



Revista Bioética

ISSN: 1983-8042

ISSN: 1983-8034

Conselho Federal de Medicina

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Revista Bioética, vol. 28, no. 4, 2020, October-December, pp. 604-609

Conselho Federal de Medicina

DOI: <https://doi.org/10.1590/1983-80422020284423>

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UPDATE

Advance directives: a standard instrument proposal

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Abstract

This study aimed to reflect on the characteristics and objectives of the patient's advance directives. This document should have a standard format, including the general terms of Resolution 1.805/2006 of the Federal Council of Medicine, and strengthen the sense of legal certainty of health professionals. Even with written determinations, the understanding between patient and staff shall prevail.

Keywords: Bioethics. Advance directives. Terminally ill.

Resumo

Diretivas antecipadas de vontade: proposta de instrumento único

O objetivo deste estudo é refletir sobre as características e finalidades do documento de diretivas antecipadas de vontade do paciente. Conclui-se que tal documento deve ter formato único, que reflita a generalidade dos termos da Resolução 1.805/2006 do Conselho Federal de Medicina, e que sua principal finalidade é fortalecer a sensação de segurança jurídica do profissional médico. Por fim, destaca-se que, ainda que se considerem as determinações escritas, prevalecerá o entendimento entre paciente e equipe.

Palavras-chave: Bioética. Diretivas antecipadas. Doente terminal.

Resumen

Directivas anticipadas de voluntad: propuesta de instrumento único

El objetivo de este estudio es hacer consideraciones sobre las características y propósitos del documento relativo a las directivas anticipadas de voluntad del paciente. Se concluye que debe tener un formato único, que refleje los términos generales de la Resolución 1.805/2006 del Consejo Federal de Medicina, y que su principal propósito es fortalecer la percepción de seguridad jurídica del profesional médico. Finalmente, se enfatiza que, incluso si se consideran las determinaciones escritas, prevalecerá el entendimiento entre el paciente y el equipo.

Palabras clave: Bioética. Directivas anticipadas. Enfermo terminal.

The authors declare no conflict of interest.

Recently, notable changes have occurred in how the process of death and final moments of life are perceived. Among them, the acknowledgement of the paradigm “maintaining life at all costs” stands out, which defined the end of life exclusively by irreversible cardiac arrest followed by cell death, and patients’ will became a more relevant factor in the treatment. The right to receive clear information and the doctors’ duty to dialogue with patients to adopt therapeutic measures are consequences of this change.

The laws of countries have reflected these changes, regulating the doctor-patient relationship (particularly regarding therapeutic decisions), such as the right to refuse treatment and how to manifest this will. It became acceptable, in cases of severe and incurable diseases, to decide with the medical team to suspend useless therapies and maintain comfort and pain relief measures. Thus, notions of terminality and palliative care became more relevant.

The laws vary in range, and this article does not intend to conduct a comparative law study, but it is worth pointing out some characteristics common to several countries. All these legislations limit patients and doctors’ power to the dictates of the law; nothing the law prohibits can be agreed to or arranged between physicians and patients as a manifestation of will. All of them allow patients to give up previous determinations at any time, without further formalities, and the attorney serves specific purposes, when patients are unable to express their will, either because of cognitive impairment or unconsciousness.

As for how will should be manifested, there are important variations, and two main paradigms are considered: the American law (Patient Self Determination Act of 1990)¹, and the Australian law (Consent to Medical Treatment and Palliative Care Act, 1995, amended in 2004)². The first is short and “informal,” as it does not establish how to manifest will or whether it should be recorded in writing. Directives can be written, but the document is not mandatory: only some conducts are described, to which doctors or care institutions are obliged, as well as patients’ rights. The Australian law is much more detailed and requires written manifestation, with a standard

form and a national register of directives to be consulted at the time of attendance. This pattern is followed by the Portuguese law 25/2012³, and Spanish law 41/2002⁴, also with a national directive file.

In Brazil, no federal law regulates the subject. There are state laws, such as Law 10.241/1999⁵ of the state of São Paulo (the so-called “Mário Covas Law”), and law 3.613/2001⁶ of the state of Rio de Janeiro. Both are similar, and do not mention terminality or advance directives as the others, mentioning only rights such as right to information, to refuse treatment and choose place of death. The only federal regulations are the Federal Council of Medicine (CFM) resolutions 1.805/2006⁷ and 1.995/2012⁸.

