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DEVELOPMENT OF NATIONAL REGULATION OF EHEALTH IN THE EAEU

DESENVOLVIMENTO DA REGULAÇÃO NACIONAL DE EHEALTH NA EAEU

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ABSTRACT

Objective: The article discusses the regulatory and legal possibilities for the development of supranational regulation of eHealth in the EAEU.

Results: The authors identify common problems of current regulation in individual EAEU countries and propose to establish basic ideas, principles, and provisions at the level of





laws with the delegation of the right to regulate public relations at the executive level at the first stage, which will allow creating effective legal regulation that meets modern requirements. Following the results of the approbation of legal regulation, it will be necessary to consolidate at the level of legislative legal acts provisions that contribute to the development of digital healthcare.

Conclusion: The authors conclude that the formation of a supranational digital contour in the field of healthcare is possible only after the formation of the main elements of digital healthcare in the EAEU countries (in particular, electronic document management, information systems, etc.).

Keywords: eHealth, legislation of the EAEU, legislation of the Russian Federation, digital medicine.

ABSTRATO

Objetivo: O artigo discute as possibilidades regulatórias e legais para o desenvolvimento da regulação supranacional da eHealth na EAEU.

Resultados: Os autores identificam problemas comuns da regulação atual em cada país da EAEU e propõem estabelecer ideias básicas, princípios e disposições no nível das leis com a delegação do direito de regular as relações públicas no nível executivo na primeira fase, que permitirá criar uma regulamentação legal eficaz que atenda aos requisitos modernos. Na sequência dos resultados da aprovação da regulamentação legal, será necessário consolidar ao nível dos diplomas legais disposições legislativas que contribuam para o desenvolvimento da saúde digital.

Conclusão: Os autores concluem que a formação de um contorno digital supranacional no campo da saúde só é possível após a formação dos principais elementos da saúde digital nos países da EAEU (em particular, gestão eletrônica de documentos, sistemas de informação, etc.).

Palavras-chave: eHealth, legislação da EAEU, legislação da Federação Russa, medicina digital.

1. INTRODUCTION

The active spread of digital technologies has led to their introduction into all spheres of life, the qualitative renewal of these areas.



The process of informatization has also affected the most important area – healthcare. The development of digital medicine will improve the quality of medical care and make it more accessible and effective.

The transition to a new management model, which will be based on high-tech products based on scientific knowledge and innovative technologies (Knyaginina, 2017), in each state is followed by its path of development; thus, the world experience is necessarily taken into account.

Considering the global transformation of social relations, due to including migration processes (both internal and external), scientific and technological progress, development and mobility (no restrictions on the interaction between people using the Internet), client-centricity (model health organization built around the needs of the patient, involving the integrated management of health), and DataContract (arrays of data about the health of the population, based on which effective decisions are made for the treatment of individual patients, as well as solutions in the field of health) (Amelin & Bessonov, 2019; Batsina et al., 2020), the formation of a supranational digital circuit in healthcare is an important issue.

2. METHODS

A qualitative study was carried out of the general problems of the current regulation of eHealth in individual EAEU countries, as well as the possibilities of creating its effective legal regulation that meets modern requirements to determine the regulatory and legal possibilities for the development of supranational regulation of eHealth in the EAEU.

Structurally, the study consisted of a consistent analysis based on selected legal acts and scientific sources of the main provisions of the transformation and integration of digital healthcare within the EAEU, as well as the possibilities of using electronic medical records as the basis of electronic document management in the modern healthcare system.



When forming the research source base, the search for scientific research on the Internet was carried out using the following keywords: "EAEU", "legal regime", "healthcare sector", "medical information systems".

The source database has been updated by the time of publication, starting from 2019 to the present, and is also limited by the requirement of free access to the necessary materials.

