INTERFERENCE BETWEEN LEGAL AND MEDICAL ISSUES
IN THE FIELD OF PALLIATIVE CARE SERVICES

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Abstract
The population of a country benefits from prevention, curative programs but also from palliative programs, addressed to patients with chronic diseases. Palliative care is defined as a holistic, complex approach to patients with chronic diseases, in order to increase the quality of life of patients and their families. From a legislative point of view, since 2018, all aspects of palliative care have been regulated in Romania as well. As can be seen from the present study, the regulation of palliative services is a complex, far-reaching one, regarding the providers of palliative services and the ways of carrying out their activity, as well as the patients.

Beneficiaries of these services and the interdisciplinary team involved in their provision. We find through this study that this regulation is a combination of the legal field with elements of medical activity.

During the Conference “Public safety and the need for high social capital”, panel VII, ”Protection of human capital in the field of the right to health and social care” was organized, and this study aims to raise the protection of human capital through palliative services, analyzing the stage and content of their regulation at national level.

Keywords: palliative care, patient, service providers, hospital, hospice
INTRODUCTION. THE PLACE OF PALLIATION IN HEALTH SYSTEMS

The population of a country benefits from preventive, curative medical programs but also from palliative programs, addressed to patients with chronic diseases.

The concept of "palliative" is made explicit as: 1. A drug or treatment that relieves or removes the symptoms of a disease for a short time without suppressing its cause. 2. FIG. (solution, measure) that temporarily or apparently solves a difficult situation. [Pr.: -li-a-] - from fr. palliative.

The sphere of human rights provided for in the European Convention on Human Rights seen from a broad, integrative perspective, includes in the concept “right to life" and the right to health (Ciocan M., 2015, p. 415-428), in the composition of which is also the right to palliative care.

Palliative care has been defined by the World Health Organization - WHO, as an approach designed to improve the quality of life of patients and their families, to address the problems caused by incurable diseases with limited prognosis; care focuses on the prevention and elimination of suffering, through the early identification, assessment and impeccable treatment of pain and other physical, psychosocial and spiritual problems. Palliative care is addressed to patients with various progressive conditions such as cancer, (Burz C., 2019) HIV/AIDS, progressive neurological diseases, chronic organ failure (heart, kidney), advanced lung disease, severe birth defects in children, other progressive chronic diseases with limited prognosis, rare diseases.

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I. Regulation on Palliative Care Services in Romania

I.1 Sedes materiae

From a legislative point of view, Order 253/2018 of the Ministry of Health approves the Regulation on the organization, functioning, and organization of palliative care services. This regulation defines palliative care services, the categories of patients eligible for these services, the identification of three levels of care according to the complexity of the services provided, the place of palliative care provision, palliative care providers, and the requirements for the activity.

Article 2 of the Regulation defines:

- palliative care: "a type of care that combines interventions and treatments aimed at improving the quality of life of patients and their families, to deal with the problems associated with life-threatening disease, by preventing and eliminating suffering, by early identification, correct assessment and treatment of pain and other physical, psychosocial and spiritual problems";

- terminal care: "care provided to a patient with the available means of treatment, when it is no longer possible to improve the fatal prognosis of the disease, as well as care provided near death".

The similar definition of the concept of terminal care is also included in the provisions of the Law on Patients’ Rights, no. 46 of January 21, 2003, art. 1, para. 1, lit. e). Also, Law 46 of 2003 provides in art. 31, paragraph 1, the patient’s right to terminal care in order to die with dignity.

I.2 Levels of Palliative Care Services

Article 3 of the Regulation identifies according to the complexity of the services three levels of palliative care indicated in Table 1.

<table>
<thead>
<tr>
<th>Level 1: Support for self-care</th>
<th>Level 2: Basic palliative care</th>
<th>Level 3: Specialized palliative care</th>
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<tbody>
<tr>
<td>Patient education and support for self-care aims to ensure adequate care in the periods between palliative care interventions of medical staff; this level is ensured by the staff of the basic and specialized palliative care services;</td>
<td>Basic palliative care is the care and support provided to patients and their families or relatives by primary care staff in community, community or hospital care, and who occasionally care for patients with chronic progressive diseases and palliative care needs;</td>
<td>Specialized palliative care is the care provided by providers authorized to provide specialized palliative care, through interdisciplinary teams for which palliative care is the basic activity;</td>
</tr>
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</table>

4 Published in the Official Gazette, no. 199 of March 5, 2018.
5 Published in the Official Gazette, no. 51 of January 29, 2003, amended and supplemented, hereinafter referred to as Law 43 of 2003.
I.3 Principles of palliative care

ANNEX no. 1 of the Regulation provides in art. 1 the following principles of palliative care: - improves the quality of life and positively influences the evolution of the disease; - ensures the control of pain and other symptoms; - considers the patient and his family as a care unit; - affirms the value of life and considers death as a natural process; - does not hasten or postpone death; - integrates psycho-social and spiritual aspects in the holistic care of the patient; - ensures the satisfaction of the complex needs of the patient through the intervention of the interdisciplinary team; - includes those investigations that are necessary for a better understanding and appropriate treatment for the clinical complications of the disease; - ensures the support of the family/relatives in the care of the patient and after his death, during the mourning period.

