

OPINION

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of a dissertation for the award of the educational and scientific degree "Doctor"

in the field of higher education 3. Social, economic and legal sciences

professional field 3.6 Law

doctoral program "Administrative Law and Administrative Procedure"

Author: Emilia Yordanova Angelova-Khovagimyan

Topic: "Public law aspects of patient safety"

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1. General presentation of the procedure and the doctoral student

The procedure was announced at the Faculty of Law of the Paisii Hilendarski University of Plovdiv. The candidate has submitted a full set of documents, according to the regulations. The contest documents correspond to Law on the Development of the Academic Staff in the Republic of Bulgaria, Rules for application of the law for development of the academic staff in the Republic of Bulgaria and the regulations of PU "Paisii Hilendarski". The evaluation of the proposed materials in the contest shows that there are conditions for applying for the educational and scientific degree "Doctor".

The doctoral student Emilia Yordanova Angelova-Hovagimyan graduated in consecutive business management / bachelor /, financial management / master / and law at the University of Plovdiv "Paisii Hilendarski" in the period between 2003-2018.

Emilia Yordanova Angelova-Hovagimyan is an active lawyer with practice in the health sector. Fluent in English and Turkish to varying degrees.

2. Relevance of the topic

The actuality of the researched problem in the dissertation in scientific and scientific-applied terms is determined by the intensive development of public relations in the field of healthcare, in a direction that puts patients safety as a priority issue worldwide. The topic is of interest during the various historical stages of development of medicine. Numerous studies have been conducted and various results have been provided in the direction of the topic discussed in the dissertation, with academics, politicians, health professionals, various organizations and others involved.

In the dissertation many specific tasks, united in the topic set for research, are developed. The most prominent of them are:

- public law aspects of patient safety;
- patient safety as a mandatory condition for the implementation of quality health care;
- criteria set out in legislation to improve health care in general and to minimize adverse medical events;
- the normative definitions for patient safety, for a patient, for the right to safe treatment;
- the main legal relationship between doctor and patient;
- analysis of the participants in the process of ensuring patient safety;
- analysis of the relationship between the health system and patient safety in Bulgaria;
- analysis of the health control authorities;
- the quality and culture of medical activity as factors for patient safety.

3. Knowledge of the problem

Emilia Yordanova Angelova-Hovagimyan presents a dissertation and three separate publications from scientific forums. The subject of research are the problems and the development of healthcare and medical law, making an impression that in all scientific activity the doctoral student has focused on the subject of the legal regime in healthcare.

The dissertation "Public law aspects of patient safety" is the first scientific research that examines the problem from an administrative point of view and relates to major institutes of medical law. This is a wide study which shows a new and original vision of patient interests as a special type of public interest. For the first time in Bulgaria, a survey on patient safety was conducted, which includes questions about its importance and needs and seeks answers to the trust of citizens in the control authorities that regulate health care.

The present dissertation is structured in three chapters. The first chapter presents a historical overview of patient safety and traces its development over different historical periods. The analysis of different countries aims to compare foreign experience with that of Bulgaria in order to offer a safer health environment for all patients. The second chapter draws attention to patient safety in Bulgaria, the adopted programs for improving the health of the nation, the health control authorities and the legal means for the protection of patients' rights. Chapter three concerns a very important and delicate problem - the quality and culture of healthcare as an integral part of patient safety.

Of interest are the six goals outlined by the author, which must be met by a new health care system - to be "safe, efficient, patient-oriented, timely, effective and fair."

We may agree with the doctoral student's firm opinion that it is necessary a single definition to be created in order to be used in all countries. Patient safety does not only consist in the absence of harm. A prior action (condition) is also required to link the medical service to the avoidance of the injury itself. Hospitals, doctors and patients are part of patient safety and it is necessary to create rules for achieving patient safety, which must be kept by all sides.

We agree with the author that the circle of participants in the patient safety monitoring processes should be expanded. Therefore, the proposal that the future definition should cover the system of rules that everyone must follow - health care, doctors, patients, nurses, midwives, laboratory technicians and pharmacists, and all other persons who are part of the Bulgarian health care. System as well.

