

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

SECTION 6: HEALTH DATA COURT

The establishment of the Health Data Court under the model law is a critical component designed to provide a specialized judicial forum for adjudicating matters related to the governance, use, and protection of health data within the relevant country. By creating a dedicated court with specific expertise in health data management, law, ethics, and technology, this model law ensures that disputes arising from the use and handling of health data are resolved in a fair, transparent, and efficient manner. The Health Data Court serves as the central authority for enforcing the provisions of this law, ensuring that all stakeholders, including individuals, communities, data controllers, and holders of proprietary rights in digital instances containing health data, are held accountable to the highest standards of legal and ethical conduct.



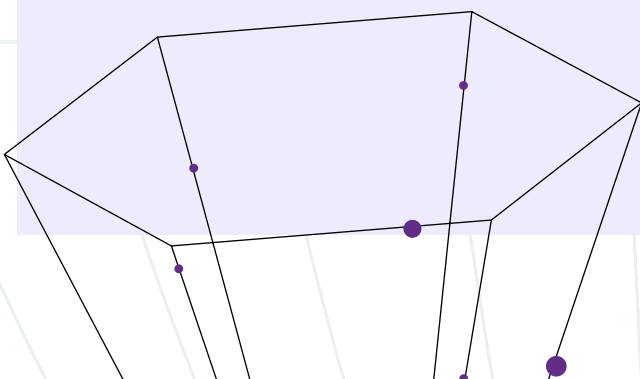
RATIONALE

ESTABLISHMENT AND OBJECTIVE OF THE HEALTH DATA COURT

The law establishes the Health Data Court designed to serve as a specialized judicial body with the necessary expertise to address the complex and sensitive issues that arise under this law. The unique nature of health data, which involves sensitive personal and community information, necessitates a specialized forum for dispute resolution. General courts may lack the specific expertise required to adjudicate matters involving health data, leading to inconsistent or inadequate outcomes. The Health Data Court provides a focused and knowledgeable environment where disputes can be resolved effectively, ensuring that all parties receive fair treatment under the law.

JURISDICTION AND POWERS OF THE HEALTH DATA COURT

The Health Data Court is granted jurisdiction over all matters arising under the model law, including disputes between the Regulator, individuals, communities, data controllers, and holders of proprietary rights in digital instances containing health data. The court is empowered to hear cases, make determinations, order remedial actions, impose penalties, and take any other actions necessary to enforce the provisions of the law. By centralizing jurisdiction over health data-related disputes in a specialized court, the model law ensures that all cases are handled with the necessary expertise and focus. The court's broad powers allow it to address a wide range of issues, from minor infractions to significant breaches of the law, ensuring that all violations are appropriately dealt with. This comprehensive jurisdiction and authority are essential for maintaining the integrity of the health data governance framework and ensuring that all stakeholders are held accountable.



COMPOSITION AND APPOINTMENT OF JUDGES

The composition of the Health Data Court is crucial to its effectiveness. By appointing judges with specialized knowledge and experience in relevant fields, the court is equipped to handle the complex and technical issues that arise in health data governance. The selection process ensures that only individuals with the highest levels of expertise and integrity are entrusted with these important responsibilities, thereby enhancing public confidence in the court's decisions.

PROCEDURAL FRAMEWORK

The Health Data Court is empowered to establish its own procedures for the hearing of cases, in accordance with principles of natural justice and fairness. Proceedings may be conducted in person, in writing, or electronically, as appropriate. The ability to establish its own procedures allows the Health Data Court to tailor its operations to the specific needs of health data-related cases. This flexibility ensures that the court can operate efficiently and fairly, adapting to the unique circumstances of each case. The emphasis on natural justice and fairness ensures that all parties receive due process, regardless of the format in which the proceedings are conducted.

APPEALS AND ENFORCEMENT

The appeal process provides a mechanism for review, ensuring that decisions made by the Health Data Court are subject to oversight and can be corrected if necessary. This helps maintain the integrity of the judicial process and ensures that justice is upheld. The enforcement provisions ensure that the court's decisions are respected and complied with, thereby reinforcing the authority of the court and the effectiveness of the legal framework.

FUNDING AND RESOURCES

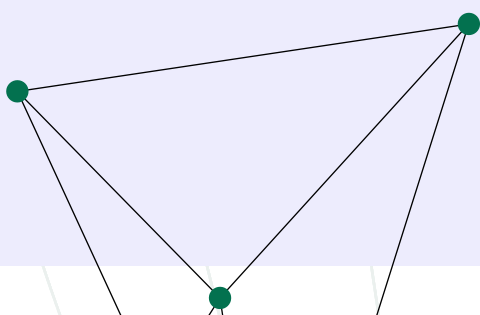
Adequate funding and resources are essential for the effective operation of the Health Data Court. Without the necessary support, the court may struggle to handle its caseload efficiently or to maintain the high standards required for the adjudication of health data-related disputes. Ensuring that the court is properly funded and resourced is crucial for its success and for maintaining public confidence in its ability to deliver justice.

REMEDIES AND PENALTIES

The Health Data Court is empowered to impose penalties for violations of the law, including requiring offenders to provide restitution to affected data subjects and ordering specific measures to rectify violations and prevent their recurrence. The court may also consider aggravating and mitigating factors in determining penalties. The ability to impose penalties and order remedies is central to the court's role in enforcing the model law. By holding violators accountable and providing compensation to those harmed by breaches of the law, the court helps to ensure that justice is served and that the rights of individuals and communities are protected. The consideration of aggravating and mitigating factors allows for a balanced approach to penalties, ensuring that they are proportionate to the offense and take into account the specific circumstances of each case.

