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DIGITALIZATION OF HEALTHCARE IN UKRAINE: LEGAL SUPPORT OF PUBLIC AND PRIVATE INTERESTS

Abstract. During 2017-2020, Ukraine underwent systemic changes and digital innovations in healthcare. An important tool for modernizing the medical, economic and managerial components of the health care system in Ukraine was the creation of the eHealth system based on the latest information technologies. Modern challenges and threats to public welfare give a powerful impetus for the full use of the potential of digital technologies. Due to the rapid spread of COVID-19, the advantages of digital technologies have worked, which enabled the remote interaction of participants in medical relationships without the risk of transmission. New challenges for the eHealth system were created by Russia's military aggression against Ukraine.

Purpose. The article examines the state of legal regulation of digital technologies in the health care system, keeping a balance between public and private interests, the protection of the rights of participants, some growing threats to public welfare, their impact on the sustainable functioning of eHealth.

Research methods. The research was conducted on the basis of analysis of the legal framework, literature sources, description and generalization of the range of existing achievements and problems in the eHealth sector. Using the dialectical method, the subject of research is considered not in a static one-sided form, but as one that is in the process of formation, development and permanent connection with other processes and phenomena of modern Ukrainian society. Through the use of formal and dialectical logic, objective causal links were established in the subject and conclusions were made on certain areas of improving the legal regulation of eHealth.

Results. The influence of eHealth and some electronic tools on ensuring the interests of the state, society, and the rights of individuals is analyzed. An objective causal link between the digitalization of the health sector and the indicators of quality and safety of health care has been established. Identified current threats to public welfare, their impact on the health care system and the use of digital technologies, analyzed possible ways to resolve them legally.

Conclusions. Based on the study, problems and gaps in the use of digital technologies in the health sector were identified, the need to improve the legal regime of electronic health care services, quality control and safety of their operation / use, integration and electronic interaction of electronic systems health care with other information and communication systems. Among the promising research tasks is the problem of ensuring the standardization of software systems and information security; finding adequate legal balances between ensuring publicity and transparency of open data and protection of private information from unauthorized access; technological and legal regulation of service provision through a modern telemedicine mechanism.

Key words: digitalization of health care, balance of public and private interests, threats to public welfare.

1. Introduction

The eHealth system is an information foundation and an important tool for medical reform in Ukraine, which ensures the rights and interests of all participants in the relationship: patients, doctors, medical institutions, and the state. The use of the latest communication and information technologies has a significant positive impact on overall efficiency and compliance with current public expecta-

tions in such a significant area as health care. In particular, this applies to the efficiency of administration, the accessibility of medical care, and the quality of services.

The combination of tools and services using information and communication technologies at all stages of healthcare management is expected to be a source of efficient use of resources, improving the quality of service, and increasing compliance with standards and overall efficiency of the health sector. The benefits of digitalization have become obvious to ensure the interests of both society as a whole and an individual; both the state and economic entities of service providers; and specific communities and individuals. However, positive shifts do not work automatically without proper legal support, risk management, and threat response.

Some problems of legal support of relations in the eHealth realm have been the subject of scientific analysis of the interrelation of the health sector's digitalization with indicators of medical care quality and safety (Ustymchuk O. V., 2020); the effectiveness and social role of medical institutions in the context of services' digitalization (Horoshko V. I., Hordiienko O. V., 2021; Popovycheva M., Belovycheva M., 2020); the benefits of electronic tools to ensure the interests of the state and the rights of individuals (Batsenko D., Brahinskyi P., Buchma M., 2018); risks and threats to the protection of personal data and privacy (Krytskyi O. 2020; Shcherbak V., 2020); the improvement of technological and legal mechanisms to overcome existing problems (Karpenko O., Osmak A., 2018; Pashkov V., 2018).

At the same time, the following tasks remain relevant: generalization of the current state and prospects of legal regulation of the use of digital technologies in the health care system of Ukraine; striking a balance between public and private interests; analysis of modern problems of protecting the rights of participants in relations, the impact of current threats to public welfare, in particular, new challenges for the eHealth system in the context of military aggression.

