



EXPLANATORY MEMORANDUM TO THE DIGITAL HEALTH (HEALTH INFORMATION MANAGEMENT PROCEDURES) REGULATIONS, 2025

PART I

Name of the Statutory Instrument: Digital Health (Health Information Management Procedures) Regulations, 2025

Name of the Parent Act: Digital Health Act, No. 15 of 2023

Enacted Pursuant to: Section 60(a) and (b) of the Digital Health Act, 2023

Name of the Ministry/ Department: Ministry of Health/ Digital Health Agency

Gazetted on:

Tabled on:

PART II

1. Purpose of the Statutory Instrument

1.1. The purpose of the Digital Health (Health Information Management Procedures) Regulations, 2025 is to give effect to the provisions of the Digital Health Act, No. 15 of 2023 of the *Laws of Kenya* in relation to health information management, which are not self-executing.

1.2. The Regulations provide for, among other things, the object of the Regulations, security of health data, processing of personal health data, provision of access to health data to data subjects, health data controllers, health data processors and third parties in accordance with the law, safe and secure sharing of health data, disclosure of personal health information, correction of health information, provision of e-health through e-health applications and technologies, the certification process and certification of digital health solutions by the Digital Health Agency based on functionality and interoperability of the digital health solution with the Comprehensive Integrated Health Information System established under section 15 of the Digital Health Act, 2023, and the handling of complaints on matters such as data breaches and unauthorized sharing, access and use of health data.

2. Legislative Context

2.1. The right to privacy including the right not to have information relating to private affairs unnecessarily required or revealed is enshrined under Article 31 of the

Constitution. The Digital Health Act, No. 15 of 2023 gives effect to the right to privacy in relation to private information on health matters.

- 2.2. The right to the highest attainable standard of health including the right to health care services is also enshrined under Article 43 of the Constitution. The Health Act, Cap. 241, which is the primary law that gives effect to the progressive realization of this right, under section 105 obligates the Ministry of Health to establish and maintain a Comprehensive Integrated Health Information System. The Digital Health Act, No. 15 of 2023 was subsequently enacted on 19th October 2023. The principal object of the Act is to provide a framework for the provision of digital health services. The Act which came into force on 2nd November 2023 establishes this Comprehensive Integrated Health Information System and mandates the Digital Health Agency to manage the System which facilitates the provision of digital healthcare services and manages the core digital systems and the infrastructure required for seamless health information exchange. The Act also provides for data governance and protection of personal health information and service delivery through digital health interventions such as telemedicine, e-waste disposal and health tourism
- 2.3. To ensure full operationalization of the Digital Health Act, No. 15 of 2023, a multi-agency Technical Working Group with membership drawn from the Ministry of Health, the Council of Governors, County Governments, the Digital Health Agency, Office of the Attorney-General and the Department of Justice and the Kenya Law Reform Commission was formed to develop the necessary draft Regulations for the better carrying out of the provisions of the Digital Health Act, No. 15 of 2023. The Technical Working Group was also tasked to develop a Regulatory Impact Statement in respect of the Regulations since the Regulations would occasion the charging of fees in relation to the use of health data by persons such as research institutions and university students.
- 2.4. Section 60 of the Digital Health Act, No. 15 of 2023 provides that the Cabinet Secretary for health may, in consultation with the Digital Health Agency and the county governments, make regulations providing for several matters including health information management policies and procedures and the use of e-Health applications and technologies, medical devices and innovations.

3. Policy Background

3.1. The Digital Health Act, 2023 was assented to by His Excellency the President on 19th October 2023 and under section 62 of the Act, health data controllers and processors are required to comply with the requirements of the Act within six months from the date of the coming into force of the Act. The Act solely cannot be fully operational since it does not provide a clear framework for the management of health information and health data including the security, privacy and access of health data, the processing of personal health data and sensitive personal data and the handling of complaints arising from the use, access, sharing and management of health information. The Act also does not set out the process of certification of digital health solutions, the requirements for certification such as functionality and interoperability with the capacity to perform information exchange as well as the framework for the monitoring of compliance by digital solution providers or health data controllers with the certification requirements.

3.2. The Regulations have been divided into four parts namely: Part I: Preliminary; Part II: Management of Health Information; Part III: Procedure for Lodging, Admission and Response to Complaints and Part IV: Provision of E-health and Certification.

4. Consultation outcome

4.1. The Ministry of Health jointly with the Digital Health Agency and the County Governments pursuant to Article 10 of the Constitution subjected the Regulations and the Regulatory Impact Statement to stakeholder consultation and public participation physically. The technical working group identified, mapped and engaged key stakeholders and members of the public for consultations on the Regulations. The stakeholders engaged included the digital health stakeholders, development partners, healthcare providers, healthcare associations, healthcare unions, Semi-Autonomous Government Agencies (SAGAs), the private sector, patient groups, civil society organizations, media, faith-based organisations, research institutions and academia and the general public who are directly or indirectly affected by the proposed statutory instrument. The Digital Health (Health Information Management Procedures) Regulations, 2025 and the Regulatory Impact Statement have therefore taken into

account the views from the public participation and stakeholder consultation engagements.

