Self-Determination, Dignity and End-of-Life Care

Regulating Advance Directives in International and Comparative Perspective

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PART III

THE ONGOING DEBATE ON ADVANCE DIRECTIVES REGULATION IN ITALY

ADVANCE DIRECTIVES IN SPAIN

*José Antonio Seoane**

I. Introduction

The recognition and protection of patient autonomy as a right in Spain began with the Spanish Constitution of 1978 (CE). This has neither a right to autonomy nor a general right of liberty. This does not have a right to informed consent either, but informed consent is an expression of and based on the basic right to physical and moral integrity (article 15 CE). Furthermore, the Spanish Constitution includes a catalogue of fundamental rights and liberties which support and develop patient autonomy: human dignity and free development of personality (article 10.1 CE), the right to life (article 15 CE), the freedom of conscience (ideological and religious freedom) (article 16 CE) and other fundamental rights and liberties, such as the right to health protection (article 43 CE).

Its first significant legislative development was the General Health Act (Act 14/1986, of 25 April: LGS), recognising the patient's right to autonomous decision-making—to be informed and to choose among different treatments—as consent (article 10 LGS), but only for the present, without regulating advance directives.[1]

A second step consolidating and enhancing patient autonomy came from the European Council's Convention on Human Rights and Biomedicine (CHRB),[2] a kind of bioethics Constitution whose most eminent legislative development is Act 41/2002, of 14 November, regulating patient autonomy, and rights and obligations regarding clinical information and documentation (LBAP). For the first time in Spanish Law,

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[1] See Juan María Pemán Gavín, *Asistencia sanitaria y Sistema Nacional de Salud. Estudios jurídicos* (Granada, 2005); José Antonio Seoane, "Las autonomías del paciente", 3 *Dilemata* (2010), pp. 61–75.

[2] Convention of 4th April 1997 (ratified by Document of 23rd July 1999), for the protection of human rights and dignity of the human with regard to the applications of biology and medicine (Convention on human rights and biomedicine).

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the CHRB introduces the institution of advance directives (article 9 CHRB: "previously expressed wishes"). Following the example of the CHRB and some Autonomous Communities' laws which preceded it,[3] the LBAP regulates advance directives (article 11 LBAP) for the entire State.

In a third stage of increasing patient autonomy, the creation and regulation of the national Registry of advance directives[4] and other options of advance care planning[5] deserve a special mention in national area. In Autonomous Communities the legislative development of advance directives ensued, setting out legal concepts and clinical situations in order to specify the scope of patient autonomy and advance directives.

II. Legal Framework

A. *Legislation*

The legislative scene of advance directives in Spanish Law is difficult to summarise. Besides the State regulation, applicable on the entire Spanish territory, all Autonomous Communities possess their own regulation of advance directives,[6] resulting in a huge normative body which contains diverse institutions of advance care planning.[7]

This normative heterogeneity is both quantitative and qualitative. On one hand, neither the State nor the Autonomous Communities have regulated the question with similar extension and detail. On the other hand, the quality is unequal: there are laws that appropriately guide the clinical decision-making, as well as imprecise, confused and also contradictory laws.[8] Moreover, the legal accuracy and the terminology are varied.

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[3] The first was Catalonia: Act 21/2000, 29 December, on information rights concerning health, patient's autonomy and clinical documentation (article 8).

[4] See Royal Decree 124/2007, 2 February, regulating the national Registry of advance directives and the corresponding personal data file.

[5] See *infra* Section X.

[6] The Spanish State is made up of seventeen Autonomous Communities and two Autonomous Cities (articles 137 ff. CE). Each Autonomous Community has authority to legislate in health matters, including advance directives (article 149 CE).

[7] See Appendix. *Legal norms on advance directives in Spain*.

[8] And maybe unconstitutional, because some regional legislation on advance directives deals with Civil Law matters, and not every Autonomous Community has authority to legislate in these matters.

Finally, some contents of a suitable legal development are still pending, because of a defective previous regulation.

1. *State legislation*

Advance directives are a recent legislative phenomenon in Spanish Law. The first legal regulation which was directly applicable was article 9 CHRB, signed 4 April 1997 and in force in Spain since 1 January 2000:

> Article 9. *Previously expressed wishes*
> The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.

The need to establish and clarify this regulation and guarantee the autonomy and rights of the patient, amongst other reasons, led to the enactment of the LBAP, whose article 11 is the basic and common regulation of advance directives for the entire Spanish territory:

> Article 11 LBAP. *Advance directives*
> 1. For the advance directives document, a person who is of age, competent and free states in advance his will regarding healthcare and treatments or, after his death, the destination of his body or his organs, with the aim that his will will be complied when he is no longer competent to express them personally. The person who issues the document can appoint a proxy who, in the event, acts as an interlocutor with the doctor or medical team to ensure that advance directives are complied with.
> 2. Each health service will regulate the correct procedure so that, if the case arises, compliance with everyone's advance directives is guaranteed. Advance directives must always set down in writing.
> 3. Advance directives which are contrary to the norms of the legal order or to the *lex artis* shall not be applied, nor those which do not correspond with the previous statement of the interested party at the time of issuing them. The patient's clinical history shall include a reasoned record of the notes related to these considerations.
> 4. Advance directives can be freely revoked at any time recording it with a written statement.
> 5. In order to ensure in the entire national territory the efficacy of advance directives expressed by patients and formalised in accordance with the legislation of the respective Autonomous Communities, the national Registry of advance directives will be created within the Ministry of Health and Consumer Affairs, which will be governed by the norms determined by regulation, with prior agreement of the Inter-territorial Council of National Health System.

Later, according to article 11.5 LBAP, and again after Autonomous Communities' legal norms, the national Registry of advance directives was created.[9]

Finally, two special laws have regulated the use of advance directives in their respective areas, widening its content and allowing the patient to decide on the use of his reproductive material[10] and on obtaining or analysing his biological samples after he has died.[11]

2. *Autonomous Communities' Legislation*

Regional legislation on advance directives preceded national legislation (LBAP). From the end of the year 2000 many legal norms have been enacted, leading to the current complicated and huge normative body. Such variety complicates the knowledge of legal regulation even though at the time it contributes to complete the national legislation and define the characteristics of advance directives.