2. Legal principles of functioning of the electronic health care system in Ukraine

The latest information technologies have acted as a catalyst and an essential tool for modernizing the medical, economic, and managerial components of the health care system in Ukraine. The Concept of Healthcare Financing Reform approved by the Ordinance of the Cabinet of Ministers of Ukraine No. 1013-p dated 30.11. 2016 notes that the transition to a new system of procurement of healthcare services is accompanied by the creation and continuous improvement of a modern platform for collecting and exchanging medical and financial information in electronic form. From the very beginning, the Ukrainian government set the task of the phased introduction of e-health tools.

Legal issues of the functioning and implementation of eHealth in Ukraine are regulated by the basic normative legal acts: the Law of Ukraine "On State Financial Guarantees of Health Care Services" dated 19.10.2017 No. 2168-VIII and the Resolution of the Cabinet of Ministers of Ukraine "Some Issues of the Electronic Health Care System" dated 25.04.2018 No. 411. These legal documents define fundamental concepts, subjects, tasks, functions, components, and introduction stages of new mechanisms for realizing state-guaranteed medical care in Ukraine.

The Law of Ukraine No. 2168-VIII introduced a new legal mechanism for providing patients with necessary medical services and medicines of adequate quality at the expense of the State Budget of Ukraine under the program of medical guarantees. The advanced principles of ensuring the implementation of the program of medical guarantees and payment for the provision of medical services and medicines are actualized based on the electronic interaction of participants via eHealth. The Resolution of the Cabinet of Ministers of Ukraine No. 411 determines the technical and managerial architecture of the selected two-component eHealth model, which comprises a central database and electronic medical information systems. There is an automated exchange of information, data and documents via an open software interface (API).

The system provides compatibility and electronic interaction of the central database with other information systems and state information resources, i.e., the Unified State Demographic Register; the Unified State Register of Legal Entities, Individual Entrepreneurs and Public Associations; the State Register of Civil Status Acts; the State Register of Individual Taxpayers; information systems of the Ministry of Social Policy; the Unified State Electronic Database on Education; the Unified State Register of the Ministry of Internal Affairs; the Information and Analytical Platform of Electronic Verification and Monitoring.

Document circulation in the electronic health care system is carried out in accordance with the requirements of the Laws of Ukraine, in particular, "On electronic documents and electronic document circulation" dated 22.05.2003 No. 851-IV and "On Information" dated 02.10.1992 No. 2657-XII. The protection of information in the central database is guaranteed by the provisions of the Law of Ukraine

"On Information Protection in Information and Communication Systems" dated 05.07.1994 No. 80/94-VR, and the processing of personal data in the electronic health care system is carried out in compliance with the requirements of the Law of Ukraine "On Personal Data Protection" dated 01.06.2010 No. 2297-VI.

As of now, eHealth is one of the largest electronic systems in Ukraine. E-health functionality allows for a conclusion, amendment, and termination of public health contracts and contracts for reimbursement under the medical guarantees program; preparation and submission of electronic reports, primary, settlement, and other documents under contracts through the central database; registration of users in the central database; preparation, submission, and review of healthcare declarations, prescriptions, referrals, and medical records; exchange of information and documents through electronic offices following user access rights; giving patient (their legal representatives) consent to access their personal data; searching and reviewing information in the central database in accordance with user access rights. The available functionality is constantly updated.

Thus, the essence of medical reform in Ukraine is characterized by two main innovations: a change in financing principle and the introduction of an electronic health care system. E-health acquired its institutionalization precisely as a system of information relations among all participants in medical relations – the state, service providers, medical workers, and patients. The relevant relationships are based on the cost-effective and safe use of information and communication technologies designed to support the health care system, including health services, preventive health surveillance, health literature and health education, knowledge and research.

3. The impact of the digital transformation of health care in Ukraine on striking a balance between private rights and interests of the state

In the course of the actualization of the core elements of medical reform in Ukraine – legal, financial, managerial, technological, and information – important goals of solving existing urgent problems were achieved; the state interest in creating conditions for providing high-quality, affordable services and appropriate guarantees of citizens' rights to health care and medical care was guaranteed. Scholarly studies have established the objective causal relation of the digitalization of the health sector with the indicators of medical care quality and safety. A team of researchers from the University of Sydney prepared a report on behalf of the Australian Commission on Safety and Quality in Healthcare, "Impact of Digital Health on Safety and Quality of Health Care. The experts concluded the following: e-patient portals provide patients with the secure access to their health information and help consumers to become active participants in decision-making about their health care; introducing digital health initiatives into healthcare organisations can produce significant benefits to patients and healthcare providers, in particular, improvements to quality, safety and efficiency of patient care (Shaw T., Hines, M., Kielly-Carroll C., 2017, p. 4, 6).