In order to provide palliative care, on the three levels and in accordance with the principles indicated in point.2.2. and 2.3. the classification of patients is done according to their own needs in:

- patients with basic needs and a low degree of complexity are people with progressive chronic disease, with palliative care needs manifested as mild or moderate physical, psycho-emotional or spiritual suffering, who have no comorbidities and who have carers in the family.

- patients with complex needs are people with progressive chronic diseases who are in one or more of the following situations: a) moderate/severe suffering in the physical, social, spiritual, psycho-emotional field, including refractory physical suffering or complex existential suffering; b) lack of family or the existence of major conflict situations in the family; c) the presence of multiple comorbidities; d) exceeding the medical care capacity, situation established following the evaluation of the health condition performed by the family doctor or by the specialized doctor.

I.4 Palliative care providers

Patients will be provided with palliative care by providers who can be: health units with beds in the network of the Ministry of Health, in the network of ministries and institutions with their own health network, units whose management has been transferred to local public authorities and health units private. Therefore, palliative care services can be provided by public health or private health care providers. It is noteworthy that some of the providers of public or private health services are those already authorized to provide in general any category of medical services. Regarding the health units that intend to carry out the palliative care activity, it is expressly regulated, the development of this activity based on the principle of authorization of operation prior to starting the activity, authorization given in the competence of the following entities, namely:

(i) the authorization of the operation of palliative care services at home is made by the Ministry of Health, a provision that is corroborated with art. 238, paragraph
(5) of Law 95 of 2006 on health care reform⁶, according to which home health care services, including home palliative care, are provided by providers evaluated and authorized in this regard and with art. 245, para. 1 and 2, of the same law, according to which the insured have the right to receive some home health care services, including palliative home care, provided by an authorized provider and evaluated under the law, and the conditions for providing home health care services are established by the framework contract.

(ii) the authorization of the operation of other structures providing palliative care services is made by the territorial public health directorates.

Moreover, the monitoring of the activity of palliative care providers in Romania during its development is given in the competence of the General Directorate of Health Care and Public Health of the Ministry of Health, and the National Association of Palliative Care has taken over the task of accrediting them for bed units and services at home.⁷

We also note that the Regulation contains a number of annexes which provide: the conditions for authorizing palliative care providers at home - annex no. 9; the model of the application form for the operation authorization in the field of palliative care at home - annex no. 10; the model of the operation authorization form in the field of palliative care at home - annex no. 11, hygienic-sanitary conditions, endowment and equipment in palliative care services in sanitary units with beds - annex no. 5; patient management in palliative care - annex no. 6.

I.5 The multidisciplinary team involved in palliative care

An effective approach to the patient in palliative care requires good communication of the multidisciplinary team that provides holistic care services with the patient and his family.

The interdisciplinary palliative care team is a group of professionals with appropriate training and experience in providing palliative care services, confirmed by the rules established by current regulations, and the composition of the team varies depending on the particular needs of palliative care beneficiaries.

According to the principles of palliative care, the approach of the patient with incurable diseases must be complex, holistic. Identification of physical symptoms, but also of psychosocial, emotional, social and spiritual needs is an essential condition for adequate support provided to the patient and his family. Due to the complex needs, the palliative care team must be multidisciplinary, consisting of a doctor, nurse, psychologist, priest, social worker, nutritionist, masseur, volunteers.⁸

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⁶ Published in the Official Gazette, no. 372 of April 28, 2006, the consolidated version on 20.11.2021, hereinafter referred to as Law 95 of 2006.


Communicating the diagnosis and prognosis of the disease, along with consulting the patient regarding therapeutic decisions are essential conditions in palliative care. The discussion with the patient and the family must be realistic in terms of diagnosis, treatment efficacy, treatment complications or related to the evolution of the disease as well as the prognosis.

Moreover, art. 32 of Law 43 of 2003 provides for the patient's right to benefit from the support of family, friends, spiritual, material support and advice throughout medical care. Moreover, at the patient's request, as far as possible, the care and treatment environment will be created as close as possible to the family one.

![Fig. 2 The multidisciplinary team involved in palliative care](Image)

From the point of view of the location where palliative care services can be performed - palliative care is individualized in the hospital either in the bed unit or provided by the mobile palliative care team, in the hospital outpatient clinic, at home or in palliative care centers. Regarding the time of intervention of palliative care services, we find that palliative care is provided: at diagnosis or onset of symptoms; during the course of the disease, for the terminally ill patient.

