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

SECTION 11: USING HEALTH DATA IN THE PUBLIC INTEREST

The purpose of this section is to establish a legal framework that allows for the use of health data in situations where it serves the public interest, even when such data is held under proprietary rights by a health data proprietor. This section is akin to the concept of compulsory licensing in patent law, where an entity may be granted the right to use a patented invention without the consent of the patent holder, typically in cases where the use is deemed essential for the public good.

In the context of patent law, the TRIPS Agreement provides for compulsory licensing under specific conditions, particularly to address public health needs. TRIPS allows countries to issue compulsory licenses in situations such as public health emergencies, where access to essential medicines or technologies is necessary for the well-being of the population. Similarly, this section enables the Health Data Court (or the body that is the alternative to the heath data court as set out in section 6) to grant use-licenses for health data when it is necessary to advance the public interest, ensuring that critical health data can be accessed for research, public health initiatives, or other socially beneficial purposes, even if the health data proprietor does not consent.

The section carefully balances the rights of the health data proprietor with the need to serve the public interest. By providing a legal mechanism for accessing health data in the public interest, this section ensures that proprietary rights do not obstruct the use of data that could significantly benefit society.

RATIONALE

DISCLOSURE OF PROPRIETARY RIGHTS

This provision mandates that any individual or entity with proprietary rights related to health data instances must disclose these rights upon request. The requirement to disclose proprietary rights ensures transparency in the ownership and control of health data, which is essential for assessing the potential public interest in the data's use. Transparency in proprietary rights is critical for enabling stakeholders, including researchers, public health officials, and policymakers, to identify and access health data that could serve the public interest. It reduces barriers to data access and facilitates informed decision-making regarding the use of health data for public benefit.

EXCLUSION BY SUBSIDIARY LEGISLATION

This provision allows the relevant national authority to exclude certain classes of individuals or entities from the disclosure requirement. Such exclusions may be necessary to protect sensitive information or to accommodate specific legal or regulatory considerations. Providing the flexibility to exclude certain entities ensures that the law can be adapted to protect national security, sensitive commercial interests, or other critical considerations, without undermining the broader goal of promoting transparency and public interest.

DETAILED DESCRIPTION OF HEALTH DATA

This clause requires health data proprietors to provide a description of the kinds of health data they hold upon request. This ensures that those seeking to use the data for public interest purposes have enough information to determine its relevance to their needs. Access to detailed descriptions of health data is crucial for enabling effective public health research and other initiatives that rely on specific data types. This provision ensures that potential applicants can make informed decisions about pursuing access to the data.

APPLICATION FOR PUBLIC INTEREST USE-LICENCE

This provision allows individuals or entities to apply to the Health Data Court for a use-license when the data is deemed necessary for advancing the public interest. This process provides a legal mechanism to override proprietary rights in favour of public benefit. Public interest use-licenses are a vital tool for ensuring that health data is accessible for purposes that benefit society, such as medical research, public health initiatives, and policy development. This provision strikes a balance between respecting proprietary rights and promoting the common good.

CRITERIA FOR GRANTING USE-LICENCES

The Health Data Court is tasked with evaluating the application for a use-license by considering several factors, including the nature of the public interest, potential benefits, reasons for refusal, market practices, and potential risks. This ensures that the decision to grant a license, including possibly subjecting the licence to certain conditions, is well-informed and balanced. By considering a broad range of factors, the Health Data Court can ensure that use-licenses are granted only when it is clearly in the public interest, and that the rights of individuals and communities are protected. This thorough evaluation process helps to prevent misuse of the data while maximizing public benefits.

DETERMINATION OF LICENCE FEE

This provision allows the Health Data Court to set a reasonable license fee for the use of health data, considering various factors such as the public interest, the costs incurred by the health data proprietor, and the applicant's financial position. Setting a fair license fee ensures that the health data proprietor is compensated for their investment while not imposing prohibitive costs on the applicant, particularly when the public interest is at stake. This helps to encourage the use of health data for socially beneficial purposes.