Resolution CFM 1.805/2006 regulates the conduct of physicians in cases of severe and incurable diseases at terminal phase. Excluding the last article, which deals with formal aspects of law implementation, it contains only two articles. The first heading is typically permissive: it authorizes physicians *to limit or suspend procedures and treatments that prolong the life of terminally ill patients*⁷, always respecting their (or their legal representative) will. The article has three paragraphs of mandatory content: the doctor must clarify to the patient or legal representative *the appropriate therapeutic measures for each situation* (§ 1st); *the decision referred to in the heading must be justified and noted in medical records* (§ 2nd); and *patients or their legal representative have the right to request a second opinion* (§ 3rd)⁷. The second article determines that patients *will continue to receive all necessary care to alleviate (...) physical, psychological, social, and spiritual suffering (...)*⁷.

In addition to being brief, the norm has three other important features. The first is generality: concepts such as “terminality,” “terminally ill” and even “severe and incurable illness” are ill-defined, but treated as self-explanatory (in legal jargon, they are treated as a “legal standard”). Gimenes expresses well that imprecision: *in most cases it is possible to determine the moment when therapy is no longer effective and its maintenance would only prolong*

*patient's suffering, especially in chronic patients in terminal phase*⁹.

The second characteristic is specificity and personal character due to the absence of concept definition. The text ends up attributing the terminality diagnosis to physicians' opinion. The third characteristic is the presence of "legal representative" next to "patient" or "person" in all decisions (Art.1st, heading, § 1st and § 3rd)⁷.

Resolution CFM 1.995/2012⁸ regulates the so-called "advance directives of will" and has only two articles as well. Its main feature is also generality. The directives are defined in its first article as a *desire set, previously expressed by the patients*⁸ on how they want to be treated if they could not manifest their will. The factors that may or may not be included in the list of "desires" are not described; and the limitations in § 2nd of the 2nd article⁸ are generic, and follow the laws of the other countries referred to in this text: the directives may not include decisions in disagreement with the Code of Medical Ethics, that is, they may not be against the law.

A second characteristic of Resolution CFM 1.995/2012⁸ is the presence of a "representative" figure, expressly cited and in these terms in § 1st of Article 2nd. The third and last relevant characteristic is negative: decisions are not required to be written, only that the doctor register them in the medical record, following a CFM protocol.

After presenting these two norms, two comments are timely before continuing. The first is that, until now, no convincing data, in the medical literature, proves that written manifestations are more effective, in the sense of being easier to understand and more likely to be fulfilled. The greatest difficulty is making the document reach the medical team, especially in emergency sectors, where patients with altered levels of consciousness or even unconscious patients are common. In such cases, doctors tend to proceed according to the current medical culture.

The second observation is that the generic terms of the two norms address the doctor-patient relationship and the specific and concrete nature of facts related to the health of patients, but also the almost endless clinical situations

that lead to death (or that may regard the patient's will, even if he or she is not terminal), which are usually defined only when very close to the outcome. Such circumstances do not allow details with appreciable temporal anticipation, otherwise it would be a divination exercise.

Given this, a written document, as in all forms of manifestation of will, tends to serve as evidence and to guarantee legal certainty to those who apply the directives, rather than to fulfill the patient's will. Such will should be manifested by the patients or their representatives at the appropriate time, when the clinical terminality conditions are defined.

If this document is admitted, it should reflect the generality of the two resolutions that regulate the matter. Despite the complexity and variety of end-of-life situations, the document would be relatively simple and standardized, based on CFM resolution 1.805/2006⁷, including the expressions used in it. In the appendix, we propose a model for this manifestation, in the regular format of manifestation – preferably public – of will, after a standard introduction of the theme.

Discussion

The text (Appendix) is generic and comprehensive, and determines the therapy suspension only when it is considered a "futile treatment". Any difficult situation should be resolved by the declarant or, when they cannot do this, by the appointed attorney, at the proper time. It is not feasible to record procedures the declarant wishes to undergo or avoid to prolong their life, if hospitalized in intensive care unit¹⁰, since it is not necessary to identify them in a detailed way and impossible to do so in advance.

The same observation applies to sequelae¹⁰, since they do not imply terminal conditions, and depending on the degree of cognitive impairment, the patient, an attorney, or even a family member who informally assumes the role of caregiver – which is common in these situations – can make decisions. It is impossible to predict what kind of aftereffect will be caused by a harmful event (the event itself is unpredictable), and the decision can only be

taken after it, being thus impossible to have a previous document in this case.

