

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

SECTION 4: EXCLUSIONS

The exclusions section of the model law outlines specific circumstances where the law does not apply. By delineating these exclusions, the law acknowledges situations where the governance of health data might either be inappropriate or already adequately covered by other legal frameworks. This section helps to ensure that the law is focused on relevant activities and does not overextend into areas where its application could be unnecessary or counterproductive.



RATIONALE

PERSONAL OR HOUSEHOLD ACTIVITIES

This exclusion applies to health data collected, processed, stored, or used for personal or household activities with no connection to a public or professional context. Examples might include an individual tracking their own health metrics through a fitness app or maintaining personal medical records at home.

The purpose of this exclusion is to prevent the over-regulation of private activities that do not impact public health or involve any professional or commercial use of health data. Applying the law to personal or household activities would be overly intrusive and would unnecessarily burden individuals with compliance requirements intended for more formal data handling contexts.

NON-HEALTH-RELATED PERSONAL DATA

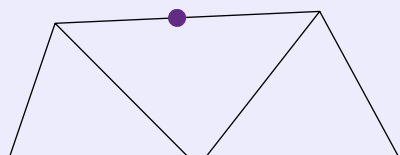
This exclusion makes it clear that the model law does not apply to personal data that is not classified as health data or health-related data. For instance, personal information such as name, address, or financial information that does not pertain to health or is not used to infer health-related information would fall outside the scope of this law.

By excluding non-health-related personal data, the law maintains a focused scope that specifically addresses the unique challenges and sensitivities associated with health data. This ensures that the legal framework is not diluted by extending its reach to personal data that does not require the specialized protections provided by this law.

PUBLIC BODY EXEMPTIONS FOR SPECIFIC PURPOSES

This exclusion allows health data to be exempted from the provisions of the law when required by a public body for purposes such as identifying and financing terrorist activities, money laundering, defence, or public safety. However, any such exemption must be approved by the Regulator, and it must be clearly defined, necessary, proportionate, and justified.

National security and public safety are critical concerns that sometimes necessitate the use of health data in ways that may not align with the protections established in this law. This exclusion allows for necessary flexibility while ensuring that exemptions are carefully controlled and only granted when absolutely necessary. The requirement for Regulatory approval ensures that there is oversight and that the use of such exemptions is justified and transparent.



JOURNALISTIC, LITERARY, OR ARTISTIC EXPRESSION

This exclusion pertains to the use of health data within the realms of journalistic, literary, or artistic expression. For example, a journalist reporting on a public health issue or an artist creating a work that explores medical themes would not be subject to the constraints of the law.

Freedom of expression is a fundamental right, and this exclusion protects this right by ensuring that the law does not unduly restrict journalistic, literary, or artistic activities. These activities often serve the public interest by informing, educating, or challenging societal norms, and they should not be hampered by the legal constraints that apply to more formal uses of health data.

JUDICIAL FUNCTIONS OF A COURT

This exclusion clarifies that the model law does not apply to the judicial functions of a court. This means that health data used in court proceedings or related to judicial decision-making processes is not governed by this law.

The judicial process operates under its own set of rules and protections, designed to ensure fairness and justice. By excluding judicial functions from the scope of the law, this provision ensures that the courts can operate without interference from external legal requirements that might complicate or hinder the judicial process.



OTHER OPTIONS OF FORMULATING THE SECTION

CONDITIONAL EXEMPTIONS WITH OVERSIGHT

Instead of outright exclusions, the law could introduce conditional exemptions where certain activities are exempted from the law's provisions but only under specific conditions and with ongoing oversight by the Regulator or another appointed body. Conditional exemptions would allow for flexibility while still ensuring that exempted activities are monitored and that any potential risks are managed. This approach could be particularly relevant for activities related to national security or public safety, where ongoing oversight could help prevent abuse of the exemption. While providing flexibility, conditional exemptions could increase the complexity of the law and create additional administrative burdens for both the Regulator and the entities seeking exemptions. Clear guidelines and streamlined processes would be necessary to manage these challenges effectively. Conditional exemptions can also be applied for a limited time for the purposes of managing a health emergency.

NARROWING THE SCOPE OF EXEMPTIONS

The law could narrow the scope of certain exemptions, particularly those related to national security and public safety, to ensure that only the minimum necessary data is exempted and that any exemptions are subject to strict limitations. Narrowing the scope of exemptions helps to protect individual and community rights by ensuring that exemptions are not overly broad or misused. This approach would reinforce the law's commitment to data protection while still allowing for necessary flexibility in exceptional cases. Narrowing exemptions could limit the ability of public bodies to access health data in urgent situations, potentially hindering efforts to address national security threats or public safety concerns. A balance would need to be struck between protecting privacy and ensuring public safety.



INTERNATIONAL CONSIDERATIONS

The International Health Regulations (IHR) and the Pandemic Influenza Preparedness (PIP) Framework govern international sharing of health data during pandemics and public health emergencies. These frameworks emphasise the need for rapid data sharing to support global responses. The law might exclude data sharing activities directly covered by these international agreements. Agreements such as the US-Mexico-Canada Agreement (USMCA), EU adequacy decisions, or bilateral agreements may already provide rules for data transfers across borders, including health data. The law could exclude these specific cross-border data transfers from its scope to avoid overlapping with these existing frameworks. The TRIPS Agreement and other IP-related treaties govern proprietary data or health technologies, which might be excluded from the law's scope if they are already covered by IP protections. Certain health data related to national defence or military operations might be excluded from the model law's scope, as such data is often covered by international security treaties or national laws designed to protect sensitive information. This exclusion would be necessary to ensure compliance with these frameworks. International frameworks like the Declaration of Helsinki or CIOMS International Ethical Guidelines for health-related research might already govern the handling and sharing of health data in research contexts, which could warrant exclusion from the law's provisions. Data used by international organisations in global health initiatives or emergencies might be excluded from the model law if these organisations operate under specific international agreements that govern data sharing and use. Bilateral or multilateral agreements often contain their own detailed provisions for health data sharing, privacy, and security. If such agreements are already in place, the law could exclude these activities to avoid legal conflicts or duplication of effort.



IMPLEMENTATION TIPS

All exclusions within this section must be aligned with existing data protection law or health law. If this model law is used to amend an existing data protection law, then the exclusion in section 4(1)(b) should be omitted.



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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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