B. *Case Law*

There are just five rulings on advance directives. Three of them referring to Jehovah's witnesses. An early ruling (*Auto*) of Ciudad Real Provincial Court of 31 December 2001[12] examines article 9 CHRB, and concludes that its invocation would require legislative development (at that time, there was no LBAP nor Autonomous Community legal norm applicable to the case), and that art. 9 CHRB does not establish a link with the previously expressed wishes but simply requires "taking into account". Therefore, the Court rejects the appeal to the previous judicial decision authorising blood transfusion to the patient. The two remaining cases, the rulings (*Autos*) of Guipúzcoa Provincial Court (section 2) of 22 September 2004[13] and of 18 March 2005,[14] adopt a different way of reasoning. They recognise the validity and priority of a Jehovah's witness' opposition to a blood transfusion included in his advance directives document, in the first case in opposition to the medical doctors request of judicial authorisation to

[9] See Royal Decree 124/2007, 2 February. Also see Order SCO/2823/2007, 14 September.
[10] Act 14/2006, 26 May, on techniques of assisted human reproduction (Article 9.2 LTRHA).
[11] Act 14/2007, 3 July, on biomedical research (Article 48.2 LIB).
[12] [Tirant TOL 142.031].
[13] Appeal N. 2086/2004 [JUR 2004308812].
[14] Appeal N. 2006/2005 [JUR 2005196739].

carry out a blood transfusion, and in the second case after the judge *a quo's* decision authorising the blood transfusion.

The fourth case, the ruling (*Auto*) 160/2010 of 2 June 2010 of Tenerife Provincial Court (section 3), regarding the use of reproductive material of a deceased husband to inseminate his wife, correctly states that a typed letter signed by the deceased husband can not be deemed an advance directive.[15]

Finally, the judgement (*Sentencia*) 353/2010 of 8 October of A Coruña Provincial Court (Section 5) deals with the designated proxy in an advance directive, and concludes that this designation provides a strong argument for choosing him/her for the guardianship.[16]

III. Concept

Advance directives are the most important legal instrument of *advance care planning*, but only a part of it.[17] Advance care planning is a wider and overall continuous process which includes a host of dimensions (clinical, cultural, familiar, social, psychological, emotional) to improve the quality of care and decisions at the end of life, enhancing communication among the patient, the healthcare professionals (doctors, nursing, psychologists, …), relatives and other close people, and guaranteeing the respect of patient's autonomy, values and rights.

Advance directives develop the general theory of informed consent and enhance autonomy. They are a singular specification because consent and the faculty of autonomous decision-making are protected like prospective or *ad futurum* autonomy. Unlike current informed consent, which is granted for an immediate or almost immediate action or intervention, advance directives consist of two moments: the moment of issue, which coincides with the patient's competence to take autonomous decisions, and the moment of application, which occurs later when the patient lacks the competence to decide autonomously.

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[15] Appeal N. 296/2010 [AC20101755].

[16] Appeal N. 139/2010 [JUR2010411796].

[17] See Inés M. Barrio, Pablo Simón, Javier Júdez, "De las voluntades anticipadas o instrucciones previas a la planificación anticipada de la atención", 5 *Nure Investigación* (2004), pp. 1–9; Pablo Simón, Inés M. Barrio, *Quién decidirá por mí? Ética de las decisiones clínicas en pacientes incapaces* (Madrid, 2004); Diego Gracia, Juan José Rodríguez Sendín (dir.) et al., *Guía de ética de la planificación anticipada de la asistencia médica: historia de valores, instrucciones previas, decisiones de representación* (Madrid, 2011).

Article 11.1 LBAP states a legal definition, also referring to its content:

> For the advance directives document, a person who is of age, competent and free states in advance his will regarding healthcare and treatments or, after his death, the destination of his body or his organs, with the aim that his will will be complied when he is no longer competent to express them personally. The person who issues the document can appoint a proxy who, in the event, acts as an interlocutor with the doctor or medical team to ensure that advance directives are complied with.

Taking into account the national and regional legal norms, a more precise and comprehensive legal concept of advance directives can be proposed:

> Advance directives are the free, voluntary and informed expression of a competent person (who is of age) on his preferences of healthcare and treatments; and/or the designation of a proxy who acts as an interlocutor with the healthcare professionals and contributes to the interpretation, respect and compliance of his instructions and wishes; and/or the expression of his personal values, preferences and objectives; and/or, after death, the destiny of his body and/or organs and/or tissues, and/or the use of his reproductive material, and/or the prohibition to obtain and analyse his biological samples. The advance directives are issued with the aim of being respected and complied in the event that the patient cannot not longer express his will autonomously, and must be set down in writing and issued in compliance with the legal procedure.

Two issues need a further commentary. Firstly, the host of legal denominations of advance directives, especially in Autonomous Communities' legislation, generates legal uncertainty and insecurity. Is this a simple variety of terminology or, on the contrary, is it a semantic or conceptual variety? For the variety of terminology does not imply conceptual or semantic variety, the different denominations must be understood as different ways to formulate the same reality or concept. Therefore, the national and regional norms must be interpreted in the same way and referred to a single institution.[18]

[18] Spanish legal norms on advance directives comprehend the following denominations: deseos expresados anteriormente (CDHB); instrucciones previas (LBAP, Asturias, Canaries, Castile and Leon, Galicia, La Rioja, Madrid, Murcia); voluntades anticipadas (Aragon, Balearics, Cantabria, Castile-La Mancha, Cataluña, Navarre, Basque Country, Valencia); expresión anticipada de voluntades (Extremadura); manifestación anticipada de voluntad (Canaries); voluntad expresada con carácter previo (Cantabria); voluntades previas (Cantabria); voluntad vital anticipada (Andalusia, Balearics); testamento vital (Andalusia, Valencia).

Secondly, a more relevant matter comes from conceptual imprecision: the confusion between advance directives and the advance directives document, which can potentially lead to a misinterpretation and to an unsuitable application, with harm to patient's rights and autonomy and lack of protection to healthcare professionals. Even when it is necessary a formal and documentary expression of advance directives, which actually matters is not the document but the decisions expressed within it. The advance directives document supports and expresses patient's will, resulting from a process of reflection and dialogue with healthcare professionals on how the patient wants to be treated when he can no longer make autonomous decisions. And furthermore, advance directives must be understood as a part of the broader advance care planning process.