Dadalto states that *medical treatment aspects such as the Suspension of Therapeutic Efforts (STE), the desire of patients of not using machines and not receiving medical interventions, among other aspects* should be included in the document¹¹. The author faces the same contradiction of trying to define unpredictable procedures. Without formally expressing it, Dadalto¹² manifests the difficulty in pre-establishing guidelines by citing as a limit to the declaration of will the creation of new therapies that could treat the disease, and thus mischaracterizing therapeutic futility.

The author¹² also points out that “advance directives” are generally understood as manifestations, such as the living will of terminal patients and durable power of attorney for healthcare – which must integrate the first and can be used in transient (not terminal)

disability situations. The same limitations apply to the latter regarding the impossibility of anticipating details, which reinforces the need and importance of legal representatives.

Final considerations

It is not possible to pre-establish in detail what measures should be taken if the patient is unable to make decisions – even because such measures mean discontinuing any procedure considered as “futile treatment”. Thus, we propose the generic and comprehensive term presented in the Appendix, with the purpose of strengthening the sense of security of doctors and health professionals, but above all considering the dialogue between medical teams and patients and their families (or legal representatives). However, the determinations in the document may be revoked at any time.

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Participation of the authors

Sergio Domingos Pittelli conceived and wrote the article and reviewed the literature. All authors discussed and corrected the text.

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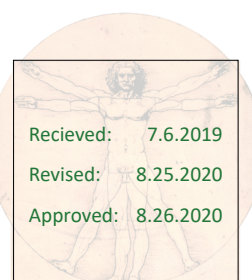
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Appendix

Advance Directives: Document Proposal

To whom this public deed of manifestation of will may concern, on this ___ day of _____ of the year ____, at the city of _____, this declaration was executed before a notary, and five competent witnesses, called here especially for this act, who are later identified and have undersigned. The declarant, Mr./Mrs. _____, natural from _____, marital status _____, occupation _____, currently living at _____, is recognized by the notary and the five witnesses, who have certified that the declarant is here willfully and of his/her sound mind.

Always in the presence of the witnesses, the declarant makes the present manifestation of will in Brazilian Portuguese, exercising his/her legal rights guaranteed by the Federative Republic of Brazil's constitution, which I, the notary, have hereby registered: 1) The declarant was born in _____, on the _____ day of _____ of the year ____, child of _____; 2) married to _____; 3) father/mother of _____, born on _____, married; 4) exercising the right to manifest his/her will concerning medical treatments, allowing or refusing them, as guaranteed by the Brazilian Constitution (Law 10.406/2002, article 15), Resolutions CFM 1.805/2006 and 1.995/2012, and the Code of Medical Ethics (Resolution CFM 2.217/2018, article 41, single paragraph); in case of severe and incurable illness in terminal phase, determined by the attending physician, the declarant does not wish to prolong his/her life artificially or to undergo any treatments that could be considered "therapeutic futility" (or "therapeutic excess," "futile treatment," "useless treatment," and other denominations), which only intend to delay death, without the possibility of cure or return to a healthy life; such as cardiopulmonary resuscitation, any artificial ventilation procedures (intubation, tracheostomy, or mechanical ventilation), invasive procedures to maintain cardiac output or blood pressure, including blood transfusion or vasoactive substances, as well as hospitalization in intensive care unit, allowing only the necessary measures to prevent pain, and physical and spiritual suffering ("Palliative Care"); this declaration extends to other procedures, such as chemotherapy, radiotherapy and surgical and/or invasive procedures either major or minor. Their execution shall be decided by the appointed attorneys bellow, in case the declarant is unable; 5) the declarant agrees to palliative extubation, sedation, and artificial nutrition suspension, which the attorneys shall also decide if needed; 6) the advance directives must be followed and respected by family, friends, and attending medical professionals, if the declarant is permanently unable to manifest his/her will, exempting them of responsibilities regarding the declarant or his/her successors; 7) among the witnesses, the declarant names a) _____ (identification) and b) _____ (identification) as his/her legal representatives (one must stand in for the other in case of absence or impediment), to fulfill his/her wishes and decide on other procedures not mentioned in this document, when the declarant can no longer manifest his/her will. Thus, the declarant concludes his/her advance directives manifestation, which I, the notary, have read out loud clearly to the declarant and witnesses. The declarant agrees willfully to this declaration, and has hereunder signed, as well as the witnesses who are: _____, all of age, capable, acquainted to the notary, residents of this city, and present throughout the declaration, in which all legal formalities were honored. I, _____, the notary, wrote, certified, and signed in official capacity.