/2003, dated 9th October.

3. Healthcare professionals are required to respect the values and instructions contained in the advance healthcare directive, under the terms of this Act, Act 41/2002, dated 14th November, and Act 5/2003, dated 9th October, and their corresponding implementing regulations.

Article 20. Duties with regard to individuals who may *de facto* be incapacitated.

1. The attendant physician shall assess whether the person under care may be incapacitated thus preventing him/her from taking his/her own decisions. This assessment must be correctly stated on the clinical record. In order to determine incapacity status, the following shall be assessed, amongst other factors considered to be clinically relevant:

a) If the patient has difficulty in comprehending information provided.
b) If the patient cannot retain such information during the decision making process.
c) If the patient does not use the information in a logical way during the decision making process.

d) If the patient fails to appreciate the possible outcome of different alternatives.

e) If the patient is unable to make a final decision, or convey such a decision.

2. Other professionals directly involved in treating the patient can be called in to contribute their opinions during the assessment process. Likewise, physicians may also confer with the family in order to ascertain their opinion.

3. Once the status of incapacity has been established, the attendant physician must record in the clinical record the name of the person appointed to act for the person in the event of incapacity, pursuant to the provisions contained in article 10.1.

Article 21. Duties with regard to the limitation of therapeutic efforts.

1. The doctor in charge of each patient must engage in good clinical practice by limiting their therapeutic efforts when the clinical situation so dictates, avoiding therapeutic obstinacy. Said limitation must be justified in the clinical record.

2. Such limitation shall be exercised after seeking the professional opinion of the nurse in charge of the patient, and must be seconded by at least one other physician involved in the patient's care. The names of these professionals together with their opinions shall be entered into the clinical record.

3. Nonetheless, the attendant physician, together with other healthcare personnel caring for the patient, are required to provide any healthcare interventions needed to guarantee the patient's care and comfort.

TITLE IV

GUARANTEES TO BE PROVIDED BY HEALTHCARE INSTITUTIONS

Article 22. Guarantee the rights of patients.

1. The health administration, together with the institutions listed in article 3, within their respective areas of responsibility, must guarantee the exercise of the rights established in Title II of this Act.

2. Health institutions directly responsible for patient care must implement measures to ensure that the rights of the patient are not undermined under any circumstances, including the refusal or absence of the healthcare professional, or for any other reason.

Article 23. Patient support.

1. Healthcare facilities and institutions shall make it possible for dying citizens to receive the support of their family, reconciling this with the set of healthcare measures needed to provide quality care for the patient.

2. At the request of patients, of their representatives or family members, healthcare facilities and institutions shall provide access to any individual able to provide the last rites in accordance with his/her convictions and beliefs, without this hampering the actions of the healthcare team.

Article 24. Support for family and carers.

1. Healthcare facilities and institutions shall provide the carers and family of dying patients with support and help, both at home and within healthcare facilities.

2. Healthcare facilities and institutions shall provide family members and carers with bereavement counselling, and shall promote measures to help them to accept the death of a loved one and to prevent complications during bereavement.

Article 25. Advice on palliative care.

Dying patients shall be guaranteed information on their health status and the aims of the palliative care they will receive during their final days, in accordance with their needs and preferences.

Article 26. Private rooms for terminal patients.

1. Healthcare facilities and institutions shall guarantee that, during their time in the facility, terminally ill patients who require hospitalisation shall have the use of a single room with the level of comfort and privacy required by their health status.

2. Likewise, these patients may be permanently accompanied by a relative or close friend.

Article 27. Healthcare Ethics Committees.

1. All healthcare facilities or institutions shall either set up, or, where appropriate, shall have access to a Healthcare Ethics Committee, to advise on clinical decisions that raise conflicting ethical issues. These committees must be accredited by the Regional Ministry for Health. The

reports or opinions issued by the Healthcare Ethics Committee shall never override decisions that must be taken by healthcare professionals.

2. If disagreements arise between healthcare professionals and patients or, where applicable, those appointed to exercise their rights, or between such persons and healthcare facilities, the Healthcare Ethics Committee will be consulted on any issues concerning the care provided to dying patients that cannot be resolved amicably by the parties involved, and may propose ethical alternatives or solutions for these contested decisions.

3. The members of the Healthcare Ethics Committee shall be required not to disclose the substance of their discussions and to protect the confidentiality of the personal information on healthcare professionals, patients, family members and close friends revealed to them as Committee members.

4. The composition, operation and accreditation procedures applied to Committees shall be established by law.

TITLE V

INFRINGEMENTS AND PENALTIES

Article 28. General provisions.

1. Without prejudice to the provisions of Act 14/1986, dated 25th April, on General Health, and Act 2/1998, dated 15th June, on Health in Andalusia, the infringements set forth in this Act and in the specifications implementing the said Act in the exercise of regulatory powers shall be punished by an administrative fine, following a thorough investigation, notwithstanding any civil, criminal or other liabilities that may be applicable.

2. Pursuant to the provisions of article 133 of Act 30/1992, of 26 November, on the Legal System applicable to Public Administration and the Common Administrative Procedure, penalties may not be applied to actions that have already been sanctioned criminally or administratively in cases where the party, facts and legal grounds have been duly found.

3. The parties responsible for the infringement, in any matter regulated by this Act, are natural or legal persons who, by act or omission, have been party to the said infringement intentionally, through carelessness or negligence.

Article 29. Minor infringements.

