Implementation Guide for using the Model Law on Health Data Governance to Strengthen National Frameworks

SECTION 7: INDIVIDUAL RIGHTS; PORTABILITY OF ELECTRONIC MEDICAL RECORDS

The scope section of the model law delineates the extent and boundaries of the law's applicability. By specifying who and what is covered under the law, this section ensures that all relevant individuals, entities, and types of data are included in the legal framework, thereby providing comprehensive governance over health data. The section covers a wide range of activities related to health data, from collection to disposal, and applies to both digital and non-digital formats, ensuring that the law remains relevant in various contexts and mediums.

KEY DEFINITIONS

Electronic medical record means a digital collection of a patient's medical history, treatments, diagnoses, laboratory testing results, immunisations, and other health-related information maintained and held by a healthcare provider.

Healthcare provider means any individual or entity offering health services, including health professionals, as regulated by [relevant legislation that regulates health professionals], and any facility, like hospitals, clinics, and other institutions, that provide health services, like treatments and diagnostics, whether they operate for profit or not.

RATIONALE

PRIVACY RIGHTS IN PERSONAL HEALTH DATA

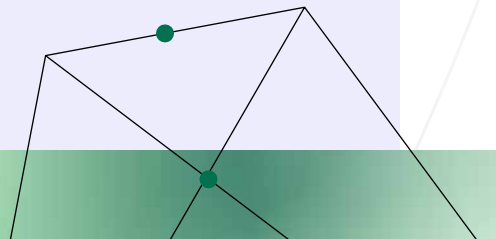
This provision affirms that all individuals have privacy rights concerning their health data, aligning with the overarching goal of protecting individual privacy within the existing data protection legislation and the broader framework of health data governance. It ensures that individuals have control over how their personal health data is handled, thereby fostering trust in the health system. Privacy is a fundamental human right and a cornerstone of data protection laws worldwide. By reinforcing this right within the model law, the section seeks to prevent unauthorized access, use, or disclosure of personal health data, which is essential for maintaining the confidentiality and integrity of such data.

PORTABILITY OF ELECTRONIC MEDICAL RECORDS

In addition to the existing rights contained in the data protection legislation, the right to portability of electronic medical records (EMRs) is designed to empower individuals by enabling them to transfer their health data from one healthcare provider to another. This provision supports the model law's objective of facilitating seamless and efficient healthcare delivery by allowing patients to move their records easily, enhancing continuity of care and improving health outcomes. Portability ensures that individuals can receive uninterrupted healthcare, even when switching providers or relocating to a different country. It also promotes patient autonomy by giving individuals the ability to manage their health information more effectively.

INTEROPERABILITY STANDARDS

The requirement for the Regulator to establish interoperability standards ensures that EMRs can be transferred and used across different healthcare systems and providers without compatibility issues. This is crucial for achieving the model law's goal of harmonizing health data governance and facilitating cross-border health data exchanges. Interoperability is essential for the efficient and accurate exchange of health data. Without standardized guidelines, the portability of EMRs could be hindered by technical barriers, leading to delays in care and potential health risks.



OTHER OPTIONS OF FORMULATING THE SECTION

EXPANDED SCOPE OF PORTABILITY

The section could include provisions that allow not only the transfer of EMRs between healthcare providers but also enable individuals to access and manage their EMRs directly through secure patient portals. This approach would further enhance patient autonomy by providing real-time access to health information.

MANDATORY TIMELINES FOR TRANSFER

Instead of simply requiring healthcare providers to transfer EMRs "without delay," the section could specify a maximum timeframe within which the transfer must be completed (e.g., within 48 hours of the request). This would ensure prompt action and reduce the risk of delays in patient care.

ENHANCED INTEROPERABILITY REQUIREMENTS

The section could mandate that interoperability standards include not only technical specifications but also compliance with international best practices for data security, privacy, and patient safety. This would provide a more comprehensive framework for the safe and effective exchange of EMRs.

NOTES ON INTERACTION WITH OTHER SECTIONS

HEALTH DATA COURT (SECTION 6)

Disputes regarding the portability of EMRs or the application of privacy rights may fall under the jurisdiction of the Health Data Court. Thus, the mechanisms for enforcement and resolution provided by the Health Data Court are essential for the practical implementation of this section.

EMERGING TECHNOLOGIES (SECTION 13)

As emerging technologies are increasingly integrated into healthcare, their impact on EMR portability and privacy rights must be considered. Interoperability standards will need to evolve to accommodate new technologies, ensuring that the law remains relevant in a rapidly changing technological landscape.

SUBSIDIARY LEGISLATION (SECTION 17)

The standards and guidelines for interoperability are likely to be detailed in subsidiary legislation, making this section dependent on the timely development and issuance of such regulations by the Regulator. The adaptability of these standards to emerging needs and technologies will be crucial for the long-term effectiveness of the portability provisions.

DEVELOPING OF REGULATIONS

To guide the Regulator in developing regulations under this section, the following reference documents and existing instruments can be consulted:

INTERNATIONAL STANDARDS

The Regulator should reference the Health Level Seven (HL7) standards, particularly the Fast Healthcare Interoperability Resources (FHIR) framework, which is widely recognized for enabling the exchange of healthcare information electronically.

GDPR GUIDELINES

The GDPR provides comprehensive guidance on data portability and can serve as a model for establishing robust data protection and transfer mechanisms.

OECD RECOMMENDATION ON HEALTH DATA GOVERNANCE

This document offers principles for health data governance that emphasize the importance of interoperability and cross-border data flows while ensuring the protection of individual rights.

ISO 27799

This International Organization for Standardization (ISO) standard provides guidelines for information security management in health systems, which could be integral in ensuring that interoperability standards include robust security measures.

NATIONAL LEGISLATION

The Regulator should review existing national data protection and health information laws to ensure that the new regulations complement and enhance current legal frameworks without duplicating efforts.

INTERNATIONAL CONSIDERATIONS

In addition to the above international instruments, the HL7, Fast Healthcare Interoperability Resources (FHIR), and WHO guidelines on digital health systems provide the standards necessary for the interoperability of electronic health records. Compliance with these international standards ensures that health data can be shared efficiently and securely across different healthcare providers, systems, and countries. The portability of EMRs must also be aligned with the WHO's Global Strategy on Digital Health, which encourages countries to adopt digital health technologies to improve healthcare access and management. The OECD's Guidelines on the Protection of Privacy and Transborder Flows of Personal Data also encourage data portability as a way to empower individuals and enhance data protection. Agreements like the US-Mexico-Canada Agreement (USMCA) and similar treaties include provisions on the transfer and protection of personal data across borders. In the context of healthcare, ensuring that EMRs can be ported across borders while complying with these trade agreements is essential for the international mobility of patients and healthcare providers.

IMPLEMENTATION TIPS

Before individuals can exercise their right to electronic portability of records, minimum standards for interoperability of health data must not only be created, but a concerted campaign to align healthcare providers must be conducted. It does little good to enforce this right, only for health data to be compromised due to insufficient security, insufficient understanding of the complexity of health data portability and a lack of understanding of international health data portability protocols and standards. Giving effect to this section prematurely may result in more harm than good if successive security / legal breaches occur which in turn will damage public trust in health providers. Additionally, the cost of implementing this section is significant and careful coordination with and assistance to healthcare providers will be required.

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Transform Health is a global coalition of organisations that work to harness the potential of digital technology and the use of data to achieve universal health coverage (UHC) by 2030. To learn more about Transform Health visit: www.transformhealthcoalition.org.

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