IV. Justification and Purpose

From an ethical point of view, the justification of advance directives is the principle of respect for autonomy, which has led to a new model of doctor-patient relationship, decision-making and definition of health[19]. In Spain, a patient's right to take autonomous decisions on his own life and health and on the treatments he wishes to receive belongs to the basic right to physical and moral integrity (article 15 CE)[20] and is legally recognised.[21] This patient's right co-exists with a duty of healthcare professionals to know, respect and apply advance directives (articles 2.6 and 11 LBAP).[22]

As an instrument of advance care planning, advance directives have different aims and purposes. An immediate purpose is to strengthen the patient's right to express his will in advance, widening the scope of informed consent. Moreover, they are a relevant assistance in interpreting the patient's directives and guiding clinical decision-making when the patient can no longer express his will in an autonomous way. They allow forecasting future situations and planning healthcare in an integral

[19] See Diego Gracia, *Como arqueros al blanco. Estudios de bioética* (Madrid, 2004), p. 84.

[20] See Judgement (*Sentencia*) of Spanish Constitutional Court 37/2011, of 28 March.

[21] See Mónica Navarro-Michel, "Advance directives: the Spanish perspective", 13 *Medical Law Review* (2005), pp. 137–169, at 140–146; Federico de Montalvo Jääskeläinen, *Muerte digna y Constitución. Los límites del testamento vital* (Madrid, 2009).

[22] Art. 2.6 LBAP: "Every professional involved in the healthcare activity is required to perform not only the correct techniques, but to comply with the duties of clinical information and documentation and to respect the decisions freely and voluntarily adopted by the patient".

and continuous way. Finally, advance directives contribute to improve patient's well-being and also that of the professionals and relatives involved in healthcare.

V. Who Can Issue the Document?

"A person who is of age, competent and free…" is the answer of article 11.1 LBAP to the question on who can issue a document of advance directives. Here, there are two elements of the theory of informed consent and also of advance directives: competence and voluntariness. To these a third basic element must be added: information.

Article 11.1 LBAP requires that the person who issues the advance directives is competent and legally of age. He must be at least 18 (article 12 CE), the age from when he is considered (*iuris tantum* presumption) competent (articles 315 and 322 Civil Code: CC). Some regional legal norms set exceptions to being of age and allow certain minors to issue advance directive documents: a mature minor, an aged 16 and above individual who has intellectual and emotional competence to understand the purpose and consequences of the intervention (article 9.3.c) LBAP), and the under 16 year old minor who is emancipated by his legal parents or a judicial decision (articles 314–321 ff. CC) or the minor from the age of 14 when emancipated through marriage (articles 46 and 48 CC).[23]

The reference to the patient's liberty or free character (article 11.1 LBAP) means voluntariness and refers to guaranteeing that the decision-making process takes place without coercion, intimidation or any other unlawful influence.

Thirdly, and even when it is not included as a legal requirement in article 11.1 LBAP, information must be considered a further requirement for the valid issue of advance directives, in order to avoid other defect of consent: error about the object (articles 1265 and 1266 CC), and to control own decisions. Despite this, the patient has the right that his wish not to be informed will be respected (articles 4.1 and 9.1 LBAP). Information must be truthful and be communicated to the patient in a comprehensible way and suited to his needs, and it shall help him to express in advance his wishes regarding his care (article 5 CHRB; articles 2.3, 4.2 LBAP).

[23] See Andalusia, Aragon, Navarre, Valencia.

Issuing an advance directive is so personal that can only be exercised by the right-holder, i.e. the patient. This is not a right which can be exercised by a proxy or third party. When a patient is incompetent to make his own decisions it cannot be used an advance directive (whereby a competent patient takes an autonomous decision which will be applied when he is no longer able to do so: article 11 LBAP) but rather a substitute or surrogate decision-making (whereby a surrogate takes a decision on behalf and for the benefit of the incompetent patient: article 9 LBAP).

VI. Content

What can the patient decide in his advance directives? Article 11.1 LBAP highlights three distinct statements, which must be completed with the regional and health legislation to arrive at the six statements which constitute the current legal contents of advance directives. In any case, those legal references to the content of advance directives might not be understood as a *numerus clausus* but as an open set, in accordance with the broad scope of autonomy.

1. *Medical interventions, care and health treatments*

Due to the increasing chances of extending life, advance directives (living will) were originally issued to limit healthcare professionals' interventions. Nevertheless, the patient can decide both on the interventions he does not wish to receive and on the interventions and care which he wishes to receive in concrete clinical situations, including the withholding and the withdrawal of life-sustaining treatments as well as decisions on palliative treatment, sedation, comfort and other measures.

2. *Designation of a proxy*

Advance directives can include the designation of a proxy. He plays an important role in the advance care planning process, and should be a trustworthy person, aware of patient's wishes and values. The proxy cannot take decisions on behalf of the patient on situations previously issued in the advance directives document. Otherwise it would imply misunderstanding advance directives and confusing them with surrogate decisions. The function of the appointed proxy is to act as an interlocutor with healthcare professionals helping them to interpret patient's wishes and

guaranteeing the respect of values and the compliance of instructions included in the advance directives document.[24]

3. *Personal values, preferences and objectives*

Another important support for interpreting advance directives is the patient's expression of his values, preferences, objectives and life prospects.[25] The so-called *values history* provides information on the patient's general stance to life and health, illness, pain and death; his family relationships; his relationships with healthcare professionals; his thoughts on autonomy, independence and self control; his religious beliefs or personal values; or his preferences on healthcare. Despite the incompetence of the patient at the moment of clinical assistance, his values history can guide decision-making process, eliminate conflicts and reduce the uncertainty and anxiety of those who undertake this task.

It is recommended to communicate the values history to the doctors, to the appointed proxy and to relatives or close friends who will probably accompany the patient during the healthcare process. It should be updated in cases of relevant changes (e.g. death of a close friend or relative, previous experiences of illness, etc.) so that it contains the patient's real and current values. Likewise, in order to being known, implemented and documented, the values history must be included in the clinical history as a part of the advance care planning process.

4. *Destiny of the body, organs or tissue*

The patient can donate his body for research or for training future healthcare professionals, or simply indicates what he desires for his body after death. Likewise, when death has been confirmed, the patient can donate all or some of his organs and tissues. Despite the fact that Spanish legislation adopts the model of presumed consent in the case of a deceased donor (we are all potential organ donors unless we have an expressed

[24] Some Autonomous Communities norms admit the appointment of a proxy as a substitute or surrogate in decision-making. Most of them (e.g. Andalusia, Basque Country, Cantabria, La Rioja) require the acceptance of the appointment, and some also regulate the designation procedure and establish incompatibility criteria for the appointment (e.g. Castile-La Mancha).