Failure to fulfil obligations or circumvention of any bans set forth in the Act are deemed minor infringements, provided they cannot be classified as serious or very serious infringements.

Article 30. Serious infringements.

1. The following are deemed serious infringements:

a) Failure to comply with the rules regarding entering clinical data.
b) Preventing dying patients from receiving family support, unless justified by clinical circumstances.

2. Minor infringements may become serious when the following conditions are met:

a) *De facto* harm.

- b) Extent of possible benefit achieved.
- c) Severity of the resulting health impairment and social distress.
- d) Degree of intentionality.

Article 31. Very serious infringements.

1. The following are deemed very serious infringements:

a) Hampering or preventing citizens from exercising one or more of the rights set forth in Title II of this Act.

b) Actions that infringe the duties set forth in Title III of this Act.

2. Serious infringements may become very serious when any or all of the conditions set forth in paragraph 2 above are fulfilled, unless such circumstances have been classified as serious infringements.

Article 32. Sanctions.

1. The infringements set forth in this Act shall be subject to the administrative sanctions laid down in article 36 of Act 14/1986, dated 25th April, on General Health.

2. Notwithstanding the provisions of the preceding paragraph, if such infringements are committed by statutory Andalusian Public Health System personnel, they will be penalised in accordance with the provisions contained in Chapter XII of Act 55/2003, dated 16th December, of the Framework Statute for statutory health service personnel, referring to the disciplinary system, pursuant to the power granted under article 72.5 therein.

3. Without prejudice to any applicable economic penalty, in cases involving serious infringement, the Government Council may decide to revoke authorisation granted to operate in healthcare facilities and establishments.

Article 33. Responsibility.

The Regional Ministry with responsibility for health matters is empowered to impose sanctions, under the terms set forth in the regulations, without prejudice to the powers granted the Government Council in paragraph 3 of the preceding article.

Additional provision one. Assessment of the Act.

The Regional Ministry of Health shall, within one year, conduct a survey on how Andalusian citizens die. This survey will be updated periodically in order to facilitate regular assessment of the enforcement and effect of this Act.

Additional provision two. Dissemination of the Act.

The Regional Ministry of Health shall establish the appropriate mechanisms to ensure the broadest possible dissemination of this Act among healthcare professionals and citizens in general.

Additional provision three. Palliative care.

To best serve the aims of this Act in respect of palliative care, the Public Health Administration shall seek to provide specific, high quality training for its professionals in this area, and shall promote the measures needed to endow the Andalusian Public Health System with sufficient, fully equipped palliative care units and support teams.

Single temporary provision. Consulting the Advance Healthcare Directive Register.

Notwithstanding the provisions contained in article 9.2 of Act 5/2003, dated 9th October, until the advance healthcare directive is entered in the clinical record, pursuant to the provisions of article 9.2 of this Act, the dying patient's attendant physician is required to consult the Advance Healthcare Directive Register.

Final provision one. Amendment to Act 2/1998, dated 15th June, on Health in Andalusia.

Letters h and ñ of paragraph 1, article 6 of Act 2/1998, dated 15th June, on Health in Andalusia, are hereby amended as follows:

“h) That [patients] must be provided with adequate and readily understandable information regarding their health status, including diagnosis and prognosis, the risks and benefits of treatment and treatment alternatives.”

“ñ) That [the patient's] free decision on health care to be received must be respected, subject to informed consent, except in the following cases:

1. When public health is at risk due to health causes laid down by Law. In any event, once the appropriate measures have been taken, pursuant to Act 3/1986, dated 14th April, on special public health measures, the judicial authorities shall be notified within 24 hours, provided the said measures require mandatory internment.

2. When there is an immediate, serious risk to the physical or mental integrity of the patient, and it has not been possible to secure their permission, wherever possible, their advance healthcare directive shall be checked for provisions and, in the absence of such a directive, their family members or partner shall be consulted.”

Final provision two. Amendment to Act 5/2003, dated 9th October, on advance healthcare directives.

Act 5/2003, dated 9th October, on advance healthcare directives, is hereby amended as follows:

One: A new paragraph, number 4, is added to article 3, and reads as follows:

“4. The life values on which their decisions and preferences are based.”

Two: article 6 is now worded as follows:

“Article 6. Verification of the capacity and formal requirements of the directive.

Public officials empowered to this effect by the regional ministry responsible for health issues shall confirm the identity and capacity of the signee of the directive, and verify formal requirements that determine the validity of the aforementioned directive set forth in articles 4 and 5 of this Act.”

Three: paragraph 2 of article 9 is hereby amended as follows:

“2. When healthcare is delivered to a person who, as a result of their personal circumstances, is prevented from deciding for themselves under the terms established in this

Act, the healthcare professionals involved in his/her care shall consult the patient's clinical record to ascertain the existence of an advance healthcare directive, and shall act according to the provisions thereof.”

Final provision three. Healthcare Ethics Committee.

The Government Council of the Regional Government of Andalusia shall set forth the rules governing Healthcare Ethics Committees within six months of the entry into force of this Act.

Final provision four. Legislative development.

The legislative development of this Law shall be implemented in accordance with the provisions of articles 112 and 119.3 of the Statute of Autonomy for Andalusia and 44 of Act 6/2006, dated 24th October, on the Regional Government of Andalusia.

Seville, 8th April 2010

JOSÉ ANTONIO GRIÑAN MARTINEZ
President of the Regional Government of Andalusia