O. V. Ustymchuk, in her dissertation research, summarized that healthcare management technologies based on digitalization come into action as factors "reducing the total costs of budgets at all levels to maintain the industry while simultaneously increasing the efficiency, availability, convenience, ubiquity, equality, and gratuitousness of its basic services for primary care, such as: collection, preservation and ensuring the systemic availability of patient data, his/her history; automatic queue management; software assistance to the patient regarding compliance with the treatment regimen; electronic prescription and ordering of drugs, electronic primary counseling" (Ustymchuk O. V., 2020, 4).

As proven by V. I. Horoshko and O. V. Hordiienko, the digitalization of services amid a backdrop of the digital economy improves the efficiency and social role of medical institutions by increasing the availability of services (Horoshko V. I., Hordiienko O. V. 2021, 74). Slovak researchers highlighted the social contribution of an electronization factor towards advancing medical care of patients and protecting their rights in the following areas: reducing the level of financial and pharmaceutical load driven by no duplication in prescriptions, supporting preventive programs and improving public health, home care for immobile patients, continuous monitoring of chronic conditions, etc. (Popovycheva M., Belovycheva M. 2020, pp. 25–26).

Particular electronic tools bring significant benefits to guarantee the interests of the state and the rights of private individuals. The digital format of the certificate of incapacity for work solves several problems in a single shot: control is strengthened, and abuse options are highly reduced; budget funds for the manufacture and procurement of paper forms are saved; time spent by the staff on paper work is cut. Maintaining a special Register of certificates of incapacity for work provides a wide range of opportunities for users, in particular, for entering, processing, searching and publishing information using handbooks and classifiers of state registers, the International Statistical Classification of Diseases and Related Health

Problems (ICD-10) and the International Classification of Primary Care (ICPC-2-E); publishing the registered data periodically. Such legitimate opportunities are available to information exchange entities, insured persons, and insurance carriers.

A crucial part of the central component of the database is the integrated electronic medical record of the patient (EMR), which is a systematic and standardized list of patient medical records in electronic form that can be created in different health care facilities or links to records that can be stored in other information and communication systems. Under its key concept, an EMR is a digital recording available in real-time and focused on the patient's which provides immediate and secure access to patient data for registered users. An EMR gathers patient information.

As clinicians note, "A personalized patient card, which includes specific features, of which the doctor identifies the necessary ones, allows for recording the concrete manifestations of diseases that are crucial for assessing the social adaptation of the patient and his need for medical, psychological, and pedagogical correction. An EMR is developed under a single scheme in the form of questions with alternative answers and text boxes to enter information about the individual characteristics of the disease. The coding of characteristics is carried out automatically when selecting characteristics on the display screen from built-in classifiers, which comprise not only diagnoses and functional changes but also the nature of changes in body organs and systems" (Azarkhov O. Yu., Zlepko S. M., Bielousova O. V., 2012, p.12-14).

The digital model of medical records is of paramount importance for realizing universal coverage of health care services, facilitating the processes of making a diagnosis and treatment of the patient by providing prompt, comprehensive and up-to-date data on the patient directly at the place of medical care (Batsenko D., Brahinskyi P., Buchma M., 2018, p. 14).

The advantage of maintaining an EMR compared to paper medical records is advanced patient privacy. The electronic personal account permits each patient to gain access to information about the results of medical services provided and all medical records, submit or cancel the declaration and review its status, download and print the necessary documents and take other actions under the legislation on the electronic health care system.

4. Modern threats to adequate protection of personal data processing and their legal elimination

The information and technological component of the healthcare sector has many problems related, in particular, to the compatibility of information and communication systems, the imperfection of information and network infrastructure and interaction between country-wide registers, the lack of automation and change management specialists, the lag of financial support and the development of effective international, interdepartmental and intersectoral interaction, etc.