With the necessary diligence for a researcher, the doctoral student has analyzed international and regional European acts in the field of health insurance and patients' rights, such as the Universal Declaration of Human Rights; The International Covenant on Economic, Social and Cultural Rights - ratified on September 21, 1970, in force on January 3, 1976; International Covenant on Civil and Political Rights; The European Social Charter - in force for Bulgaria from 01.08.2000; Declarations and Recommendations of the World Medical Association (WMA) and the World Health Organization (WHO) regulating patients' rights - European Convention for the Protection of Human Rights and Fundamental Freedoms 1950, International Covenant on Civil and Political Rights 1966, European Charter of Hospital Patients' Rights 1979; Declaration on Human Organ Transplantation (1987); Declaration on Euthanasia (1987); Recommendation on the legal protection of persons suffering from mental disorders placed in involuntary treatment (CoE Committee of Ministers 1983); Declaration on the Human Rights and Personal Freedom of Physicians (1985); Opinion on trade in viable organs (1985); Oslo Declaration - Opinion on Therapeutic Abortion (1983); Opinion on in vitro fertilization and embryo transplantation (1987).

The analysis of the normative regulation of the patient's rights in Bulgaria makes a good impression in the work. According to the doctoral student, an important problem is the cases when a general norm must be applied as a subsidiary with a medical standard. Some of the medical standards happens very often to be abolished, despite the proper referral. The norm to be referred to good medical practices is a possible solution proposed.

Another good suggestion made in the dissertation is the foundation of a Register of Adverse Medical Events. The author substantiates his proposal in detail. She believes that the registration of adverse medical events, the analysis of their occurrence, the omissions and possible options for their prevention in the future, is the right direction for patient safety. According to her, a "Register for

reporting adverse medical events" in Bulgaria is also needed. This measure would give a clearer picture of the real problems in medical institutions. We support the author's belief that this will be a real opportunity to introduce patient safety systems, as well as to improve the existing rules for the safety of medical care.

The problem with health management is also discussed in detail in the dissertation. The doctoral student defines the healthcare manager as an expert whose task is to perform selected tests, registrations, current appointments, to track the dynamics of the condition, assisting in archiving the collected clinical and paraclinical information according to the current register of medical documents. The conclusion made is that an effective management is possible only when health managers assume the ability to analyze in unity the specific state of the three elements of the health system - entrance, process and exit.

A separate subject of research is e-government, as a guarantor of the development of many of the public problems in the field of health, which will develop in the direction of democratic management of processes and phenomena in society and the establishment of the rule of law: the right to seek, receive and spread information and ideas; the protection of personal data and the correspondence; the integration of disadvantaged people; improving the interaction between public authorities and civil society; to improve the quality of public services and the efficiency of public administration. According to the draft electronic prescription of the National Health Insurance Fund, the benefits for the insured persons are: availability of the prescription in electronic format at any time and from any pharmacy; reducing errors caused by misinterpretation of the manuscript on recipes; history of prescribed medications - part of the electronic file; reduction of waiting time in pharmacies.

Another problem that was discussed in the study was medical mistake. The medical mistake, according to the author, supposes illegal or incorrect behavior of the medical specialist, which can be both action and inaction. This behavior is a break of the established rules of medical science. But it is also a break of the rules established by legal norms. The basis of the medical mistake is the incorrect action, where: a) there is a break of the rules of medical science and practice; b) there is a offence of the patient's rights (for information, etc.); c) there is a break of legal and administrative requirements.

The study also research the questions of compulsory professional liability insurance. In this regard, the author makes an interesting proposal *de lege ferenda* a "National Patient Benefit Fund" to be created. This fund will be state-owned and will participate in the future compensation of damages. The collection of the obligatory contributions to this fund might be realized by the private insurers, collecting allowances from the participants and depositing them in the state treasury. Future benefits need to have a predetermined maximum threshold.

Attention is also paid to the main differences between medical professional crimes and good faith mistakes, most often the different conditions and reasons for their occurrence.