[25] This content is not included in LBAP, but it is included in some Autonomous Communities' norms (e.g. Andalusia, Aragon, Balearics, Basque Country, Canaries, Extremadura, La Rioja, Navarre).

opposition),[26] in practice the family of the deceased are asked for authorisation and their opposition to donation would prevail. Therefore every decision on donation (acceptance or refusal, total or partial) included in the advance directives document states doubtlessly patient's will about it and promotes the respect of his autonomy.

5. *Use of reproductive material*

Health legislation offers a new content to be included in an advance directives document. Concerning the assisted human reproduction, the husband of a woman receiving fertility treatment can decide about the use of his reproductive material within the year following his death.[27]

6. *Obtaining and analysing biological samples*

Health legislation provides a sixth content, that refers to the possibility of using the advance directives document to prevent the deceased patient's biological samples from being obtained and analysed after his death.[28]

VII. Limits

Article 11.3 LBAP expressly establishes three limits for applying advance directives, enforcing the healthcare professional to include a reasoned record of the notes relating to it in the patient's clinical history.

[26] Act 30/1979, 27 October, on organ extraction and transplantation (article 5); Royal Decree 2070/1999, 30 December, regulating the activity of clinical obtaining and use of human organs and the territorial co-ordination of organs and tissues donation and transplantation (article 10); Royal Decree 1301/2006, 10 November, establishing the quality and safety norms for donation, obtaining, evaluation, process, preservation, storage and distribution of human cells and tissues and the co-ordination norms and functioning for their use in humans (article 8).

[27] Article 9.2 LTRHA: "Despite what is stated in the previous section, the husband can give his consent for his reproductive material being used to inseminate his wife in the 12 months following his death, in the document which is referred to in article 6.3, in a public document, in a testament or in an advance directives document. […]".

[28] Article 48.2, first paragraph LIB: "Samples of deceased people can be obtained and analysed in health area, providing it is always for health protection, unless the deceased has expressly forbidden this when alive and thus this is proved. With this aim the advance directives documents and, when not available, the opinions of the closest relatives to the deceased will be consulted".

Moreover, the Autonomous Communities' norms qualify the second of these limits and add, in a questionable manner, another two.[29]

1. *The legal order*

This limit aims to reaffirm not taking into account any request for assisted suicide or euthanasia included in a document of advance directives. Both behaviours are criminal offences in Spanish Criminal Code (article 143 CP).[30] On the other hand, a request to refuse treatment, both withdrawing or withholding life-supporting treatment (incorrectly labelled "passive euthanasia"), is lawful and protected by Spanish legislation (articles 2.4 and 8.5 LBAP).

2. *The* lex artis

The legal criteria to determine the correction and diligence of medical practice is *lex artis*. It is an undetermined and imprecise limit whose meaning changes over time and from one action to another. Moreover, it is difficult to set as it demands positive determination by law. Interpreting *lex artis* solely from medical or technical criteria, without taking into account patient's wishes and values stated in advance directives, could lead to paternalism and unjustified restrictions of patient's rights.[31] Because of this, instead of *lex artis* or, similarly, good or sound medical practice,[32] it has been suggested a new limit instead: contra-indication, i.e. an intervention that the healthcare professional must neither indicate nor carry out even under patient request.[33]

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[29] See Azucena Couceiro Vidal, "Las directivas anticipadas en España: contenido, límites y aplicaciones clínicas", 22/4 *Revista de Calidad Asistencial* (2007), pp. 213–222, at 217–221.

[30] Article 143 CP. 1. Anyone who induces another to commit suicide shall be punished by imprisonment from four to eight years. 2. The punishment of imprisonment from two to five years shall be imposed for cooperating with necessary acts to the suicide of a person. 3. When cooperation amounts to implementing the person's death shall be punished by imprisonment from six to ten years. 4. Anyone who causes or actively cooperates through necessary and direct acts to the death of another, when there is an express, serious and unequivocal request, in the case where the victim suffers a serious illness which will necessarily lead to his death or which causes serious and permanent suffering which is difficult to withstand, shall be punished to imprisonment in one or two degrees lower than those mentioned in numbers 2 and 3 of this article.

[31] See Judgements (*Sentencias*) of Supreme Court (Civil Section) 830/1997, of 2 October; 1132/2006, of 15 November; 1267/2006, of 5 December. See also Judgement (*Sentencia*) of Constitutional Court 37/2011, of 28 March.

[32] See e.g. Aragon, Cantabria, Catalonia, La Rioja, Valencia.

[33] See Basque Country, La Rioja.

3. *The lack of correspondence with advance directives statement*

Advance directives can be drawn up in a generic way or in a more specific one. The professional must establish the correspondence between the statements of the advance directives document and the actual situation in which it has to be implemented. This limit to implementing advance directives is at stake when the statement of the document does not match the current situation. Correspondence between previous and current situation must not be understood as an exact match or identity but rather as an analogy, established by the healthcare professional after interpreting patient's will. For this, two contents of advance directives have special significance: the designation of a proxy and the expression of patient's values and objectives.

4. *Professional ethics or medical ethics*

Some Autonomous Communities have unfortunately and unjustifiably introduced two additional limits to the application of advance directives. Firstly, *professional ethics* or *medical ethics*,[34] a confusing limit which wrongly assumes that ethical criteria of healthcare activity are fixed unilaterally by medical profession and neglects the norms and criteria shared by all, especially those included in the legal regulation on advance directives and patients' rights.

5. *Conscientious Objection*

Even more objectable, secondly, is the consideration of the *conscientious objection* as a generic limit to applying advance directives, as it introduces more confusion amongst professionals on the meaning of advance directives and the conscientious objection.[35] On one hand, because the recognition of the conscientious objection does not vary because of the form or time of the patient's expression of his wishes (informed consent or advance directive), but depends on the activity to which the professional claims to object. On the other hand, one cannot recognise the conscientious objection in a generic form but one must specify to what concrete activity one wants to oppose such an objection.[36]

[34] Aragon (medical ethics), Madrid (professional ethics).

[35] See Balearics, Cantabria, Extremadura, La Rioja, Madrid, Murcia, Valencia.

[36] See Azucena Couceiro, José Antonio Seoane, Pablo Hernando, "La objeción de conciencia en el ámbito clínico. Propuesta para un uso apropiado (I)", 26/3 *Revista de Calidad Asistencial* (2011), pp. 188–193.

