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Text n°40

Decree n° 2016-1066 of August 3, 2016 modifying the Code of Medical Deontology concerning collegial procedures and the use of deep and prolonged sedation until death provided for by Law n° 2016-87 of February 2, 2016 establishing new rights for patients and for the terminally ill

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Actors concerned: doctors and medical professionals involved in the decision-making process regarding end-of-life treatment, as well as all other people concerned (patients and their family and close friends).

Aim: collegial procedures regarding the ending of treatment and the use of deep and prolonged sedation until death.

Entry into force: the law shall be enacted as of the day after its publication.

Note: The Decree lays down the rules for the organization of the collegial procedure which frames the decisions, on the one hand, concerning the ending and the limiting of treatment in the case of unreasonable obstinacy when the patient is not in a state to express his/her will, and, on the other hand, regarding the use of deep and prolonged sedation until death. It also sets out the conditions in which the doctor may refuse the application of the advance decisions of the patient, when they appear in appropriate or inconsistent with the medical condition.

References: the present Decree has been taken in order to apply articles 2, 3 and 8 of Law n° 2016-87 of February 2, 2016 establishing new rights for patients and for the terminally ill. The provisions of the Public Health Code which have been modified by the present Decree may be consulted in the wording which results from this modification on the Légifrance internet site (<http://www.legifrance.gouv.fr>).

The Prime Minister,

Considering the report of the Minister of Social Affairs and Health and of the Minister of

Justice,

Having regard to the Public Health Code, especially its articles L. 1110-5-1, L. 1110-5-2 et L. 1111-11;

Having regard to the deliberation of the National Council of the Order of Doctors of May 12, 2016;

Decreases that:

Article 1

The third paragraph of article R. 4127-36 of the Public Health Code shall be replaced by the following provisions:

“If the patient is not in a state to express his/her will, the doctor can only intervene if the designated support person, or failing that the family or one of the patient’s close friends, is warned or informed, except in the case of emergency or impossibility”.

Article 2

Article R. 4127-37 of the same code is replaced by the following provisions:

“Art. R. 4127-37.- In all circumstances, the doctor must relieve the pain of the patient by all methods which are appropriate for his/her state and must bring moral support. He must refrain from all unreasonable obstinacy and can refuse to implement or to carry on treatment which appears useless, disproportionate or which have the sole effect of artificially maintaining life.

Article 3

After article R. 4127-37 of the same code, four articles have been added with the following wording:

“Art. R. 4127-37-1.-I.-When the patient is not in a state to express his/her will, the doctor in charge of the patient is required to respect the desire expressed by the patient in advance decisions, except in the cases provided for in II and III of the present article.

II.-In the case of vital emergency, the application of the advance decisions shall not be imposed during the time required for the complete assessment of the medical situation.

III.-If the doctor in charge of the patient judges the advance decisions to be entirely inappropriate or Inconsistent with the medical condition, a decision to refuse to apply them may only be taken following the collegial procedure provided for by article L. 1111-11. For this to occur, the doctor shall gather the opinions of the members present of the healthcare team, if it exists, and also that of, at least, one other doctor, chosen as a consultant, with

whom no hierarchical link exists. He may also gather from the designated support person or, failing that, the family or a close friend, the attestation of the wish expressed by the patient.

IV.-In the case of a decision to refuse the advance decisions, such a decision must be reasoned. The attestations and opinions collected as well as the motivations for the decision are included in the medical records of the patient.

The designated support person, or failing that, the family or a close friend of the patient, are informed of the decision to refuse the application of the advance decisions”.

“Art. R. 4127-37-2.-I.-The decision to limit or to end treatment must be the will of the patient previously expressed in the advance decisions. When the patient is not in a state to express his/her will and in the absence of advance decisions, the decision to limit or to end treatment, in the light of a refusal of unreasonable obstinacy, may only be taken following the collegial procedure provided for in article L. 1110-5-1 and after having gathered information concerning the patient’s wishes from the designated support person, or failing that, the family or a close friend of the patient

II.-The doctor in charge of the patient may engage the collegial procedure on his own initiative. He must do it if requested by the designated support person, or failing that, the family or a close friend of the patient. The designated support person, or failing that, the family or a close friend of the patient, are informed of the decision to engage the collegial procedure, as soon as it has been taken.