Among the urgent problems that need to be legally resolved, a separate block involves settling issues regarding the proper protection of personal data processing. The issue of accessibility, proper storage, and access to data is global and triggers concern at the level of intergovernmental bodies. The European Parliament Resolution of 14 March 2017 on fundamental rights implications of big data: privacy, data protection, non-discrimination, security and law-enforcement (2016/2225(INI)) recognises the significant potential of data-driven technologies, services and big data as catalysts for economic growth, innovation and digitalisation in the EU. However, big data also pose considerable risks to personal data protection and privacy. O. Kritskyi noted that "one of the most dangerous ones is data leakage when confidential patient information may become publicly available" (Krytskyi O., 2020, pp. 88-89). V. Shcherbak also indicates the danger of data security vulnerability in electronic communication (Shcherbak V., 2020, p. 141).

The Ukrainian version of eHealth is built according to world standards of quality and security of information systems and considering the experience and mistakes of other states. In particular, the central database complies with the best world practices in data protection and with the involvement of international specialists, and the system architecture has undergone expert appraisal. Its construction relies on the advanced experience of organizing complex systems: access control, two-factor authentication, isolation of individual components and databases, and much more. The central database is protected against attacks and intrusions and, in addition, has a unique business logic that verifies data integrity to avoid any spoofing or unauthorized data interference. When developing components of the electronic healthcare system, cybersecurity specialists from several independent companies were involved and cybersecurity audits were conducted at each stage. As a result, it was found that the data center meets international standards (certificate of conformity ISO 27001:2013, certificate No. IND17.0398/U issued by Bureau Veritas) and Ukrainian standards (SSSCIPU certificate of conformity No. 14162 dated 22.07.2016) of data protection.

However, the threat of "cyber theft" of patient data remains acute in Ukraine, as well as in democratic European countries. When discussing the choice of technological and legal paths that can protect privacy and data, an expert environment increasingly raises the issues of the fundamental shortcomings of a centralized data storage system. Nevertheless, a blockchain, as a decentralized platform for operations between equal partners in a secure environment protected from unauthorized access, makes it possible to perform homogeneous transactions safely, helps simplify and accelerate the processes of collecting and sharing information, and protects them from many risks, including fraud and counterfeiting. Experts recommend using the healthcare blockchain in several areas: tracking drug supply chains, maintaining public registers (Klymenko I., Lozova H., Akimova L., 2017), storing patient data (Karpenko O., Osmak A., 2018, p. 60), and smart contracting.

According to the project "Digital Agenda of Ukraine – 2020", launched in 2016 on the initiative of the Ministry of Economic Development and Trade of Ukraine, blockchain, the technology of a distributed peer-to-peer public network that can store data about transactions permanently and without the possibility of changing it and which is protected by cryptographic means, is among the 10 key strategic technologies for Ukraine that can transform such public sectors of Ukraine as education, medicine, transport, and service (Tsyfrova adzhenda Ukrainy-2020, 2016, p. 55). However, as V. Pashkov rightly notes, "there is a problem with legal support of the relevant innovation, not only in the health care sector but in society as a whole" (Pashkov V., 2018, p. 33). The lack of proper imperative rules will make it impossible to guarantee the rights and interests of all stakeholders and hence, neutralize all the positive effects of the latest technologies in the health care system.

Some ways and means of solving the existing problems are proposed in the "Concept of the electronic healthcare system" approved by the Ordinance of the Cabinet of Ministers of Ukraine dated 28.12.2020. The document defines the priority areas of regulatory and legal support for the development of e-health by 2025. They involve the determination of requirements for elaborating e-health services and control over the quality of advanced functionality; improvement of approaches to electronic identification, authentication of e-health users and standards for the exchange of health care data, procedures for maintaining registers in the central database of the electronic health system, keeping forms of medical documentation, and the functioning of medical statistics, etc.; the regulation of access of subjects providing administrative and other services to the data about client health, considering legislative requirements for the protection of information and personal data; ensuring the integration and electronic interaction of the e-health system with other information and telecommunication systems; regulation of the processing of personal data, in particular, those that pose a specific risk to the rights and freedoms of data (health data) subjects, their repeated depersonalized use for statistics, scientific research, and other purposes different from providing medical care; harmonization of national standards with worldwide standards and classifiers, implementation of internationally accepted and common standards in Ukraine for further integration with the world information space.