**I.6 Settlement of palliative care services**

Regarding the settlement of palliative care services, this is specified in Order no. 1068/627/2021 of June 29, 2021 on the approval of the Methodological Norms for the application in 2021 of the Government Decision no. 696/2021 for the approval of the service packages and of the Framework Contract that regulates the conditions for providing medical assistance, medicines and medical devices, technologies and assistive devices within the social health insurance system for the years 2021-2022.⁹

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II. INFORMED PATIENT CONSENT FOR PALLIATIVE CARE SERVICES

The provisions of Law 95 of 2006, art. 660-662 and those of Law 46 of 2003, art. 5-10 and the rules for the application of the latter law, constitute the legal basis in regulating the obligation of medical staff to obtain informed consent of the patient and the patient’s right to be informed.

Law 95 of 2006, art. 660, establishes, with few exceptions, the obligation for the doctor to request the informed consent of the patient on the methods of prevention, diagnosis and treatment, with potential risk, after their explanation by the medical staff.

According to Law 46 of 2003, art. 6, the patient has the right to be informed about his health condition. The content of this right includes: the proposed medical interventions, the potential risks of each procedure, the existing alternatives to the proposed procedures, including those regarding non-performance of treatment and non-compliance with medical recommendations, as well as data on diagnosis and prognosis. This in the conditions in which, the same normative act, provides in art. 1, lit. d), as by medical intervention is meant any examination, treatment or other medical act for the purpose of preventive, therapeutic or rehabilitation diagnosis.

The informed consent of the patient is requested in writing in the conditions in which the medical staff is obliged to present the information to the patient at a scientifically reasonable level for his understanding, according to the provisions of Law 95 of 2006, art. 660, para. 2, article that corroborates with the provisions of art. 8, paragraph 1 of Law 46 of 2003, according to which, the information is brought to the patient’s knowledge in a respectful, clear language, with the minimization of the specialized terminology.

Law 95 of 2006, art.660, paragraph 3, expressly regulates the content of information that must be transmitted to the patient to obtain informed consent: diagnosis, nature and purpose of treatment, risks and consequences of proposed treatment, viable treatment alternatives, risks and consequences, prognosis of the disease without the application of treatment.

The paradigm of the patient’s informed consent regarding the medical act and the patient’s right to information, both prior to obtaining the informed consent and during the medical act, widely developed in the doctrine (Turcu I., 2010) are two constants of medical activity.

In our opinion, they are applicable and palliative care services, regardless of their level, except self-care and independent and the location where the services are performed, so for those provided at home patient or locations of "hospice".

We base this support on the fact that, within the meaning of Law 46 of 2003, art. 1, paragraph 1, letters c, d and e, the concepts of "health care" and "terminal care" are defined. If the first concept designates both medical services and community and related services, the concept of "terminal care" refers to the care provided to a patient with the available means of treatment, when it is no longer possible to improve the fatal prognosis of the disease and care granted near death. Consequently, for all these categories of care, in extensor indicated ut supra, the
rights of patients, provided in Law 46 of 2003, including the right to be informed, are objectified.

Moreover, according to the provisions of art. 662 of Law 95 of 2006, because obtaining the informed consent of the patient is a legal obligation of medical staff, failure to fulfill this obligation, except in cases expressly provided by law, entails the liability of medical staff. The fact of not obtaining the informed consent of the patient attracts the civil liability of the medical staff, according to the provisions of art. 653, para. 3.

Consequently, the fulfillment of the obligation of the medical staff to obtain the informed consent of the patient and the assurance of the patient’s right to information, become qualitative criteria in the content of palliative services. We support this all the more as palliative services are provided to people in a degree of acute vulnerability, for patients among the most exposed and in a state of emotional fragility.

But, it is necessary to point out another nuance here, the patient’s right to information does not turn into the obligation for the patient to receive information on his health. The patient may refuse medical information regarding the diagnosis, prognosis of an incurable disease or may designate another person to be informed in his place. The provision is based on the right of each being to decide whether he wants to be informed if the information presented by the medical staff would cause him suffering. Providing quality palliative services is a difficult goal to achieve. Even if at the legislative level the field is regulated, we find the applicability of a series of regulations in the medical field, such as those regarding informed consent and the obligation to inform the patient, which are true standards of performance in palliative services.

**CONCLUSIONS**

Development care palliative is a necessity national aspect revealed by R intake "assessment of palliative care services in Romania" implemented by the Ministry of Health for the World Bank, where he notes that "Over 172,000 patients have needed annually palliative care Romania, but in almost half of Romania’s counties (17) there is no such service ... only less than 2% of family doctors in Romania have basic training in palliative care."

There are many barriers in providing palliative care services related to health policies, medical education, training of health professionals, but also patients and their families, limited availability of palliative services at the national level. Along with these barriers, psychosocial aspects such as communication and perception of bad news, the state of vulnerability given by terminal illness, the financial impact of illness and death, are factors that medical staff, with all the vicissitudes of the profession during the pandemic, revealed in the doctrine. (Apan. R.D., Bala C.G, 2021), as well as all persons involved in palliative services should be taken into account.
account. And that's because "You only see clearly with your heart. The core of things cannot be seen with the naked eye." Antoine de Saint Exupery, "The Little Prince". (Sections 1 and 2 were drafted by Burz C and section 3 by Apan R).

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