VIII. Formal and Procedural Requirements

Advance directives must be set down in a written form (articles 11.1 and 11.2 LBAP).[37] The Autonomous Communities' norms have regulated in great detail the formal and procedural requirements, establishing two general procedures to issue advance directives (before a notary and before three witnesses) and, in the case of some Autonomous Communities, adding a third procedure (before the person in charge of the Registry of advance directives or corresponding public Administration).[38]

Compliance with formal requirements is a condition of validity and efficacy in advance directives. This *ad solemnitatem* requirement is sound, in order to protect patient's autonomy and rights in such a delicate and relevant matter. Consequently, oral or unsuitably documented expressions are not advance directives but, at the most, relevant indications in surrogate or substituted decision-making.

A. *Issuing Procedures*

1. *Before a notary*

The first way to issue an advance directives document is before a notary, a legal practitioner who confers authenticity, veracity and legal force to the acts and declarations made before him. The notary states the authenticity of the advance directives document and the patient's true identity, competence and will as well as the correspondence of the document's content with the patient's wishes. In this case, witnesses are not needed.

2. *Before three witnesses*

Secondly, the document of advance directives can be issued before three witnesses. Legislation establishes the requirements and causes of incompatibility of witnesses. They must be over 18 and full competent; and at least two of them cannot be in the second level of lineal consanguinity or affinity nor be linked by patrimonial relations.[39] Like the notary, the witnesses' function is to guarantee compliance of the validity of authorisation, that the patient is competent, acts freely without being subject to

[37] The patient can draw up and document his advance directives in the way that he wants. He can follow one of the existing guideline models or forms. Some Autonomous Communities (e.g. Andalusia) requires that an official form or model is completed.

[38] See Andalusia, Basque Country, Castile and Leon, La Rioja.

[39] In some cases (e.g. Cantabria, La Rioja) the incompatibility is stricter.

unlawful influence and that the expression contained in the document corresponds to his wishes with no errors in the declaration.

3. *Before the person in charge of the Registry of advance directives or the corresponding Administration*

Finally, some Autonomous Communities establish a third procedure before the civil servant or member of the Registry of advance directives or the corresponding Administration, and the latter will check compliance with the minimum legal requirements and contents of the advance directives document presented.

B. *The Registry of Advance Directives*

The National Registry and Autonomous Communities' Registries of advance directives were created to ensure the efficacy of advance directives.[40] Their main objectives are to collect information of advance directives (the existence of the document, the place and date of inscription, the contents) and facilitate healthcare professionals in knowing about the advance directives document and its consultation in the event that it must be applied. In order to guarantee the efficient compliance of its purposes, the Registry acts in accordance with certain basic functioning principles: coordination, interconnection, security and confidentiality.

Registration of advance directives documents must be voluntary and with a merely declarative effect of the document's existence and content, rejecting thus its mandatory and constitutive nature, according to which advance directives would only achieve validity after registration.[41] Registration is not a requirement of validity although it influences the efficacy of advance directives. In this sense, it is highly advisable to register advance directives documents to ensure and to permit the access, knowledge and application of its updated version on the entire national territory.

IX. Validity and Efficacy

Once the advance directives have been issued in the aforementioned manner, and having met the remaining requirements, they are valid with

[40] Art. 11.5 LBAP and Royal Decree 124/2007, 2 February. See Appendix.

[41] In some Autonomous Communities (e.g. Andalusia, Cantabria) the registration of advance directives is constitutive and mandatory.

no further requests. For their validity and efficacy Spanish legislation does not demand renewal or ratification. Providing there is no evidence or proof of the contrary, the instructions and wishes included in the advance directives document remain. Nevertheless, a lack of ratification could impact the efficacy of advance directives in some cases (e.g. a considerable length of time has passed and a notable change in conditions or values stated in the advance directives document, contravening the patient's initial purpose). To guarantee its applicability and efficacy, temporal ratification is advised. This will facilitate the interpretation and application of advance directives; it will avoid legal uncertainty to professionals and will strengthen the protection of patient's autonomy and rights. In short, ratification or renewal of advance directives is not nor should be a requirement for its validity. Although this could impact its efficacy, the lack of ratification or renewal must not cause the invalidity or inapplicability of advance directives, for the continuance and respect of the patient's autonomy and will.[42]

What is relevant is revocation, which can be exercise freely and at any time by the patient, just doing so in writing (article 11.4 LBAP). Revocation *stricto sensu* means the cancellation of the previously issued document and the inexistence of a new one. The faculty of revocation also encompasses the modification, or partial alteration of the document maintaining its validity and effects, and the substitution, or total revocation followed by a new issue of advance directives.[43]

With regards to its nature, advance directives become effective and applicable once the patient becomes incompetent to express autonomously his own wishes. Until then, the patient's current will and decision prevail over the wishes and decisions stated in the advance directives document.

Healthcare professionals must respect and take into account advance directives because of their ethical and professional obligation to respect patient's autonomy and rights. They have a categorical duty to know the existence and the content of the advance directives and also the duty to comply with the content, even though this is a *prima facie* duty and not an automatic or *all things considered* duty of application.

[42] There is a legal solution in cases of uncertainty: the limit of application due to the mismatch of the current clinical situation and the circumstance expressed in the document (art. 11.3 LBAP).

[43] See Appendix of Royal Decree 124/2007, 2 February.

Like legal field, medical field requires prudential reasoning which leads to the respect of the patient's autonomy but not to blind or unconditional obedience of every autonomous decision. The patient's advance directives are not an exclusionary reason for the healthcare professional which obliges him to comply with them without balancing and harmonizing the principles, values, duties and rights at stake.[44] Advance directives, often imprecise as it is humanly impossible to accurately and completely forecast future situations, need to be interpreted and contextualised by the healthcare professionals, using the values history and the appointed proxy as support. This interpretative task must go beyond literal and subjective criteria in favour of a teleological interpretation. Only in this way the patient's real will and wishes can be understood and respected, determining their meaning in each concrete case and complying with them or, if necessary, not applying them, where the healthcare professional must record the reasons of non application of advance directives in clinical history (article 11.3 LBAP).