The problem of patient safety training was also observed in an informative manner. The author takes the position of the World Health Organization, according to which patient safety

education should begin at the bachelor's level. This training should be not only for medical students, but also for all students in health professions. In some countries, studies have been launched to include patient safety training. Interesting examples are countries such as the United States, Canada, and Australia, which have initiated a gradual approach to patient safety education by providing patient safety training in nursing schools and other health schools.

4. Research methodology

The research is presented mainly in a descriptive and analytical perspective. The methodology chosen by the author is based on a collective approach, which aims to consider the chosen topic from all possible angles of knowledge. A huge amount of information has been collected, mainly from Internet sources, which are indicated and arranged earnestly. The number of literary sources, which are not fully presented in the dissertation, is not small. The collective approach is also part of the contributing moment of the dissertation work, which represents a really serious volume of information in the field of public law regulation of medical activity.

A lot of information is presented about the state of the considered problems in international aspect. This helps to achieve the set goals, namely, an up-to-date analysis of the state of the considered problems in our country, compared with the leading countries in Europe and North America.

5. Characteristics and evaluation of the dissertation and contributions

The work is dissertable. The topic is voluminous, undeveloped and provides an opportunity for the author to contribute with enough innovations in the field of medical law and medical administration in our country. This predetermines the serious number of *de lege ferenda* proposals that the doctoral student has tried to offer to the doctrine and practice. The aspiration of the doctoral student to formulate specific normative draft proposals is also the main prerequisite for deriving the contribution moments in the work.

Contributing moment in the study is the considered many definitions of patient safety in a global aspect. Although they are different, they are united by the idea of safe medical care and safety for patients when they are treated. The author finds that there is no single definition that is perceived as uniform. A comparison is made between the most common definitions that have been imposed around the world and continue to be the basis and philosophy of patient safety.

Manifestation of research courage is the author's proposed definition of patient safety.

Other contributions that the dissertation contains are:

- listing the important steps that have been taken in Bulgaria in recent years for the overall improvement of the health of the citizens, the created programs and strategies.
- the proposed measures to improve the health policy, which will guarantee at the same time to all citizens / patients quality and safe treatment;
- proposals for improving the work of the Academy of Medical Sciences;

- a proposal de lege ferenda to set up a "Patient Safety Agency" and a "Registry for reporting adverse medical events";

- presentation of the global models for quality management in various branches of human activity, including in the field of medical care - the Deming cycle - Deming Plan-Do-Check-Act (PDCA), the excellent model of the European Foundation for Human Resources Management quality - (EFQM - excellence model), standards from the series International Organization for Standardization (ISO) and accreditation;

- a proposal de lege ferenda that the continuing education of the IMP and the IDP be compulsory, which obligation is regulated by law, as well as the attestation of all doctors every three years (attestation to be anonymous) in order to monitor the level of each medical institution and the offered health services.

6. Evaluation of the doctoral student's publications

Along with the dissertation, Emilia Angelova-Hovagimyan presents for review three separate publications, presented as reports at established scientific forums. The publications meet the legal requirements as they are published in referenced collections and carry the necessary points for obtaining the educational and scientific degree "Doctor".

The report "Patient safety in a state of emergency in Bulgaria" summarizes the main topics that have been extensively developed in the dissertation. Its relevance is related to the detailed analysis of the current state of emergency in Bulgaria.

The report "Administrative violations and types of administrative penalties imposed on providers of medical and dental care - contractual partners of the NHIF" examines the administrative and criminal liability of providers of medical care, regulated by the National Framework Agreements. The administrative-punitive authorities, the specific administrative violations, the administrative penalties imposed for these acts are considered. An interesting point is the analysis of the different types of control carried out by the National Health Insurance Fund.

CONCLUSIONS

Based on the findings set out above, I evaluate "positively" the research work of doctoral student Emilia Angelova-Hovagimyan. I believe that it meets the requirements of Law on the Development of the Academic Staff in the Republic of Bulgaria and the Regulations for its application for the award of educational and scientific degree "Doctor" and I propose to the esteemed Scientific Jury to take a positive decision on the procedure announced by the Faculty of Law of Paisii Hilendarski University.

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Prepared the opinion:

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