5. New challenges to the eHealth system under military aggression

The military aggression of the Russian Federation launched on February 24, 2022, made adjustments to the functioning and development of eHealth in Ukraine. At present, dozens of health facilities and health workers have been attacked. And these numbers are growing every day. Internal displacement of Ukrainians caused an uneven distribution of the burden on the health care system: the number of users increased in the west of the country and decreased in the east. The above also affected the load on some medical information systems.

Due to new challenges, the development of some planned projects was shifted in time, and the launch of others was postponed. The tasks of stable functioning of the entire health care system under martial law became a priority. It is primarily about maintaining the stable operation of eHealth, safe entering of medical data into the system, providing and improving key services, and ensuring maximum protection of the entire eHealth cyberspace.

A set of innovations were initiated as the need of the hour. Given the necessities of martial law, nursing staff functionality was finalized "Nursing staff workplace". It allows users to register with the system and get the appropriate access rights; search for electronic medical records; form packages of diagnostic reports; record treatment procedures; check, process, and reject electronic referrals; enter vaccination data; view manipulation details, etc.

The work of nursing staff in the system makes it possible to redistribute the digital load of doctors and provide the necessary permanent access of nursing staff to patient medical data, treatment history, manipulations, etc., and therefore to be involved in the treatment process more effectively.

Nowadays, the MoH Order "On Amendments to the MoH Order dated 01.06.2021 No. 1066 and the Procedure for Issuing (Forming) Certificate of Incapacity for Work in the Electronic Register of Certificates of Incapacity for Work" dated 22.04.2022 No. 675 regulates the possibility of remote registration of a certificate of incapacity for work by the categories of pregnancy and childbirth, orthopedic prosthetics, systemic disease or injury, and care for a sick child. During martial law, consulting physicians controlling pregnancy under outpatient treatment are entitled to provide women with medical reports in the category "Pregnancy and childbirth" without a personal examination of such women but by relying on the results of remote interaction with them. Such an option is now available to those citizens who are abroad.

A new basis for the awarding a paper certificate of incapacity for work has been regulated: the patient's violation of the term of application for the prolongation of temporary disability due to force majeure in martial law, if the patient remains incapacitated at the date of application.

However, the current major challenge to the entire health care system of Ukraine is the ability to provide all those who need it with medical care regardless of the distance and request time. In the context of hostilities, the remote forms of interaction of medical care subjects become critically important. It especially applies to the implementation of medical interventions according to vital indications, which are urgent.

Modern technological solutions permit connecting experts from different countries in real-time, which contributes to receiving valuable professional recommendations specifically during operational interventions. Thus, *international humanitarian assistance to Ukraine includes a supply of medical equipment and IT services that provide constant access to medical care*.

Remote provision of medical care to the injured military and civilians, in particular, the treatment of blast and gunshot wounds, is an innovation of telemedicine. In the regions of active hostilities, a joint pilot project on teleconsultation in the treatment of blast and gunshot wounds is being implemented with international partners. Within the pilot framework, a telemedicine service will be available to doctors, and thus, they will obtain video advice from a specialist from a highly specialized healthcare institution. Starting from March this year, in Lviv doctors have been using a unique innovation for treating the wounded – a state-of-the-art augmented reality device. (1st generation device HMT-1 of the American company RealWear). Equipped with a powerful camera with a convergence function and two microphones, the device is attached to the doctor's head and controlled by voice. Such a technological solution is indispensable when helping injured and wounded patients due to military activities.

In today's circumstances, telemedicine is the most demanded mechanism capable of ensuring timely access of the population and the military to the necessary medical services. Telehealth services are an element of the global eHealth standard without which modern electronic health services are incomplete. Such alloy of the latest technologies, medical science, and medical skill generates a synergistic effect in the health care system, which will assist in achieving a new quality of medical services available to the country's entire population. At the same time, the widespread use of telemedicine tools that should take place in the short term requires simultaneous reformatting of several components: the readiness of medical care subjects; the availability of modern technological platforms; conformability of regulatory framework.

