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

SECTION 3: SCOPE

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

Health data means data related to human health, irrespective of whether such data can identify such individual or not and includes personal-level data, population-level data, facility data, and system data that relate to human health.

Non-identifying health data means health data that either is inherently non-personal, such as population-level data, or has been anonymised or pseudonymised to remove personal identifiers. As such, this type of health data cannot legally be used by an unauthorised individual or entity to identify a data subject.

Personal health data means health data which is inherently sensitive and that relate to an identified or identifiable individual: an identifiable individual is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that individual.

Community health data means health data that contain information that is significant to the identity, heritage, cultural practices, or collective health of a community as a whole.

Health-related data means data that is not directly connected to the human health, but can by indirect means be used to make conclusions about health data.

RATIONALE

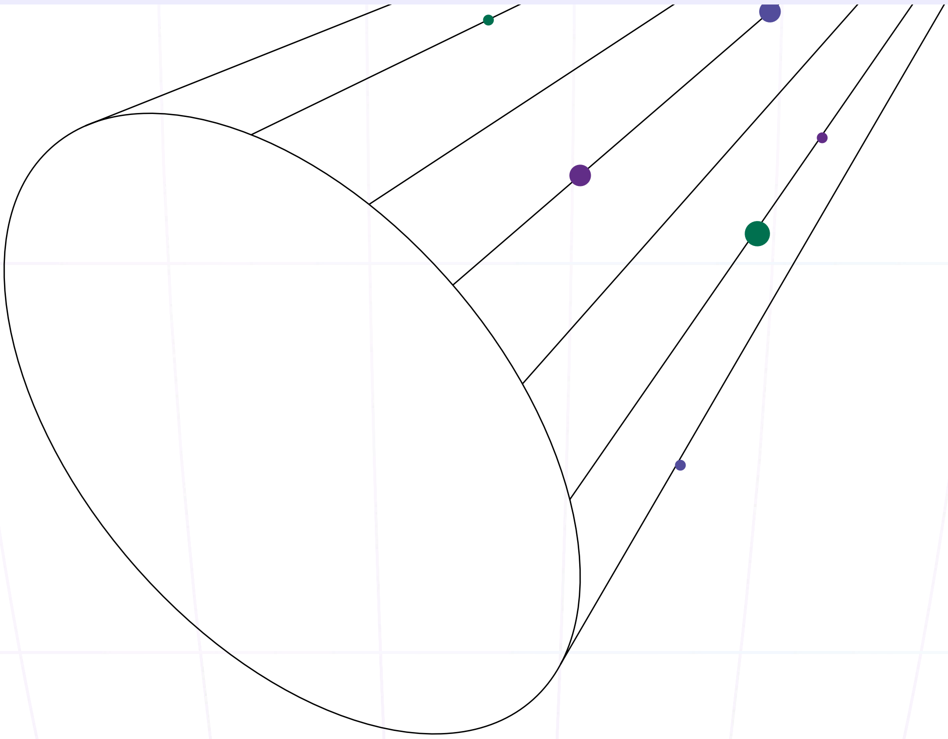
This provision specifies that the law covers both health data and health-related data. Health data can be categorised in two ways, which may overlap:

- First, whether it is 'personal health data' or 'non-identifying health data'.
- Second, whether it is 'community health data' or not. Community health data may or may not include personal health data, depending on whether it can be used to identify individual community members.

Health-relevant data includes lifestyle data (e.g., fitness tracker data), social determinants of health (e.g., socioeconomic status), and environmental data (e.g., pollution levels).

Aligned with the purpose of augmenting existing data protection legislation, the objects that the model law aims to govern—health data and health-relevant data—are on the one hand more specific than the typical ambit of data protection legislation, as they relate specifically to health, but on the other hand also broader, as they are not limited to personal data.

The main reason for the broad scope of "health data" is to include not only personal health data but also non-identifying health data is to recognise that not only personal health data, but also non-identifying health data has value and should, for the sake of comprehensiveness be included in the model law. In particular to ensure that proprietary rights in health data extends to non-identifying health data, create a positive duty on the state to provide access to non-identifying health data, and provide for the right to request access to all types of health data including non-identifying health data.



OTHER OPTIONS OF FORMULATING THE SECTION

TIERED APPLICATION BASED ON DATA SENSITIVITY AND PROCESSING SCALE

The law could adopt a tiered or risk-based approach, where different levels of regulation apply depending on the sensitivity of the data and the scale of the processing activity. For example, highly sensitive data like genetic information might be subject to stricter controls, while less sensitive data could be governed by more flexible rules. However, implementing a tiered system could add complexity to the law, making it more difficult for entities to understand their obligations. Clear guidelines and support from the Regulator would be necessary to ensure that stakeholders can navigate the different tiers effectively.

PROVISIONS FOR RETROSPECTIVE APPLICATION

The scope could include provisions for the retrospective application of certain aspects of the law, requiring entities to bring existing data practices into compliance within a specified timeframe. Retrospective application ensures that all health data, not just newly collected data, is governed by the standards set out in the law. This is particularly important for ensuring that historical data, which may still be sensitive or valuable, is protected under the new legal framework. Retrospective application could place a significant burden on entities that need to audit and potentially re-process existing data to meet new standards. Providing a reasonable compliance window and support from the Regulator could help mitigate these challenges.

INTERNATIONAL CONSIDERATIONS

The scope of this law, which covers both personal and non-identifying health data as well as health-related data, is influenced by a range of international regulations, guidelines, treaties, and agreements. These include data protection laws (e.g., GDPR), public health regulations (e.g., IHR), intellectual property treaties (e.g., TRIPS), environmental health guidelines (e.g., WHO, UNEP), and global health security frameworks (e.g., GHSA). Aligning the scope of the model law with these international frameworks ensures that it effectively governs health data in a way that supports both individual privacy rights and public health goals, while remaining compliant with global legal standards.

IMPLEMENTATION TIPS

It is likely that this model law will overlap with the existing data protection law and (unexpected) conflict between the laws is dealt with in the interpretation (section 5) below. Despite this, it is obviously better to amend the existing data protection law to be consistent with this model law where the conflicts between the two are known.

Health Data Governance

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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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