In this sense, it is important to distinguish two types of normative content in advance directives, with a different form of fulfilment and application. The first one adopts the form of rules, i.e. dilemmatic or all-or-nothing norms (they are either fulfilled or not) which indicate in a direct and definitive manner what one "ought to do": e.g. the decision on organ or tissue donation, or the designation of a certain person as a proxy. In these cases, one must comply with the clearly expressed instruction as it cannot be questioned. Conversely, the second type adopts the form of principles, i.e. norms which aim to obtain or realise in the greatest possible degree a state of affairs, how they "ought to be": e.g. instructions on healthcare and treatments ("not to withhold or withdraw any life-sustaining measures to prolong my life"; "no extraordinary measures to be adopted"). The lack of precision of these decisions does not eliminate their normativity nor the obligation of the healthcare professionals to respect them, but it demands that the situation and wishes stated by the patient are defined and match real conditions in context and in the moment in which they are to be implemented, which excludes their automatic application and demands interpretation and deliberation for compliance.[45]

[44] See José Antonio Seoane, "El significado de la Ley básica de autonomía del paciente (Act 41/2002, 14 November) en el sistema jurídico-sanitario español. Una propuesta de interpretación", 12 *Derecho y Salud* (2004), pp. 41–60.

[45] See Recommendation CM/Rec(2009)11 of the Committee of Ministers to member states on principles concerning continuing powers of attorney and advance directives for incapacity (adopted by the Committee of Ministers on 9 December 2009).

X. Other Legal Answers on Advance Care Planning

Advance directives are not the only legal institution for advance care planning in Spanish Law. Almost simultaneously, self-guardianship (*auto-tutela*) was introduced into the state legal system.[46] Both institutions share the same purpose: to respect the individual's autonomy to manage his life and health and participate in advance care planning; to widen the scope of autonomous decisions forecasting future incompetence; to improve the decision-making process in the case of incompetent patients, helping them to interpret and apply their instructions and wishes. However, its significance and scope are not identical. Self-guardianship acts on a wider personal area, not limited to health matters, and also on the patrimonial area, banned from advance directives. It allows some decisions of the competent person to forecast future incapacitation and not mere incompetence, which is the case of advance directives. Amongst such decisions is the designation of a guardian, whilst advance directives refer to the possible designation of a proxy. Moreover, the only valid procedure for issuing self-guardianship is a notarial public document unlike the three procedures in advance directives.[47]

Another option of advance care planning is preventive powers of attorney, whose aim is the appointment of someone who voluntarily acts when a person's incompetence occurs or worsens. Two types of powers must be highlighted: the *ad cautelam* power of attorney, in the event of future incompetence, which takes effect when this occurs (both incompetence and incapacitation, depending on what has been established), and the power of attorney granted for immediate effect, even in a situation of competence, with continuity and subsistence of effects once incompetence occurs.[48] The granter of power must be in full competence. The proxy can be any individual or legal person and can be designed as guardian or not (separate protection of personal and patrimonial matters: art. 236 CC). Its content can be very varied: patrimonial matters (e.g. management and disposal of assets) and some personal matters, amongst which decisions on care and medical treatments or the designation of a proxy, are common. This power does not require a special form but, for the sake

[46] See article 223 CC, reformed by Act 41/2003, 18 November.

[47] With a similar purpose but less detail, article 4.2.f) Act 39/2006, 14 December, to promote personal autonomy and care of people in situation of dependence, recognises the right to decide, when he is competent, on the protection of his person and property for the case of becoming incompetent.

[48] See article 1732 CC, reformed by the aforementioned Act 41/2003, 18 November.

of its efficacy, knowledge and publicity, it is recommended being granted in public document, as the registral publicity of these appointments is limited.

XI. Conclusions

Spanish legislation on advance directives represents a step forward in the consolidation of autonomy as a core of doctor-patient relationship and in the guarantee of patients, healthcare professionals and health institutions' rights and duties. Moreover, it guides professionals and eases decision-making process in healthcare. Finally, it improves the quality, humanisation and justice of our health system.

Nevertheless, despite the comprehensive legal regulation of advance directives in Spain, there are unresolved challenges for advance care planning. Some challenges, linked to the legal system, must be resolved by jurists, in particular by the legislator, completing the normative development. Apart from the necessary homogenisation of national and regional legal norms, normative errors need to be corrected, ambiguities in terminology need to be clarified and the vagueness of some concepts needs to be dealt with.[49] Other challenges, linked to healthcare, must be dealt by healthcare professionals and institutions, trusting in Law as an instrument which improves healthcare relationships and favour its reception and suitable use by means of appropriate knowledge, respect and application,[50] moving beyond advance directives and promoting the more comprehensive advance care planning.

[49] Some *lege ferenda* proposals in José Antonio Seoane, "Derecho y planificación anticipada de la atención. Panorama jurídico en España", 14 *Derecho y Salud* (2006), pp. 285–295.

[50] See Pablo Simón-Lorda, María-Isabel Tamayo-Velázquez, Inés-María Barrio-Cantalejo, "Advance Directives in Spain. Perspectives from a Medical Bioethicist Approach", 22/6 *Bioethics* (2008), pp. 346–354; Cristina Nebot, Blas Ortega, José Loaquín Mira, Lydia Ortiz, "Morir con dignidad. Estudio sobre voluntades anticipadas", 24/6 *Gaceta Sanitaria* (2010), pp. 437–445. Also see http://www.voluntadesanticipadas.com.

Appendix: Legal Norms on Advance Directives in Spain

Legal norm	Advance directives	Registry of advance directives
SPAIN		
Convenio de 4 de abril de 1997 (ratificado por Instrumento de 23 de julio de 1999), para la protección de los derechos humanos y la dignidad del ser humano con respecto a las aplicaciones de la biología y la Medicina (Convenio relativo a los derechos humanos y la biomedicina)	9	
Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica	11	11.5
Ley 14/2006, de 26 de mayo, sobre técnicas de reproducción humana asistida	9.2	
Real Decreto 124/2007, de 2 de febrero, por el que se regula el Registro nacional de instrucciones previas y el correspondiente fichero automatizado de datos de carácter personal	All	All
Ley 14/2007, de 3 de julio, de investigación biomédica	48.2	
Orden SCO/2823/2007, de 14 de septiembre, por la que se amplía la Orden de 21 de julio de 1994, por la que se regulan los ficheros con datos de carácter personal gestionados	All	All