5. Conclusions

The application of modern information technologies is an essential tool of health care reform introduced in Ukraine, which has already improved the industry's efficiency and transparency. The chosen eHealth model combines safety, user-friendliness, and interoperability requirements for information exchange between different medical information systems. The system also ensures the compatibility and electronic interaction of the central database following the procedure established by law with other information systems and state information resources.

However, eHealth currently has many problems related, in particular, to the compatibility of information and communication systems, the imperfection of information and network infrastructure and interaction between national registers, the shortcoming of some registers, the lack of automation and change management specialists, etc. Among the urgent problems that need to be legally resolved, a separate block involves settling issues regarding the proper protection of personal data processing, incl., those that pose a specific risk to the rights of personal data subjects.

The immediate urgent tasks for legal research involve ensuring the standardization of software systems and data security; finding adequate legal balances between publicity and transparency of open data and protection of private information; technological and legal regulation of the provision of services via a modern mechanism of telemedicine.

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ЦИФРОВІЗАЦІЯ ОХОРОНИ ЗДОРОВ'Я В УКРАЇНІ: ПРАВОВЕ ЗАБЕЗПЕЧЕННЯ ПУБЛІЧНИХ ТА ПРИВАТНИХ ІНТЕРЕСІВ

Анотація. Протягом 2017–2020 років в Україні відбулися системні зрушення та цифрові нововведення в охороні здоров'я. Важливим інструментом модернізації медичної, економічної та управлінської складових частин системи охорони здоров'я в Україні стало створення системи eHealth на засадах новітніх інформаційних технологій. Потужного поштовху для широкого використання потенціалу цифрових технологій надають сучасні виклики та загрози суспільному благополуччю. Внаслідок стрімкого поширення COVID-19 спрацювали переваги цифрових технологій, які дали можливість дистанційної взаємодії учасників медичних правовідносин без ризику передачі інфекції. Нові виклики для системи eHealth було створено військовою агресією РФ проти України.

Мета. У статті досліджуються стан правового регулювання застосування цифрових технологій у системі охорони здоров'я, забезпечення балансу публічних та приватних інтересів, проблеми захисту прав учасників відносин, окремі зростаючі загрози суспільному благополуччю, їхній вплив на стале функціонування системи eHealth.

Методи дослідження. Дослідження проведено на засадах аналізу нормативно-правової бази, літературних джерел, опису та узагальнення спектра наявних досягнень та проблем у секторі eHealth. За допомогою діалектичного методу предмет дослідження розглядається не у статичному однобічному вигляді, а як такий, що перебуває у процесі становлення, розвитку та перманентної пов'язаності з іншими процесами та явищами сучасного українського суспільства. Завдяки застосуванню засобів формальної та діалектичної логіки було встановлено об'єктивні причинно-наслідкові зв'язки у предметі та зроблено висновки щодо окремих напрямів вдосконалення правового регулювання системою eHealth.

Результати. Проаналізовано вплив eHealth та окремих електронних інструментів на забезпечення інтересів держави, суспільства, прав приватних осіб. Встановлено об'єктивний причинний зв'язок цифровізації сектора охорони здоров'я з показниками якості та безпеки надання медичної допомоги. Виявлено сучасні загрози суспільному благополуччю, їх вплив на систему охорони здоров'я та на використання цифрових технологій, проаналізовано можливі шляхи для їх правового вирішення.

Висновки. На підставі проведеного дослідження виявлено проблеми та прогалини у застосуванні цифрових технологій у секторі охорони здоров'я, наголошено на необхідності вдосконалення правового режиму послуг електронної системи охорони здоров'я, порядку контролю якості та безпеки їх функціонування/використання, забезпечення інтеграції та електронної взаємодії електронної системи охорони здоров'я з іншими інформаційно-комунікативними системами. Серед перспективних дослідницьких завдань – проблема забезпечення стандартизації програмних систем та інформаційної безпеки даних; знаходження адекватних правових балансів між забезпеченням публічності і прозорості відкритих даних та захисту приватної інформації від несанкціонованого доступу; технологічне та правове врегулювання надання послуг через сучасний механізм телемедицини.

Ключові слова: цифровізація охорони здоров'я, баланс публічних та приватних інтересів, загрози суспільному благополуччю.

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