At the first stage of the study, the selected information was grouped depending on the type of documents. The first group included regulatory acts in the field of healthcare of the EAEU member states. The second group of documents: scientific research on the characteristics of the state of medical information systems and the digital transformation of the healthcare sector (articles from scientific peer-reviewed journals indexed in Scopus and Web of Science).

The collected information was processed at the second stage of the study, which made it possible to determine the regulatory and legal possibilities for the development of supranational regulation of eHealth in the EAEU.

3. RESULTS

Transformations and integration within the EAEU in the field of digital healthcare (Russia, Belarus)

The global informatization of healthcare has also affected the member countries of the EAEU, which includes Armenia, Belarus, Kazakhstan, Kyrgyzstan, and Russia.

Integration within the EAEU in the field of digital healthcare will significantly improve the quality of medical care, including the possibility of continuous exchange of experience between specialists at various levels (not only within one country).

Digitalization of healthcare primarily requires the formation of a unified information space, the introduction of electronic medical records (electronic document management), the development of telemedicine, etc. The analysis of the legal regulation of telemedicine in the EAEU countries was carried out in a separate study (Akulin et al., 2020a).



There is an active stage of transformation of the healthcare sector in Russia. The significant progress made in the digitalization of healthcare in the Russian Federation, however, is constrained by several factors at the federal level (for example, insufficient legal regulation of certain issues) and at the regional level (lack of specialized personnel, funding, etc.) that require modern solutions (Romanova, 2020). The study of certain issues in the field of digitalization of healthcare was carried out, including in the following works (Akulin et al., 2020b).

The development of digital healthcare in Russia is differentiated. Moscow has achieved great success in the development of this direction.

A.A. Kartskhia rightly notes in his work that a single information space is being successfully formed in Russia at present. Considering the features of the territorial structure of the Russian Federation, this space has a three-level structure: federal, regional (state information systems of the subjects of the Russian Federation), and individual (information systems of medical organizations) (Aptekman et al., 2017).

In the course of the analysis of the trends in the development of regional medical information systems, we concluded that there is insufficient legal regulation, identified existing legal gaps and conflicts (Akulin et al., 2020c). The development of a unified information space within the country is impossible without regulating not only the technical side of the issue but also the legal one.

The problem of insufficient legal regulation of turnover and protection of medical data is of particular importance. Given the "sensitivity" of such personal data, it is necessary to properly regulate the process of exchange and processing of the personal data of the patient. The doctrine also actively discusses the need to create a solid regulatory framework that will guarantee the protection, confidentiality of medical data, as well as the availability of digital healthcare systems (Kartskhia, 2021).

The need for legislative support for effective digitalization of healthcare in the form of the development and adoption of regulatory legal acts (on telemedicine, consumer protection of eHealth services, its state regulation) is also voiced by scholars in the EAEU countries, including Belarus (Shandora, 2020).



The lack of a legal framework for the functioning of eHealth is also mentioned as one of the problems of digital healthcare in the Republic of Kyrgyzstan (Ministry of Health of the Republic of Kyrgyzstan, 2018).

Therewith, the rules prescribed in detail at the level of laws are often an administrative barrier, since they do not have much flexibility and adaptability to rapidly changing social relations. In this connection, we believe that at the first stage it is necessary to consolidate exclusively basic ideas, principles, and provisions at the level of laws with the delegation of legal regulation to the level of executive power. This delegation will allow quickly creating legal norms that meet the conditions of flexibility.

In particular, in the Russian Federation, based on Federal Law dated July 31, 2020, No. 258-FL "On experimental legal regimes in the field of digital innovations in the Russian Federation", experimental legal regimes in the branch of digital innovations in the field of medicine can be created, including on the application of telemedicine technologies and technologies for collecting and processing information about the health status and diagnoses of citizens, pharmaceutical activity, since this law provides for the possibility of special legal regulation (State Duma of the Federal Assembly of the Russian Federation, 2020).