III.- The decision to limit or to end treatment is taken following the collegial procedure. This collegial procedure takes the form of a dialogue with the members present of the healthcare team, if it exists, and also of the gathering of a reasoned opinion from, at least, one other doctor, chosen as a consultant. There must be no hierarchical link between the doctor in charge of the patient and the consultant. The reasoned opinion of a second consultant may be gathered by the first two doctors if either of them considers it necessary.

When the decision to limit or to end treatment concerns a minor or a protected adult, the doctor also gathers the opinions of the holders of parental authority or of the guardian according to the circumstances, except in cases where an emergency makes such consultation impossible.

IV.- The decision to limit or to end treatment must be reasoned. The designated support person, or failing that, the family or a close friend of the patient, are informed of the character and of the reasons for the decision to limit or to end treatment. The wish to limit or to end treatment expressed in the advance decisions or failing that the attestation of the designated support person, or of the family or a close friend of the patient witnessing the wish expressed by the patient, as well as the opinions gathered and the motivations, are all included in the medical records of the patient.”

“Art. R. 4127-37-3.-I.-Upon the request of the patient, in the situations provided for by 1° and 2° of article L. 1110-5-2, deep and prolonged sedation causing an altered state of consciousness until death combined with analgesia and the ending of all forms of life-support treatment, may be implemented. This happens after the collegial procedure as defined in III of article R. 4127-37-2 whose aim is to make sure that all the conditions laid down by the law, have been met.

The use, upon the request of the patient, of deep and prolonged sedation as defined in the above paragraph, or its refusal must be reasoned. The reasons for the use or non-use of such sedation are included in the medical records of the patient and he/she is informed of them.

II.-When the patient is not in a state to express his/her will and a decision has been taken to end life-supporting treatment in the framework of unreasonable obstinacy, in application of articles L. 1110-5-1, L. 1110-5-2 and L. 1111-4, in the conditions laid down by the present article, the doctor in charge of the patient, even if the pain endured by the latter cannot be measured on account of his/her cerebral state, may implement deep and prolonged sedation causing an altered state of consciousness until death combined with analgesia, unless the patient declared him/herself opposed to this in the advance decisions

The use of deep and prolonged sedation thus defined, must, in the absence of opposition expressed by the patient in the advance decisions, be decided upon according to the collegial procedure provided for by article R. 4127-37-2.

In the absence of advance decisions, the doctor in charge of the patient will gather from the designated support person, or failing that, the family or a close friend of the patient an attestation of the patient's will.

The motives for the use of deep and prolonged sedation must be reasoned. The wish expressed in the advance decisions or failing that the attestation of the designated support person, or of the family or a close friend of the patient witnessing the wish expressed by the patient, as well as the opinions gathered and the motivations behind the decision, are all included in the medical records of the patient.

The designated support person, or failing that, the family or a close friend of the patient are informed of the reasons for the use of deep and prolonged sedation.

Art. R. 4127-37-4.-The doctor accompanies the person according to the principles and the conditions laid down in article R. 4127-38. He also makes sure that the family and close friends of the patient are informed of the situation and that they receive the necessary support.

Article 4

In Title IV of Book IV of the fourth part of the Public Health Code, the following Chapter is to be inserted:

Chapter I

Medical Professions

Art. R. 4441-1.-Articles R. 4127-36, R. 4127-37, R. 4127-37-1, R. 4127-37-2, R. 4127-37-3 and R. 4127-37-4 are applicable in New Caledonia and in French Polynesia in the wording laid down by Decree n° 2016-1066 of August 3, 2016.

Article 5

The Minister for Social Affairs and Health, the Minister of Justice and the Minister for Overseas Communities are responsible, each in their own area, for the implementation of the present Decree, which shall be published in the Official Journal of the French Republic.

Signed, August 3, 2016

By Manuel Valls,
Prime Minister

Minister of Social Affairs and Health,
Marisol Touraine

Minister of Justice,
Jean-Jacques Urvoas

Minister for Overseas Communities,
George Pau-Langevin