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The legal protection of individual rights in the health care sphere: overcoming the ambiguity of the legal regulation of voluntary and informed consent to treatment

Introduction

The legal protection of individual rights presupposes provision of legal certainty in the regulation of social relations. First of all, legal certainty depends on law making activity carried out in the law creating process of legislative bodies of the state authority as well as participation in law creating (law establishment) of other state bodies and their officials. However, attention should be drawn to the problem of providing bodies by the application of law, above all judicial, for the legal certainty of regulation where there is: legal ambiguity, collisions and contradictions between law provisions (statute provisions) of the legislature and a gap in law (legislation).

The ways of overcoming legal ambiguity are discussed in modern scientific literature and used in the legal practice. Traditionally, formal certainty of law is considered one of its key characteristics. In the context of the matter under inquiry formal certainty means clarity in the requirement to determine the sphere of legal regulation, circumstances, and the facts which are of a legal nature and bring about legal consequences. The formal certainty requirement of normative-legal regulation presupposes that acts containing law provisions must be stated (written) according to the rules of the state language as well as technical legal rules of law making (legislative in a broad sense) activity.

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The content of legal norms must be formally expressed and in this sense technically legally defined: in the legal prescripts (provisions) of articles and clauses of legislative acts.[1] The structure of a legal norm as a logical model of legal regulation of social relations cannot coincide to a full extent with the structure of a particular article or a clause of a legislative act.[2] Thus, the question about certainty or ambiguity of legal regulation and gaps in law cannot be resolved from the standpoint of a particular clause, article of a specific legislative act. It must be resolved in the context of the system of legal norms, legal principles, and legal practice.

1. In the process of law establishment, the content of legal norms is externally expressed in the texts of legal sources of law, with legal regulation taking on the properties of legal (formal) certainty. Following the rules of legislative drafting technique, the legislator in some cases in the very text of the norms of a statute uses the notions, terms, definitions presupposing their legal interpretation in these socio-cultural context in compliance with the requirements of the entire system of legal norms (legal regulation).[3] It is important that within the framework of a national legal system all sources of law do not exist separately but belong to a single system of sources of law of the state, to a single space of legal regulation. For example, in the Russian Federation, the inner structuredness of a legal norm as a legal-logical model (hypothesis, disposition, sanction) can be formally captured (actualized, objectivized) not only in these and those articles of one statute, but also in the articles of several statutes, for example, federal and regional statutes, in the constitutional articles, in the provisions of the highest courts' acts.[4]

As discussed in the legal literature, the properties and characteristics of legal regulation should piece together the theoretical foundation of the constitutional (legislative) definition of the state-legal regulation sphere. This will eliminate and stand against legislative drafting and law appli-

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[1] M.A. Kapustina, *Normativno-pravovoe regulirovanie: formalnaya opredelennost' pravoustanovleniy v usloviyakh integratsii v evrasiyskom prostranstve*, „Evrasiyskiy yuridicheskiy zhurnal" [*Normative-legal Regulation: Formal Certainty of Law provisions in the Context of Integration in Eurasian Space*, "Eurasian Legal Journal"] 2016, no. 7 (98), p. 134.

[2] S.S. Alekseev, *Voshozhdenie k pravu. Poiski i resheniya* [*The rise to law. Search and solutions*], Moscow 2001, p. 97-98.

[3] For example, in Art. 205 of the Civil Code of the Russian Federation, the notion "valid excuse" is used (St. 205 Grazhdanskogo kodeksa RF//SZRF [Art. 205 of the RF Civil Code//The Corpus of the Legislation of the Russian Federation], 1994, № 32, Art. Art. 3301, 3302).

[4] M.A. Kapustina, *Pravovaya opredelennost' i formalnoe ravenstvo kak printsipy normativno-pravovogo regulirovaniya,* „Printsip formalnogo ravenstva i vzaimnoe priznanie prava: kollectivnaya monografiya" [*Legal Certainty and Formal Equality as Principles of Normative-Legal Regulation*/ "Principle of Formal Equality and Mutual Recognition of Law", ed. V.V. Lapaeva, A.V. Polyakov, V.V. Denisenko, Moscow 2016, p. 29-30.

cation arbitrary behavior (abuse of power) while detecting and filling gaps in law. The lack of legally defined boundaries of state-legal regulation can lead to: violation of the principle of lawfulness; abuse of state authoritative powers; restriction of human freedom; and infringement of human rights. In a constitutional state, the principles and limits of state-legal regulation, and the boundaries of possible gaps in legal norms must be entrenched (formalized) in the Constitution as a fundamental law that no other normative or law application acts may contravene, as well as in codified legislative acts. Gaps are taken for granted, considered as an obligatory element of any legal system due to its imperfection. However, one should admit that in the legal literature there is no consensus of opinion about the question of the definition of the concept of a gap in legal regulation. In particular, it is not correct to confuse the notion of a gap in a statute and the abstractiveness of a normative prescript of a statute. This is because the legislative technique is developing from casuistical prescripts in detail, regulating a particular question to an abstract, normative regulation. As a result, in a norm stated in an abstract way, for example, in a permissive rule, the law enforcer can spot a gap of the legislator who has not thoroughly regulated the right of the party to legal relations.