DISCRETION TO SET LICENCE FEE AT ZERO

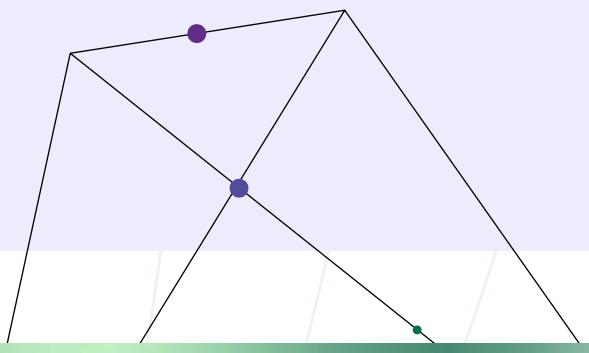
The Health Data Court has the discretion to waive the license fee entirely if the use of the data serves a paramount public interest or if the data was obtained or maintained using significant public funds. This ensures that financial considerations do not obstruct critical public interest uses of health data. Waiving the license fee in cases of significant public interest or publicly funded data ensures that important health data is accessible to those who need it most, without financial barriers. This is especially important for public health emergencies and related research.

DURATION AND SCOPE OF USE-LICENCE

The Health Data Court is responsible for specifying the duration of the use-license and any limitations on the scope of the data's use. This ensures that the data is used appropriately and only for the intended public interest purpose. Limiting the duration and scope of the license ensures that the use of the data remains focused on the public interest goal and prevents potential misuse or overreach. It also allows for reassessment if the circumstances or public interest needs change.

MONITORING COMPLIANCE

This provision allows the Health Data Court to establish mechanisms for monitoring the use of the health data under the granted license. This ensures ongoing compliance with the terms of the license and protects the rights of individuals and communities. Continuous monitoring is essential to ensure that the health data is used in accordance with the agreed terms and that any risks to individuals or communities are mitigated. It provides a safeguard against misuse and helps maintain trust in the data governance system.



OTHER OPTIONS OF FORMULATING THE SECTION

MANDATORY PUBLIC INTEREST DISCLOSURE

Instead of requiring individuals or entities to disclose proprietary rights upon request, the law could mandate automatic public disclosure of all proprietary health data instances, unless specifically exempted by the relevant national authority. This would further enhance transparency.

CENTRALIZED PUBLIC INTEREST REVIEW BOARD

Rather than relying solely on the Health Data Court, a centralised public interest review board could be established to assess applications for use-licenses. This board could include public health experts, ethicists, and community representatives, ensuring a multidisciplinary approach to evaluating the public interest.

SLIDING SCALE FOR LICENCE FEES

The section could introduce a sliding scale for license fees based on the applicant's ability to pay and the scale of public benefit. This approach would provide greater flexibility in setting fees and ensure that smaller entities or non-profits are not unduly burdened.

NOTES ON INTERACTION WITH OTHER SECTIONS

HEALTH DATA COURT (SECTION 6)

The role of the Health Data Court is central to this section, as it is the body responsible for adjudicating applications for public interest use-licenses, setting license fees, and monitoring compliance. The Court's decisions will have a significant impact on how health data is accessed and used for public benefit.

EMERGING TECHNOLOGIES (SECTION 13)

The use of health data in emerging technologies may require special consideration under this section, particularly regarding the scope and duration of use-licenses. As technologies evolve, the Health Data Court may need to revisit or update licenses to reflect new risks or opportunities associated with technological advancements.

RIGHTS AND OBLIGATIONS OF HEALTH DATA GENERATORS (SECTION 10)

This section interacts directly with the proprietary rights outlined in Section 10. It limits those rights by providing a legal pathway for overriding them in the public interest, ensuring that proprietary claims do not obstruct important public health or research initiatives.

OFFENCES AND PENALTIES (SECTION 15 AND 16)

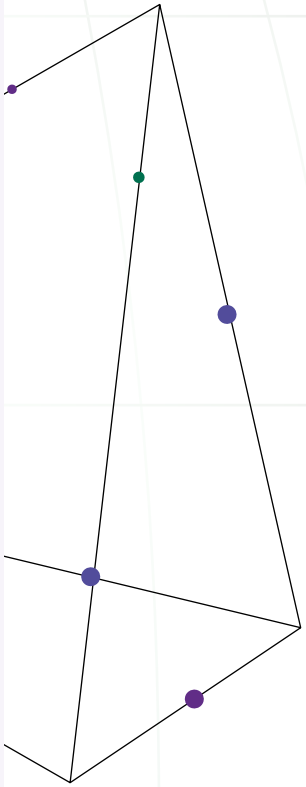
Compliance with the terms of a public interest use-license is critical. Any breach of these terms could be subject to penalties outlined in Sections 15 and 16, ensuring that the licensee adheres to the conditions set by the Health Data Court.

