NATIONAL COUNCIL OF ETHICS FOR THE LIFE SCIENCES

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Opinion on the Proposed Decree Orders regulating the Living Will Model and the National Living Will Registry (RENTEV)

(December 2012)

CNECV

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I – INTRODUCTION

Following the request for Opinion formulated by the Parliamentary Health Committee on 18 October 2010, the National Council of Ethics for the Life Sciences (CNECV) analysed the Draft Bills no. 413/XI, 414/XI, 428 / XI and 429/XI and approved on 22 December of the same year its Opinion no. 59/2010 on Advance Health Care Directives (AHCD)

In 2012, when the Parliamentary discussion ended, Law 25/2012 of 16 July was approved, which regulates advance health care directives, particularly in the form of living wills, the nomination appointment of a health care surrogate and creates the National Living Will Registry (RENTEV).

Pursuant to no. 3 of article 3 of this legislative order, 'The ministry responsible for the health area approves, upon prior opinions of the National Council of Ethics for the Life Sciences (CNECV) and the National Commission for Data Protection, a model of advance health care directives, for optional use by the grantor.'

His Excellency the Deputy Secretary of State to the Minister of Health sent the CNECV a request for an urgent hearing and Opinion on two Decree Order proposals, respectively on a model of advance health care directive and on the regulation of the organisation and functioning of the National Living Will Registry (RENTEV).

Accordingly, and in light of its earlier Opinion, the CNECV focuses its analysis specifically on the ethical issues of the Decree Order proposals, on which it thought to comment on with constructive suggestions. Thus:

A. Decree Order proposal on the model of advance health care directive (AHCD)

The Decree Order must explicitly include, as a mandatory requirement, the following aspects:

1. The proposed model should be written in the first person singular.

2. The completion of the proposed model form is optional, and each autonomous citizen may opt for writing a free text of his own initiative, and this possibility should be included in the model itself.

3. The CNECV recommends that, in any case, when making an AHCD, the respective author previously discusses the matter with a health professional of his/her trust, or with the health team that takes care of him/her. This recommendation should be actively promoted, consisting, for example, of the explanatory notes attached to the model.

4. The citizen must be informed, both in the Decree Order and in the form to be filled in, that he/she may opt for the designation of a health care surrogate, just for the AHCD writing (in proposed model or free writing), or for both.

5. In the context of the AHCD, the CNECV recommends that the model includes space for the person, if desired, to write and expose information about the values that motivate his/her decision.

6. The list of situations that the person indicates to, cumulatively to the situation of incapacity, trigger the AHCD, as presented in the proposed model should be reformulated:

a. Under the title 'CLINICAL CONDITION IN WHICH THE AHCD PRODUCES EFFECTS', the body of the text should have the following writing: '*When I am unable to express my will autonomously, as a result of my state of physical and/or mental health, and there are or more of the following cases:*' avoiding the way it is written (When the Grantor is unable to autonomously express his personal will:) which seems to mean that it is the cases that induce condition the grantor's inability to express him/herself.

b. The note in brackets 'fill in all applicable cases' should be replaced by '*fill in the applicable cases*'.

c. The first case, 'Due to incurable or terminal disease' should be replaced by '*Incurable disease in terminal phase*'.

d. The second case, instead of 'To be in a situation where the use of additional means of diagnosis and treatment only serves to prolong artificially the natural process of death', should be replaced by '*There are no expectations of recovery in the clinical evaluation made by the doctor responsible for the care, according to the state of the art*'.

e. The third case 'To be in an emergency situation, in the event of an accident' should be eliminated as it is too broad or unclear.

f. Add '*Unconsciousness due to irreversible psychiatric or neurological disease, complicated by respiratory, heart or kidney complication*', keeping the field for other cases.

7. Under the title 'HEALTHCARE TO BE RECEIVED AND NOT RECEIVED', the body of the text should be replaced by the following: '*I thus express my clear an unequivocal will of:*'

a. The note in brackets 'fill in all applicable cases' should be replaced by '*fill in the applicable cases*'.

b. Reformulate the cases suggested, replacing them by the following:

   i. 'Not be subjected to cardiopulmonary resuscitation'

   ii. 'Not be subjected to invasive means of artificial support of vital functions'

   iii. 'Not receive artificial nutrition and hydration'

   iv. 'Stop treatments that are experimental or participation in scientific research programmes or clinical trials, for which I had given prior consent'

   v. 'Do not authorize administration of blood or blood products'

c. Add possibility of treatments that you want to receive, keeping the field for 'Others':

   i. '*I wish palliative measures to be established (including minimal oral or subcutaneous hydration)*'

   ii. '*I wish to be given the drugs needed to control, with effectiveness, pain and other symptoms that may cause me suffering, distress, or discomfort, even if this may shorten my life expectancy.*'

   iii. 'I wish to participate in pilot studies, scientific research or clinical trials'

   iv. 'When it is decided to stop the artificial means of life, I wish to be given religious assistance (faith: _____) and/or have the presence beside me, for a suitable time, of the person I here designate (_____)'

8. Under the title 'VALIDITY', rather than referring in paragraph 1 that 'This statement is effective for 5 years from the date of its signature, and may be renewed in accordance with Law No. 25/2012 of July 16', it should simply transcribe its *Article 7 - Period of validity of the document **1** - The document of advance health care directives is effective for a period of five years from the date of its signature. **2** - The period referred to in the preceding paragraph is successively renewable through a confirmation statement of the provisions in the document of advance health care directives, in accordance with no. 1 of article 3. **3** - The document of advance health care directives will remain in force when there is incapacity of the grantor in the course of the period referred to in no.1. **4** - The RENTEV services must inform in writing the grantor of the AHCD, and, if applicable, his/her surrogate, of the expiry date of the document, up to 60 days before the time limit referred to in no. 1*.'

9. Under the title 'Doctor (optional)' the following should be added '*I declare that I provided the explanations that were requested by the Grantor relating to this document and his/her state of health*'.

10.In the identification of the grantor a field for the email address could be added, if available.

B. Decree Order Proposal for the National Living Will Registry (RENTEV)

1. The body of the Decree Order proposal mentions that the National Commission for Data Protection (CNPD) was heard and omits that the CNECV was heard.

2. Article 7 of the Decree Order proposal does not state, in accordance with article 7 of Law no. 25/2012, that the '*document of advance health care directives will remain in effect when there occurs incapacity of the grantor during the period referred to in no.1*.'

3. Article 8 of the Decree Order proposal does not include the recommendation contained in the CNECV Opinion which states '*that of all these accesses automatic notifications be made to the author of the advance health care directive and, if applicable, the Health Care Surrogate*.'

Lisbon, 17 December 2012

The President, *Miguel Oliveira da Silva*
The Rapporteurs, *Lucília Nunes, Michel Renaud, Rosalvo Almeida.*

It was approved in the plenary meeting of 17 December 2012 in which, besides the President, the following Counsellors were present:

Ana Sofia Carvalho; Carolino Monteiro; Isabel Santos; José Germano de Sousa; José Lebre de Freitas; Lígia Amâncio; Maria do Céu Patrão Neves; Michel Renaud; Pedro Nunes; Rosalvo Almeida.