E. Tsytelman stressed the impropriety of the substitutions of notions of gaps in legal regulation and the abstractedness of normative regulation.[5] He drew attention to this problem a hundred years ago. Real gaps requiring filling can be detected in a situation when there is not even an abstract law for the case. The checklists of evidence that were once distinguished in the Arbitral Procedural Code of the Russian Federation (the checklist was open-ended and contained the words "… other papers and materials") and in the Civil Procedure Code of the Russian Federation (the checklist was limiting) can serve as examples of real gaps. And this led to the ambiguity (gap) of the legal status of new sources of information such as audio and video records in civil trials. In the modern Russian law a real gap is seen in the lack of legal regulation of the issue whether a fetus can be an object of civil-legal transactions, an object of clinical testing, an object of criminal-legal defense.[6] Most strikingly, gaps become apparent where ex-

[5] In support of this, E. Tsytelman referred to relatively defined sanctions of criminal law establishing the statutory cap and floor of punishment. And nobody calls such criminal law norms as containing gaps. See: E. Tsytelman, *Probely v prave (rech' proiznesennaya pri vstuplenii v dolzhnost' rektora Reinskogo universiteta im. Fridrikha Wilgelma v Bonne 18 oktyabrya 1902 g.),* „Rossiyskiy ezhegodnik teorii prava" [*Gaps in Law (the inaugural address of the President of Rhine University named after Frederick Wilhelm in Bonn on the 18th October 1902),* "Russian Annual of Law Theory"] 2010, no. 3, p. 624-625.

[6] G.B. Romanovskiy, *Pravovoe regulirovanie biomeditsinskikh tekhnologiy* [*Legal Regulation of Biomedical Technology*] „Pravovedenie" 2011, no. 4, p. 112-118; A.V. *Maleshina, Ugolovno-pravovaya okhrana "budushchey zhizni"* [*Criminal- Legal Protection of "future life"*] „Pravovedenie" 2011, no. 3, p. 140-151.

isting legal norms make provisions for the necessity of certain actions but do not establish the order or the form of performing the actions and do not settle a date or the amount of the recovery of the penalty. Similar technical gaps, according to many jurists, interfere with law application and require correction. They create legal ambiguity in the question about the way, the form and the date of the realization of legislative rule from the standpoint of the legislator.[7]

2. The institution of informed consent is included in the system of legal regulation of medical practice in many countries and into the system of international law.[8] There are the legal standards of realization of human rights to voluntary informed consent. For example, according to Article 5 of the Convention on Human Rights and Biomedicine, 1997, any intervention in the health field may only be carried out after the person concerned had given free and informed consent to it. The refusal of some medical services should not contradict the "important public interest" and "should be established unequivocally and made with full knowledge of the facts."[9] The right to information about health services is a relatively new institution in the Russian law.

The institution of voluntary and informed consent to treatment ensures for patients the implementation of human right to a voluntary decision which is not made under any form of duress, about obtaining medical services in accordance with their own attitudes, beliefs and values. It is based on the principle of legal equality of patients in the process of getting them medical care.[10] The completed and signed by the patient form of informed consent to treatment is a patient's permission to medical intervention, which was given by him deliberately, with understanding and without external influences.[11] According to Article 20 of the Federal Law of 21.11.2011 № 323-FZ "On the Basics of Citizens' Health in the Russian Federation"[12] patients

[7] M.A. Kapustina, *Konstitutsionno-pravovoe regulirovanie: ustanovlenie I vospolnenie probelov v prave* Russian "Constitutionalism in the Context of Historic-Legal Studies" [*Constitutional-Legal Regulation: Detection and Filling Gaps in Law*] St.Petersburg 2014, p. 44-62.

[8] M.A. Kapustina, E.A. Bondareva, *The right to information about health services: legal safeguards in the system of legal regulation of relations in health care*, In: *Zasada proporcjonalności a ochrona praw odstawowych w państwach Europy the principle of proportionality and the protection of the fundamental rights in the European states*, ed. P. Szymaniec, Wałbrzych 2015, p. 318.