CIVIL LITIGATION AND COMPLIANCE

Any individual, entity, or community that suffers damages as a result of a breach of this law may commence civil litigation against the responsible party in the Health Data Court for damages and/or compliance with the law. This provision empowers individuals, entities, and communities to seek justice and compensation for harm caused by breaches of the law. By allowing for civil litigation in the Health Data Court, the model law provides a clear and accessible avenue for redress, ensuring that those affected by violations of the law have the opportunity to seek remedies and hold wrongdoers accountable.





NOTES ON INTERACTION WITH OTHER SECTIONS

DEFINITIONS (SECTION 4)

The definitions section provides the foundational terms that the Health Data Court will rely on to interpret and adjudicate cases. Clear and precise definitions ensure that the court's rulings are consistent with the intent of the model law, particularly when dealing with complex issues related to health data.

PROHIBITION ON RE-IDENTIFICATION (SECTION 8)

The Health Data Court would be responsible for adjudicating cases where violations of the prohibition on re-identification are alleged. This could include assessing whether actions taken by individuals or entities constitute illegal re-identification and imposing penalties or remedial measures as necessary.

CONSENT (SECTION 9)

The Health Data Court would be involved in resolving disputes related to consent, particularly where there is disagreement over whether valid consent has been obtained or if a community's rights in health data have been respected. The court would ensure that the principles of informed consent are upheld in accordance with the model law.

RIGHTS AND OBLIGATIONS OF HEALTH DATA GENERATORS; OPEN ACCESS TO BE PROVIDED BY THE STATE (SECTION 10)

This section outlines the proprietary rights and responsibilities of entities that generate or store health data, which the Health Data Court may need to adjudicate. Disputes arising from conflicts between health data generators and other stakeholders would fall under the court's jurisdiction, ensuring that the proper balance between proprietary rights and public interest is maintained.

USING HEALTH DATA IN THE PUBLIC INTEREST (SECTION 11)

This section provides for the granting of use-licenses in the public interest, which may lead to disputes between the holders of proprietary rights and those seeking access to health data. The Health Data Court would adjudicate such disputes, ensuring that public interest is balanced with proprietary rights.

ENFORCEMENT AND PENALTIES (SECTIONS 15 AND 16)

These sections outline the penalties for violations of the model law and the enforcement mechanisms available. The Health Data Court would be the primary body responsible for determining appropriate penalties and ensuring that enforcement actions are carried out effectively.



OTHER OPTIONS OF FORMULATING THE SECTION

ALTERNATIVE NAMES FOR THE HEALTH DATA COURT

The Health Data Court can be named differently to fit within the legal culture of a country, such as “Health Data Tribunal” or “Health Information Court.” The key requirement is that it functions within the judiciary and serves as a specialized forum capable of making binding decisions on health data-related disputes.

USING THE EXISTING COURT SYSTEM

An alternative approach, although less specialized, would be to not establish a separate Health Data Court and instead provide that all disputes arising under the model law should be adjudicated by the existing court system. While this option would preserve the integrity of the model law, it is suboptimal given the specialized nature of health data law and the need for judges with specific expertise in this area. This could result in less consistent and less informed rulings on complex health data issues.

ADMINISTRATIVE ADJUDICATIVE BODY

Instead of having a specialised court within the judiciary, a country can also have an administrative body, which is situated in the executive, with adjudicative powers as set out in the model law and which guarantees their independence from the executive.

REGIONAL HEALTH DATA COURT

As the model law is country-level legislation it cannot implement a regional-level health data court which will adjudicate disputes both within and between the countries of a regional grouping. For example, the African Union (AU) could implement an AU health data court which would deal with disputes both within countries (such as a dispute between two parties in Kenya) as well as disputes between different jurisdictions (for example between Kenya and Uganda). This would require an AU-level political initiative to create an “AU Health Data Court”.



INTERNATIONAL CONSIDERATIONS

The role and jurisdiction of the Health Data Court in adjudicating matters as set out in the model law must be aligned with a range of international regulations, treaties, guidelines, and agreements, particularly those related to data protection (e.g., GDPR), global health security (e.g., IHR), human rights (e.g., UDHR), and intellectual property (e.g., TRIPS). Aligning the Health Data Court's jurisdiction and rulings with these international frameworks ensures that it operates effectively in a globalised context, protecting individual rights, ensuring ethical governance of health data, and maintaining compliance with international health and privacy standards.



IMPLEMENTATION TIPS

The court should have the necessarily legitimacy in terms of the constitution (if any) and the existing legal system. The creation of a specialised court presupposes that: a) there are sufficient financial resources to sustain the court, b) the human capacity – particularly with data protection law experience – can be obtained, and c) existing laws regarding the functioning of the judiciary do not prevent the creation of this specialised court.

In addition, procedural rules which will govern the court processes must be created, which should include: a) expediting an application by a party from compliance with section 8(5), b) resolving community disputes in a collaborative manner as required by section 9(7), c) providing licences to a party as contemplated in section 11, d) ensuring protection of whistleblowers as required by section 14, and e) determining criminal sanctions in terms of section 15.



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.

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