Based on the results of the tested legal norms, we consider it necessary to consolidate unified provisions at the level of legislative legal acts of the EAEU member states that set the vector of legal regulation in the field of digital healthcare.

In the light of the problem under consideration, the experience of the Republic of Kazakhstan is interesting, in which, to create legal conditions for the digitalization of the healthcare industry, the Code of the Republic of Kazakhstan No. 360-VI of July 7, 2020 "On the Health of the people and the healthcare system" was developed and adopted, chapter 7 of which is devoted to digital healthcare (Parliament of the Republic of Kazakhstan, 2020).

This regulatory legal act establishes definitions of basic concepts (digital healthcare, personal medical data, tele-health protection, telemedicine network, electronic health passport (EHP), etc.), principles of digital healthcare, in particular, ensuring the



protection of health informatization facilities, support for accessibility, objectivity, continuity of medical care, support for improving the quality of medical services, etc. According to Article 58 of the Code of the Republic of Kazakhstan dated July 7, 2020, No. 360-VI "On the health of the people and the healthcare system", digital healthcare is understood as "the use of digital technologies for the transformation of medical and administrative-management processes of healthcare aimed at improving the availability, efficiency, quality and safety of medical care" (Parliament of the Republic of Kazakhstan, 2020).

The Code establishes the presumption of consent to the collection, processing, and storage of data, defines the procedure for transferring data to the National Electronic Health Passport, establishes rules for access to personal medical data (defines the list of subjects who have the right to access personal medical data) and regulates other issues. It has been established that an individual has the right to access information about his/her health and medical care provided in the National Electronic Health Passport, EHP, as well as tracking the log of access to data.

Thus, in the Republic of Kazakhstan, the basic provisions and principles of digital healthcare have been formed at the level of the law, based on which subordinate regulatory legal acts are adopted and enforced (Ministry of Health of the Republic of Kazakhstan, 2021a).

The provision established by paragraph 13 of Chapter 3 of the Rules on notifying the patient through the user's account on the e-Government web portal in the automatic mode about all cases of use, changes, and additions of personal medical data within the framework of information interaction is also noteworthy.

Order of the Minister of Health of the Republic of Kazakhstan dated June 23, 2021, No. KR DSM-54 approved the Rules for the delimitation of access rights for digital health subjects (Ministry of Health of the Republic of Kazakhstan, 2021b). According to paragraphs 26-27 of these rules, cross-border transfer of personal medical data to the territory of foreign states is carried out if these states ensure the protection of personal data in the manner prescribed by the Law on Personal Data (Parliament of the Republic of Kazakhstan, 2013).



Electronic medical cards as the basis of electronic document management in the modern healthcare system

Digitalization of healthcare cannot be carried out without the creation of electronic document management, including the creation of electronic medical records.

Therewith, the issue of the legal nature of the electronic medical card is often not resolved. In addition, the legislator ignores such issues as the possibility of providing access to an electronic medical record to other persons and, accordingly, the procedure for such provision, the scope of patients' rights (permission, prohibition of access, etc.), including the possibility of making changes to it, the responsibility of persons.

According to the voiced information on the Fourth Forum of social innovations of the regions, which was held from September 9 to September 11, 2021, in Moscow (RBC, 2021), 15 million electronic medical records have already been created in Moscow. At the moment the digitalization of children's cards is being actively carried out, several children's clinics have already switched to electronic document management, due to which a huge number of obsolete documents, certificates, etc. have been canceled. A medical decision support system has been introduced in Moscow since 2019, which not only helps a doctor make a diagnosis but also contributes to the training of doctors. The exchange of experience and knowledge at such forums undoubtedly contributes to the introduction of best practices in the regions.

In the Republic of Armenia, the right has been granted to the patient to block the access of a medical professional to an integrated electronic medical history, to obtain information about all persons who had access to an electronic medical history (Armed, n.d.). In the Republic of Kyrgyzstan, the following right of patients is defined – this is the patient's management of access data to the patient's own EHP: the creation of a power of attorney and management of the entered data of other persons; management of the patient's EHP data, access to which the patient wishes to close. The authorized person has the right to view the EHP data, as well as perform actions with them (Government of the Kyrgyz Republic, 2019).