- 4.2. The Ministry conducted public participation from 9th to 19th December 2024 in ten (10) Counties namely Isiolo, Kisumu, Nyeri, Kakamega, Nakuru, Eldoret, Mombasa, Wajir, Nairobi and Kitui Counties. Prior to the public participation exercise, the Ministry vide a Notice advertised the Regulations and the Draft Regulatory Impact Statement on 21st November 2024 in three newspapers, The Star, The Standard, and The Daily Nation (See annexure 1)
- 4.3. The Regulations and the Regulatory Impact Statement were also posted on the official Ministry of Health website for ease of access by the public and stakeholders for purposes of submission of views.
- 4.4. The Ministry held stakeholder engagement meetings from 2nd to 6th December 2024 with the Media, Directorates and SAGAs within the Ministry of Health, the Ministry of Information, Communication and Digital Economy and its SAGAs, digital health stakeholders including the private sector, development partners, healthcare providers under their umbrella bodies namely Christian Health Association of Kenya (CHAK), Rural and Urban Private Hospitals Association of Kenya (RUPHA), Kenya Conference of Catholic Bishops (KCCB), Kenya Association of Private Hospitals (KAPH) and APH, research institutions and academia, healthcare associations and unions, the Civil Society Organizations, Faith Based Organizations and Patient Groups.
- 4.5. The Ministry also received and considered written submissions on the Regulations and the submitted vide the email *dharegulations@dha.go.ke* or hand delivered to the Office of the Cabinet Secretary on Afya House, 7th Floor, Nairobi. These submissions are from several stakeholders including Constitutional Commissions, professional associations, Ministries, Departments and Agencies, Civil Society Organizations and Universities, the Kenya Medical Laboratory Technicians and Technologists Board, Council of Governors, Helium Health Limited, the Kenya National Public Health Institute, Tech Hive Advisory Africa, Sky-Rock Health, Smart Applications International Limited, Kenya Nutritionists and Dieticians Institute, Center for Disease Control, Occupational Therapy Council of Kenya, Kenya Medical Research Institute,

Africa Population and Health Research Center, Office of the Data Protection Commissioner, Health X Africa, Aga Khan University Hospital, KICTANet, Daktari Online, Association of Private Hospitals, Living Goods, Catholic University of Eastern Africa, National Cancer Institute, Kenya Medical Practitioners and Dentists Council, Kenya National Blood Transfusion Services, ICT Authority, Kenya Health Professions Oversight Authority, African Institute for Development Policy and Moi Teaching and Referral Hospital.

4.6. The oral and written views of all the stakeholders are captured in the consolidated matrices on the stakeholder and public engagements. (see Annexure 3).

5. Guidance

5.1. The Digital Health Agency in collaboration with the Ministry of Health and the County Governments will sensitize stakeholders including Parliament, health data processors, health data controllers, healthcare providers, health facilities and the general public, on the provisions of the Digital Health (Health Information Management Procedures) Regulations, 2025, the obligations of the respective stakeholders, the penalties for non-compliance as well as the monitoring and evaluation mechanisms, to ensure that the Regulations serve the purpose for which they have been made.

6. Impact

6.1. **The Impact of Fundamental Rights and Freedoms:** The Regulations do not limit fundamental rights and freedoms. The Regulations in effect promote and facilitate the realization of fundamental rights and freedoms, in particular the right to highest attainable standard of healthcare.

6.2. **The Impact on Private Sector:** Private institutions providing healthcare services including private and faith-based healthcare facilities in possession of, or who are processing health data and in particular personal-level health data, are required to comply with the provisions of these Regulations. They are required to use and deploy digital health solutions certified by the Digital Health Agency in the provision of healthcare services. When private institutions and private health facilities use certified digital health solutions, they shall gain a reputation for quality healthcare services and high standards and shall have competitive advantage over its counterpart institutions

or facilities. Innovation will also be encouraged in the private sector as more persons will seek to develop digital health solutions. There will also be enhanced patient experience in the private health facilities as there will be accurate and prompt diagnosis and treatment. These institutions will further have to invest in setting up stringent safety and security safeguards for the protection of personal health data. This will in turn enhance public confidence and trust in the manner in which private health facilities are handling their personal health data.

6.3. The Impact on the Public Sector: Any public office including a public health facility is required to comply with the provisions of these Regulations. With this compliance, there will be improved quality of healthcare services in public health facilities. There will also be the use of standardized and certified systems that ensure data accuracy, improved patient privacy, data security and effective interoperability. This will in turn occasion enhanced public trust and confidence by the public and healthcare providers in the public health sector which shall ultimately ensure improved health outcomes and patient care. There will also be enhanced transparency and accountability in the handling and management of health information which shall make health information sharing seamless and efficient meaning that the public health sector will make evidence-based decisions that will in the long run reduce the healthcare burden in the country.

7. Monitoring and review

7.1. The Digital Health Agency shall monitor the implementation of the Digital Health (Health Information Management Procedures) Regulations, 2025. This shall be done through annual reports and management and audit of the Comprehensive Integrated Digital Health Information System and the certification processes.

8. Contact Person

9.1. The contact persons shall be the **Cabinet Secretary for Health, Dr. Deborah M. Barasa**, and the **Chairperson of the Digital Health Agency, Mr. Silas Simatwo**. The contact persons may be reached through:

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