Legal norm	Advance directives	Registry of advance directives
por el Ministerio de Sanidad y Consumo y se crea el fichero automatizado de datos de carácter personal denominado Registro nacional de instrucciones previas		
ANDALUSIA		
Ley 2/1998, de salud (modificado por DA única de la Ley 5/2003, de 9 de octubre)	6.1.ñ)	
Ley 5/2003, de 9 de octubre, de declaración de voluntad vital anticipada (*ex* DF segunda de la Ley 2/2010, de 8 de abril, de derechos y garantías de la dignidad de la persona en el proceso de la muerte)	All	9; 2, 5, 6, 7, 8
Decreto 238/2004, de 18 de mayo, regulador del Registro de voluntades vitales anticipadas de Andalucía	All	All
Orden 17 de enero de 2005, que regula y suprime los ficheros automatizados que contienen datos de carácter personal gestionados por la Consejería de Salud		All; Appendix I, 11
Ley Orgánica 2/2007, de 19 de marzo, de reforma del Estatuto de Autonomía para Andalucía	20.1	
Ley 2/2010, de 8 de abril, de derechos y garantías de la dignidad de la persona en el proceso de la muerte	5.d), k), p) y q); 9; 10.1 y 4; 19; sole transitory provision; final provision two	9.2 y 3; sole transitory provision; final provision two

(*Continued*)

Legal norm	Advance directives	Registry of advance directives
ARAGON		
Ley 6/2002, de 15 de abril, de salud (*ex* Ley 8/2009, de 22 de diciembre, por la que se modifica la Ley 6/2002, de 15 de abril, de salud de Aragón, en lo relativo a voluntades anticipadas)	15	15.5
Decreto 100/2003, de 6 de mayo, que aprueba el Reglamento de organización y funcionamiento del Registro de voluntades anticipadas	All	All
Ley Orgánica 5/2007, de 20 de abril, de reforma del Estatuto de Autonomía de Aragón	14.4	
Ley 10/2011, de 24 de marzo, de derechos y garantías de la dignidad de la persona en el proceso de morir y de la muerte	2.), 5.e), f), l), m), 9, 11.3, 14, 19, final provision one	5.e), 9.2, 19.2, final provision one
ASTURIAS		
Decreto 4/2008, de 23 de enero, de organización y funcionamiento del Registro del Principado de Asturias de instrucciones previas en el ámbito sanitario	All	All
Resolución de 29 de abril de 2008, de la Consejería de salud y servicios sanitarios, sobre desarrollo y ejecución del Decreto 4/2008, de 23 de enero de 2008, de organización y funcionamiento del Registro del Principado de Asturias de instrucciones previas en el ámbito sanitario	All	All
BALEARICS		
Ley 1/2006, de 3 de marzo, de voluntades anticipadas	All	8; 3.2.b), 3.4

Legal norm	Advance directives	Registry of advance directives
Ley Orgánica 1/2007, de 28 de febrero, de reforma del Estatuto de Autonomía de las Illes Balears	25.4	
Decreto 58/2007, de 27 de abril, por el que se desarrolla la Ley de voluntades anticipadas y del registro de voluntades anticipadas de las Illes Baleares	All	1, 2, 5–11; additional provisions one and two
CANARIES		
Orden de 28 de febrero de 2005, por la que se aprueba la Carta de los derechos y de los deberes de los pacientes y usuarios sanitarios y se regula su difusión	Appendix. Rights. 25	
Decreto 13/2006, de 8 de febrero, por el que se regulan las manifestaciones anticipadas de voluntad en el ámbito sanitario y la creación de su correspondiente Registro	All	9–24; 1, 6.b), additional provision, transitory provision
Orden de 30 de marzo de 2009, por la que se aprueba la creación del fichero de datos de carácter personal de Manifestaciones anticipadas de voluntad en el ámbito sanitario	All	All
CANTABRIA		
Ley 7/2002, de 10 de diciembre, de ordenación sanitaria de Cantabria	29.2.b), 34	34.5
Decreto 139/2004, de 5 de diciembre, que crea y regula el Registro de voluntades previas de Cantabria	All	All
Orden SAN/27/2005, de 16 de septiembre, por la que se establece el documento tipo	All	

(*Continued*)

Legal norm	Advance directives	Registry of advance directives
de voluntades expresadas con carácter previo de Cantabria		
Orden SAN/28/2005, de 16 de septiembre, por la que se creas el fichero automatizado de datos de carácter personal del Registro de voluntades previas de Cantabria	All	All
CASTILE-LA MANCHA		
Ley 6/2005, de 7 de julio, sobre la declaración de voluntades anticipadas en materia de la propia salud	All	9; 4.3, 5, 8.3, 10, final provision one
Decreto 15/2006, de 21 de febrero, del Registro de voluntades anticipadas de Castilla-La Mancha	All	All
Orden de 31 de agosto de 2006, de la Consejería de Sanidad, de creación del fichero automatizado de datos del Registro de voluntades anticipadas de Castilla-La Mancha	All	All
Resolución de 8 de enero de 2008, de la Consejería de Sanidad, de creación de nuevos puntos del Registro de voluntades anticipadas de Castilla-La Mancha	All	All
Ley 5/2010, de 24 de junio, sobre derechos y deberes en materia de salud de Castilla-La Mancha	24; 26.2.q)	
CASTILE AND LEON		
Ley 8/2003, de 8 de abril, sobre derechos y deberes de las personas en relación con la salud	30	30.2

Legal norm	Advance directives	Registry of advance directives
Orden SBS/1325/2003, de 3 de septiembre, de publicación de las Cartas de derechos y deberes de las Guías de información al usuario	Appendix	
Orden SAN/279/2005, de 5 de abril, que desarrolla el procedimiento de tramitación de las reclamaciones y sugerencias en el ámbito sanitario y regula la gestión y el análisis de la información derivada de las mismas	Appendix I	
Decreto 101/2005, de 22 de diciembre, por el que se regula la historia clínica	Additional provision two	Additional provision two
Decreto 30/2007, de 22 de marzo, por el que se regula el documento de instrucciones previas en el ámbito sanitario y se crea el Registro de Instrucciones Previas de Castilla y León	All	1, 10–22
Ley Orgánica 14/2007, de 30 de noviembre, de reforma del Estatuto de Autonomía de Castilla y León	13.2.e)	
CATALONIA		
Ley 21/2000, de 29 de diciembre, sobre derechos de información concernientes a la salud, a la autonomía del paciente y a la documentación clínica (*ex* Ley 16/2010, de 3 de junio, de modificación de la Ley 21/2000, de 29 de diciembre, sobre los derechos de	8; 12.7	

(*Continued*)