Earlier, the authors noted the problem of filling electronic medical records in Russia only with a certain set of medical documents and information (not everything that is available in the arsenal of a medical organization), including due to the imperfection of the legal framework on this issue (Akulin et al., 2020c).

In the Republic of Kazakhstan, Order of the acting Minister of Health of the Republic of Kazakhstan dated October 30, 2020, No. KR DSM-175/2020 approved the forms of accounting documentation in the field of healthcare (Ministry of Health of the Republic of Kazakhstan, 2020). This document determines not only the forms of accounting documentation, but the type of documentation (electronic, paper, and both options at the same time) and the terms of its storage. It seems interesting that the medical report on the state of health of a foreigner, a stateless person, a migrant, a migrant worker, (including from a member state of the EAEU) form No. 028/y is stored exclusively in paper form (shelf life is 3 years).

4. DISCUSSION

The different amount of data contained in the EHR of the EAEU member states may also give rise to different law enforcement practices, which ultimately will require harmonization of legal regulation.

As already noted, cross-border cooperation within the EAEU is necessary to improve the well-being and quality of life of citizens.

The need to develop global cooperation on the development of digital health is also indicated in the Draft Global strategy in the field of digital health for 2020-2025. The World Health Organization (hereinafter referred to as the Project) (World Health Organization, n.d.).

Special attention in the Project is paid to the need to create and comply with high standards of safety and protection regarding health data. According to WHO, this requires the creation of an effective regulatory framework



ensuring the protection of privacy, confidentiality, integrity, and accessibility of data and procedures for processing personal health data, as well as contributing to addressing issues of cybersecurity, confidence-building, accountability, leadership, ethics, equality, capacity-building and literacy, and ensuring the collection of high-quality data and subsequent exchange of such data for the planning, implementation, and transformation of relevant services. (World Health Organization, n.d.).

Considering the provisions of the Project, we believe that to form a supranational digital contour in the field of healthcare within the EAEU, it is necessary to adopt the positive experience of the EAEU member countries to improve each country's national strategy in the field of digital healthcare (Soboleva et al., 2021).

The dynamic development of technologies, their use in public and private interests, in our opinion, cannot remain without the attention of the law. Shortcomings of legal regulation (the presence of outdated norms, existing gaps, and conflicts) act as a deterrent factor affecting the development of integration processes within the framework of the EAEU (Bukhovets et al., 2020).

In this connection, the EAEU countries need to establish a new body of legislation containing unified legal norms that ensure the protection of medical data, their proper use, the possibility of recovery, turnover with the establishment of measures "against unauthorized and illegal processing of health data, accidental loss, malicious or unintentional modification or destruction of data" (World Health Organization, n.d.).

We believe that at the level of laws, it is necessary to establish exclusively basic ideas, principles, and provisions with the delegation at the first stage of the right to regulate public relations to the level of executive power. This delegation will make it possible to create an effective legal regulation that meets modern realities. According to the results of the testing of such legal regulation, it will be necessary to consolidate provisions at the level of legislative legal acts that contribute to the development of digital healthcare.

However, the formation of a supranational digital contour in the field of healthcare is possible only after the formation of the main elements of digital healthcare in the EAEU countries (in particular, electronic document management, information systems, etc.).



5. CONCLUSION

The exponential growth in the use of technology in all areas of life requires the active development of the regulatory framework since digitalization has an impact on those values the relations of which are regulated by law. Therefore, in our opinion, the opportunities provided by the digitalization of healthcare should not be hindered by the lack of a legal framework. Therewith, the legal framework of the EAEU countries should be formed on the principles of flexibility and adaptability of legal regulation with parallel harmonization and unification.

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