



## Digital Transformation of Healthcare: Between Progress and Privacy

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With the adoption of the Law on Healthcare in August 2025, the legal framework for the implementation of a comprehensive reform of the Montenegrin healthcare system through harmonization with modern standards and the legal acquis of the European Union was set. A further step in this direction is represented by the proposed amendments to this law, which, together with the Law on Data Management and Digital Health, are also in the proposal stage, and are part of a wider process of digital transformation of the healthcare system, while at the same time strengthening the protection of patient data and standardization of healthcare records.

The Law on Healthcare introduces digital health as an integral part of the system and creates institutional mechanisms for its implementation, while the proposed amendments further affirm this concept, along with telemedicine and the networking of healthcare institutions through the Integrated Health Information System (IHIS). This system will ensure standardized processing, exchange, and access to health and other relevant data. This represents a significant move, as the digitalization of records is no longer a recommendation or a technical possibility, but is established as a standard that will shape the daily operations of the system.

The Proposal for the Law on Amendments to the Law on Healthcare provides for the establishment of the Digital Health Agency, regulating its legal status, authorities, competences, and financing. The Agency's competences include operational and technical tasks related to the functioning of the IHIS, proposing the introduction of digital tools, establishing minimum connection conditions, and other duties in accordance with the law regulating health data management and digital health.

The Law on Healthcare is followed by the Law on Health Data Management and Digital Health, which aims to address a key question: how to manage health data so that the system is efficient while ensuring maximum protection of patient privacy. This Law regulates the maintenance of medical documentation, records, and data collections, as well as the rights and obligations regarding the management, processing, exchange, protection, and use of health data and information, while respecting the key principles - the principles of legality, credibility, accuracy and reliability, standardization and interoperability, traceability, and data accessibility coupled with protection.

The proposed solutions are aligned with the Personal Data Protection Act and take into account the standards and principles established by the EU General Data Protection Regulation (GDPR), as a reference framework in the process of gradual harmonization of domestic legislation with the legal acquis of the European Union, particularly with regard to lawful processing, data minimization, purpose limitation, security, monitoring of processing, and access control.

The Proposal defines in detail what constitutes medical documentation and records, as well as the obligation to maintain medical documentation in the prescribed manner. This strengthens legal security, as it precisely defines which data enters the system, who inputs it, who is liable for its accuracy, and how it may be utilized.

One of the most specific segments of the Law refers to health data collections, which include: healthcare data collections used in the provision of health services (electronic medical records, electronic health records, and healthcare resource collections); public health registries used for analytical monitoring and ensuring public health (e.g., registries of infectious diseases, immunization, malignant neoplasms, psychoses, persons with autism spectrum disorders, etc.); data collections in the field of screening programs (for breast, colon, and cervical cancer screening); and other data collections (related to outpatient care, laboratory services, radiological services, pharmacy operations, etc.).

The data sources for all these collections are medical documentation and health records, and this data should be automatically categorized into the corresponding collections. The establishment of these collections creates a systemic basis for consolidating patient information and tracking patients through the system, offering numerous practical benefits: faster decision-making, reduced duplication of examinations, and easier monitoring of therapies and medical history, while increasing the need for robust access control, clear authorization rules and the implementation of appropriate technical and organizational security measures, in order to prevent misuse and unauthorized access to data.

The proposed Law regulates the Integrated Health Information System - IHIS - as a unique system for healthcare planning and management, health insurance, and the collection and processing of data on the health status of the population, as well as the financing and functioning of the system. IHIS enables standardized data processing and exchange, and all healthcare providers are obliged to provide conditions established for connection and electronic exchange with IHIS, subject to conditions determined by the competent Ministry.

One of the most sensitive issues raised by the Law is the secondary processing of health data, i.e., its use for purposes other than direct treatment (e.g., statistics, analytics, planning, and research), subject to mandatory protection measures and respect for patient rights. The Proposal also emphasizes the obligation of data controllers to ensure information security and risk management, accompanied by oversight and penal provisions, as digital systems without clear standards can become vulnerable and undermine patient trust and penal provisions should be effective and dissuasive, as only such an approach can ensure genuine protection of patients' rights in the context of digital processing of health data.

Ultimately, the goal of these reforms is for the healthcare system to become faster, more integrated, and more functional, which is a prerequisite for restoring citizens' trust in Montenegrin healthcare. It remains to be seen to what extent this is achievable in practice, and if all the good legal proposals will truly and fully be applied.

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