INTEROPERABILITY STANDARDS

Compliance with interoperability standards, as determined by the Regulator, is essential for ensuring that the health data can be effectively utilised across different systems and platforms. This requirement ensures that data shared under a public interest use-license can be integrated and used efficiently in various applications.

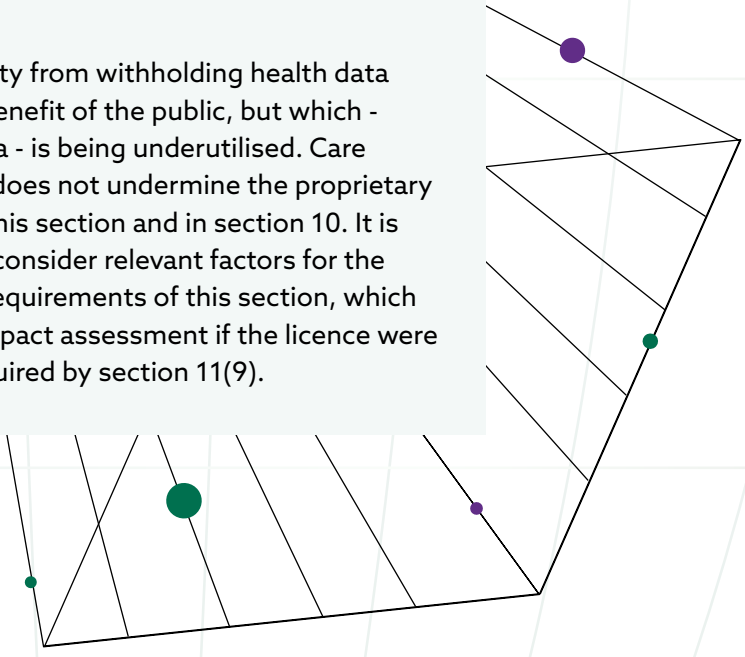
INTERNATIONAL CONSIDERATIONS

The legal framework for using health data in the public interest would likely depend on the principles established under TRIPS, particularly Articles 31 and 31bis, which deal with compulsory licensing and public health exceptions. The section on health data use would need to incorporate or reference the conditions under which compulsory licenses are issued under TRIPS which include ensuring that such use is for non-commercial purposes, providing adequate remuneration to the data proprietor, and adhering to due process. In addition, this section would also need to be harmonised with existing national IP laws to avoid legal conflicts. For example, if national laws provide for more restrictive compulsory licensing conditions, this section will need to navigate these constraints or propose amendments to existing laws to allow for the public interest use of health data. The use of health data, even in the public interest, must comply with data protection laws and public health directives. This section also needs to align with data protection regulations like the GDPR in the European Union or equivalent frameworks in other jurisdictions. It must ensure that any use of health data in the public interest does not violate data protection principles, such as the necessity and proportionality of data use, the minimisation of data collected, and the provision of adequate safeguards. Lastly, international agreements related to health data, such as those under the WHO or other global health bodies, could influence the implementation of this section. These agreements may establish guidelines on data sharing during pandemics or other public health crises. This section must therefore ensure that its provisions for public interest use of health data are consistent with international commitments, particularly those concerning cross-border data sharing and cooperation during global health emergencies.



IMPLEMENTATION TIPS

This section was developed to prevent a party from withholding health data which has the potential to be used for the benefit of the public, but which - due to commercial interests or simply inertia - is being underutilised. Care should be taken to ensure that this section does not undermine the proprietary rights of healthcare providers as set out in this section and in section 10. It is recommended that a test be formulated to consider relevant factors for the granting of the licence over and above the requirements of this section, which may include a requirement to conduct an impact assessment if the licence were to be granted and licence monitoring as required by section 11(9).



This document was developed by Transform Health. This work was funded by the Patrick J. McGovern Foundation and Fondation Botnar.

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.

Transform Health