[9] See, for example: case Hermi vs Italy (No. 18114/02)/ http://echr.ketse.com/doc/18114.02-en-20050628 and DH and Others vs Czech Republic (No. 57325/00)/ http://hudoc.echr.coe.int/sites/eng/pages/search.aspx?i=001-83256#{"itemid":["001-83256"], European Court of Human Rights.

[10] A.N. Pishcheta, *Consent to Treatment*, Moscow 2006, p. 20.

[11] A.A Etel', *Informed consent as an autonomous solution to medical intervention*, "Administrative Law and Procedure" 2006, no. 2, p. 35.

[12] Federal Law of 21.11.2011 № 323-FZ "On the Basics of Citizens' Health in the Russian Federation" [Ob osnovakh okhrany zdorov'ya grazhdan v Rossiiskoi Federatsii].// The Corpus of Legislation of the Russian Federation. 2011. № 48. art. 6724. (with amendments and additions on 29.12.2017).

have the right to obtain information about health services, to consent the rendering of service or to refuse it. She/he has a right to obtain both information about the upcoming treatment, associated risks, and forecast outcome of treatment, and the consequences of refusal of medical care.

3. The consent to medical treatment must be given by patients before any examination, treatment or care. The patient must have enough time to make the required decision, getting in some cases additional information necessary to its making. But there is the ambiguity of legal regulation of the issue of the waiting period between obtaining the patient's consent and the initiation of treatment. In the Russian Federation this waiting period is not legally established. And patients, in practice, have to give the informed consent just before the medical treatment. In the European Union, there is no clear legal regulation of this issue, either: from a few days to a week, or up to several months.[13]

She/he must give consent to treatment voluntarily, i.e. not under any form of duress or undue influence from health professionals, family or friends. The problem is that in some cases the patient may be in a such physical and (or) mental state that he or she is not able to deal adequately with the provision of information about medical intervention and, consequently, to decide on their approval or disapproval of medical services (for example, in connection with a loss of consciousness, being in coma or suffering from mental disorder).[14] In this type of situation, there may be a disabled person or a child in need of medical care. Informed consent to treatment means that the patient has received all necessary information to give a consent or to refuse medical intervention, information about all procedures, about every action of a medical nature to have the opportunity to get the necessary medical care, but to abandon any particular medical procedure or its specific form, for example, to refuse general anesthesia, but to agree to a different type of anesthesia. It is very important that the medical information is understood by the patient.[15] These legal standards are expressed in the positions of the European Court of Human Rights[16]

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[13] M. Mikkola, *Right to Health as a Human Right in Europe*, "Medicine and Law" 2012, no. 3, p. 262.

[14] M.A. Kapustina, E.A. Bondareva, *op. cit.*, p. 321.

[15] A.A Etel', *op. cit.*, p. 36; N.N. Shtykova, *Ensuring patients' rights to informed consent to medical intervention in the Russian Federation*, "Ensuring the Individual Rights and Interests of the State in Modern Society", Murom 2004, p. 37.

[16] For example, the European Court of Human Rights in the case Glass vs UK (No. 61827/00) stressed that "Parents need sufficient information before they can decide whether to give their consent: for example, information about the benefits and risks of the proposed treatment and alternative treatments. If the patients are not offered as much information as they reasonably need to make their decision, and in a form they can understand, their consent may not be valid."/ http://docs.pravo.ru/document/view/19381620.

and recommendations of the World Health Organization and aimed to protect individual rights in the health care sphere.

The legal certainty principle in the health care sphere means that the patient should be provided with sufficient and accessible medical information not only by the clear to her/him terms and words, but also in plain and understandable national language.[17] So today this principle covers several problems. How to provide the right to medical care if the patient is deprived of hearing and/or eyesight? And today there is a problem of legal protection of individual rights in the health sphere in the situation with a patient-foreigner who cannot communicate with a doctor in the same language. For example, in the Russian Federation everybody has the right to medical care irrespective of his citizenship. But these problems have not been solved yet in the Russian legislation. Moreover, since a consent to medical treatment must be given by patient voluntarily, without any form of health professionals duress or influence to her/him,[18] so the paternalistic mode of behavior of health workers must be excluded from the medical practice.[19]

Conclusions

Thus, the legal certainty and gaplessness of health services regulation is provided for by the entire system of the sources of law through systemic interconnections of the dispositions, hypothesis and sanctions of legal norms. A legal norm is formal by nature in the sense that it represents a formal standard of medical care. It serves as a legal criterion for evaluation of an entity's action as legal or non-legal. The philosophical aspect of gaps in law and legal regulation certainty reflects the essential peculiarities of original theoretical ideas about the essence of law, about legal freedom. So, in particular, from the philosophical and methodological points of view, it is very difficult to formally define the criteria for a free solution. Probably, within the framework of law philosophy the theoretical-methodological foundation for overcoming the ambiguity of legal regulation within the scope of formal jurisprudence should be worked out.