Legal norm	Advance directives	Registry of advance directives
información concerniente a la salud y la autonomía del paciente, y la documentación clínica)		
Decreto 175/2002, de 25 de junio, que regula el Registro de voluntades anticipadas (artículo 5 y Anexo II derogados por la Orden SLT/519/2006, de 3 de noviembre)	All	All
Resolución BEF/3622/2003, de 4 de noviembre, que da publicidad al Acuerdo del Gobierno de 8 de octubre de 2003, que establece la Carta de derechos y deberes de la gente mayor de Cataluña	Appendix 3.3	
Ley Orgánica 6/2006, de 19 de julio, de reforma del Estatuto de Autonomía de Cataluña	20.2	
Orden SLT/519/2006, de 3 de noviembre, por la que se regulan ficheros que contienen datos de carácter personal en el ámbito del Departamento de Salud	2, Appendix II; repealing provision	2, Appendix II; repealing provision
Ley 25/2010, de 29 de julio, del libro segundo del Código civil de Cataluña, relativo a la persona y la familia	212-3; 212-1.4, 226-2.2	
EXTREMADURA		
Ley 10/2001, de 28 de junio, de salud	11.5	
Ley 3/2005, de 8 de julio, de información sanitaria y autonomía del paciente	15.4.a, 17–22	22; 17.5, 18.2, 20.1.2), 20.1.4)
Decreto 311/2007, de 15 de octubre, por el que se regula el contenido, organización y	All	All

Legal norm	Advance directives	Registry of advance directives
funcionamiento del Registro de expresión anticipada de voluntades de la Comunidad Autónoma de Extremadura y se crea el Fichero automatizado de datos de carácter personal del citado Registro		
GALICIA		
Ley 3/2001, de 28 de mayo, reguladora del consentimiento informado y de la historia clínica de los pacientes (*ex* Ley 3/2005, de 7 de marzo, de modificación de la Ley 3/2001, de 28 de mayo…)	4; 5	5.6
Ley 7/2003, de 9 de diciembre, de ordenación sanitaria de Galicia	133.1.n)	
Decreto 259/2007, de 13 de diciembre, por el que se crea el Registro gallego de instrucciones previas sobre cuidados y tratamientos de la salud	All	All
Ley 8/2008, de 10 de julio, de salud de Galicia	8.3	
LA RIOJA		
Ley 2/2002, de 17 de abril, de salud (*ex* Disposición Final primera de la Ley 9/2005, de 30 de septiembre)	6.5	6.5.c) and d)
Decreto 37/2203, de 15 de julio, de atribución de funciones administrativas en desarrollo de la Ley 3/2003, de organización del sector público de la Comunidad Autónoma de La Rioja (*ex* Decreto 21/2005, de 4 de marzo)	4.7.11.c)	4.7.11.c)

(*Continued*)

Legal norm	Advance directives	Registry of advance directives
Ley 9/2005, de 30 de septiembre, reguladora del documento de instrucciones previas en el ámbito de la sanidad	All	10; final provision two
Decreto 30/2006, de 19 de mayo, por el que se regula el Registro de instrucciones previas de La Rioja	All	All
Orden 8/2006, de 26 de julio, sobre la forma de otorgar documento de instrucciones previas ante personal de la Administración	All	All
MADRID	All	12
Ley 3/2005, de 23 de mayo, que regula el ejercicio del derecho a formular instrucciones previas en el ámbito sanitario y crea el registro correspondiente		
Decreto 101/2006, de 16 de noviembre, del Consejo de Gobierno, por el que se regula el Registro de instrucciones previas de la Comunidad de Madrid	All	All
Orden 2191/2006, de 18 de diciembre, por la que se desarrolla el Decreto 101/2006, de 28 de noviembre, por el que se regula el registro de instrucciones previas de la Comunidad de Madrid y se establecen los modelos oficiales de los documentos de solicitud de inscripción de las instrucciones previas y de su revocación, modificación o sustitución	All	All

Legal norm	Advance directives	Registry of advance directives
Orden 228/2007, de 26 de febrero, del Consejero de Sanidad y Consumo, por la que se crean dos ficheros de datos de carácter personal para el desarrollo del Registro de Instrucciones Previas de la Comunidad de Madrid	All	All
Orden 645/2007, de 19 de abril, que regula el otorgamiento de las instrucciones previas, su modificación, sustitución y revocación ante el personal al servicio de la Administración	All	All
MURCIA		
Decreto 80/2005, de 8 de julio, por el que se aprueba el reglamento de instrucciones previas y su registro	All	8–13; 2.2.b), 7; additional provisions one and two
Orden de 22 de febrero de 2006 de la Consejería de Economía y Hacienda por la que se crean ficheros con datos de carácter personal gestionados por la Consejería de Sanidad	All, Appendix	All, Appendix
NAVARRE		
Decreto foral 140/2003, de 16 de junio, que regula el Registro de voluntades anticipadas	All	All
Ley foral 17/2010, de 8 de noviembre, de derechos y deberes de las personas en materia de salud en la Comunidad Foral de Navarra	5.8, 26.3, 54, 55, 59.1.b)	55.3
Ley foral 8/2011, de 24 de marzo, de derechos y garantías de la dignidad de la persona en el proceso de la muerte	2.b); 5.d), k), q), r); 9; 10; 11; 18; additional provisions	additional provision five; sole transitory provision

(*Continued*)

Legal norm	Advance directives	Registry of advance directives
	four and five; sole transitory provision	
BASQUE COUNTRY		
Ley 7/2002, de 12 de diciembre, de voluntades anticipadas en el ámbito de la sanidad	All	6; 2.3.a), 3.2.b), 4.2, 7, final provision one
Decreto 270/2003, de 4 de noviembre, que crea y regula el Registro vasco de voluntades anticipadas	All	All
Orden de 22 de noviembre de 2004, que establece normas sobre el uso de la firma electrónica en las relaciones por medios electrónicos, informáticos y telemáticos con el Sistema Sanitario de Euskadi	11	11
Orden de 1 de junio de 2005, del Consejero de Sanidad, por la que se regulan los ficheros de datos de carácter personal del Departamento de Sanidad	Appendix I	Appendix I
VALENCIA		
Ley 1/2003, de 28 de enero, de derechos e información al paciente de la Comunidad valenciana	17; 3.16, 22.1.c)	17.7
Decreto 168/2004, de 10 de septiembre, por el que regula el documento de voluntades anticipadas y crea el Registro centralizado de voluntades anticipadas de la Comunidad valenciana	All	6–9; 2.2, 3.2, 5.2, final provision one

Legal norm	Advance directives	Registry of advance directives
Orden de 25 de febrero de 2005, de desarrollo del Decreto 168/2004, de 10 de septiembre	All	All
Orden de 20 de julio de 2005, del Conseller de Sanidad, por la que se crea el fichero automatizado Volant Registros		