From the theoretical and methodological[20] points of view, the overcoming the ambiguity of legal regulation in health care sphere requires a def-

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[17] H.J.J. Leenen, J.K.M. Gevers, G. Pinet, *The Rights of Patients in Europe: A Comparative Study,* Deventer–Boston: Kluwer 1993, p. 45.

[18] D.W. Brock, *Paternalism and Autonomy*, Ethics 1988, v. 98, p. 550–565.

[19] See, for example, the case V.C. vs Slovakia, No. 18968/07, the European Court of Human Rights./ http://www.refworld.org/pdfid/4a648cb42.pdf

[20] See in more detail: M.A. Kapustina, *Konstitutsionno-pravovoe regulirovanie: ustanovlenie i vospolnenie probelov v prave* [*Constitutional- Legal Regulation: Detection and Filling Gaps in Law*], *op. cit.*, p. 52-53.

inition of the legal characteristics of medical activity types. These fall into the sphere of state-legal normative regulation, and hence, the boundaries of possible gaps in legal norms.[21] In the law application process the decision on whether disputed social relations are of a legal nature must rely on legislative provisions determining the frame of state-legal regulation. The relations that, for some reason, have not been regulated by the legislator and although they require, from the point of view of the law enforcer, clear legal regulation, should not have legal consequences until the legislator includes these social relations into the sphere of legal regulation.[22]

The institution of informed consent to medical intervention is aimed to protect the individual's rights in the health care sphere. It includes international legal standards of human rights and national health care legislation. The ability of a person to make a free conscious decision, in particular, to give consent to medical intervention due to his or her physical and mental state, is not an obvious question. In much of the world the legal uncertainty regarding obtaining informed consent from disabled people or children is overcome through the institution of representation. Consent to medical intervention should be due to (match) physical and mental condition of the patient, ensuring a person's ability to give consent to medical intervention. Thus, legal representatives must protect the rights and express interests of those whose legal representatives they are.

The ambiguity of legal regulation of the issue of the waiting period between obtaining the patient's consent and starting treatment question requires a legislative solution. Obviously, the waiting period between obtaining the patient's consent and starting treatment should not be unreasonably long. But it is not practical to carry out medical intervention immediately after obtaining informed consent, especially in the case of aggressive interventions (for instance, surgery).

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[21] In Russian legal doctrine, these specific legal characteristics are studied. See, for example: N.M. Korkunov, *Lektsii po obshchey teorii prava* [*Lectures on General Theory of law*], St. Petersburg 1897, p. 37-39, 57, 83; N.M. Korkunov, *Entsiklopediya prava* [*The Encyclopedia of Law*], St. Petersburg 1883, p. 392-394; R.Z. Livshits, *Teoriya prava* [*The Theory of Law*], Moscow 2001; M.A. Kapustina, *Deistvie yuridicheskikh norm vo vremeni.* [The operation of legal norms over time], St. Petersburg 2001, p. 4-5.

[22] M.A. Kapustina, *Probely v prave* [*Gaps in Law*], St. Petersburg 2014, p. 13.

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THE LEGAL PROTECTION OF INDIVIDUAL RIGHTS IN THE HEALTH CARE SPHERE: OVERCOMING THE AMBIGUITY OF THE LEGAL REGULATION OF VOLUNTARY AND INFORMED CONSENT TO TREATMENT

Abstract: The individual rights in the health care sphere are ensured, among other things, by overcoming uncertainty in legal regulation. The problem of ambiguity, filling gaps, contradictory to legal regulation is of relevance in the court hearings of specific cases in the health care sphere. The health care sphere is one of the most important spheres of the legal protection of individual's rights, because it concerns all the population. In modern medical law, the standardized approach to the regulation of relations in the health care sphere has received widespread recognition. The notions "standard" and "order" are widely applied to the regulation of medical activity and patients' rights. In the health care sphere the ambiguity of legal regulation is connected with requirements of getting from patient informed consent to treatment. The informed consent must be given by the patient voluntarily and before the medical treatment.

Keywords: LEGAL PROTECTION OF INDIVIDUAL RIGHTS, HEALTH CARE LEGISLATION, AMBIGUITY OF LEGAL REGULATION, CONSENT TO TREATMENT, LEGAL PRACTICE IN THE HEALTH CARE SPHERE