

**EXPLANATORY MEMORANDUM TO THE DIGITAL HEALTH (DATA EXCHANGE  
COMPONENT) REGULATIONS, 2025**

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**PART I**

**Name of the Statutory Instrument:** The Digital Health (Data Exchange Component) Regulations, 2025

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

**Enacted Pursuant to:** Section 60(d) of the Digital Health Act, No. 15 of 2023

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

Gazetted on:

Tabled on:

**PART II**

**1. Purpose of the statutory instrument, the Digital Health (Data Exchange Component) Regulations, 2025.**

1.1. The purpose of these Regulations is to give effect to provisions of the Digital Health Act, No. 15 of 2023 of the Laws of Kenya, which are not self-executing.

1.2. The Regulations provide for, among other things, the object of the Regulations, the implementation of the data exchange component in the Comprehensive Integrated Health Information System established under section 15 of the Digital Health Act, 2023, the exchange of health information within the System as well as the requirements of using and accessing the components of the System namely the enterprise service bus, shared or common resources which include the national health data dictionary, the client registry, the facility registry, the telemedicine health provider registry, the health worker registry, the product catalogue, the national logistics management information services platform, the health management information services platform, insurance and finance services.

**2. Legislative Context**

2.1. The right to the highest attainable standard of health is guaranteed by Article 43 of the Constitution of Kenya. The Constitution under the Fourth Schedule, recognizes health as a devolved function. It grants the National Government the role of formulating health policies while the county governments undertake county health services.

- 2.2. The Health Act, Cap. 241 which sought to give effect to the provisions of the Constitution recognizes the need to enact another legislation which provides for among other things, administration of health information banks including an interoperability framework, data interchange and security, protection of privacy of health data, and health service delivery through digital systems.
- 2.3. The Digital Health Act, enacted on 19<sup>th</sup> October 2023 and which came into force on 2<sup>nd</sup> November 2023, gives effect to this pronouncement by making provision for a framework of digital health services, while also establishing a Comprehensive Integrated Digital Health Information System. This System is intended to facilitate a people-centred quality health service delivery, to facilitate data collection and reporting at all levels of health care provision, to enable secure health data sharing for timely and informed inter-facility health service delivery, to facilitate data processing and use for informed decision-making at all levels, to safeguard the privacy, confidentiality and security of health data for information sharing and use, and to facilitate the tracking and tracing of health products and technologies in the country, among others.
- 2.4. To ensure full operationalization of the Digital Health Act, 2023, a Technical Working Group drawing membership from the Ministry of Health, Council of Governors, County Governments, the Digital Health Agency, the Office of the Attorney-General and Department of Justice and Kenya Law Reform Commission among others was constituted to *inter alia*, develop the necessary draft Regulations for the better carrying out of the provisions of the Digital Health Act, 2023 as well as the Draft Regulatory Impact Statement as fees will be charged for the use of health information in the Comprehensive Integrated Digital Health Information System.
- 2.5. Section 60 of the Digital Health Act, 2023, provides that the Cabinet Secretary may, in consultation with the Digital Health Agency and the County Governments, make Regulations providing for the establishment and implementation of the data exchange component as per the Kenya Health Enterprise Architecture.

### **3. Policy Background**

- 3.1. Parliament enacted the Digital Health Act, 2023, on 19<sup>th</sup> October 2023 and over the past two years, the Act has been implemented without Regulations. The Act on its

own, however, is not sufficient since it does not provide guidelines and procedures on the exchange of health information as well as the use and access of the essential components of the Comprehensive Integrated Digital Health Information System namely shared or common resources which includes the client registry, facility registry, health worker registry among others.

3.2. The Regulations have been divided into three parts namely: -Part I: Preliminary; Part II: Enterprise Service Bus; and Part III: Shared Resources.

#### **4. Consultation outcome**

4.1. Pursuant to Article 10 of the Constitution, the Ministry of Health subjected the Regulations and the Regulatory Impact Statement to stakeholder consultations and Public Participation. The Technical Working Group identified and engaged key stakeholders and members of the public for consultations. The stakeholders included MDAs, county governments, institutions of higher learning, private sector, development partners, the media, non-state actors, special interest groups and the general public who are directly or indirectly likely to be affected by the proposed statutory instrument. The Digital Health (Data Exchange Component) Regulations, 2025 and the Regulatory Impact Statement have therefore taken into account the views of key stakeholders and the general public.

4.2. The Ministry of Health conducted public participation from 2<sup>nd</sup> December to 19<sup>th</sup> December, 2024 in ten counties namely; Mombasa County, Nakuru County, Kakamega County, Kisumu County, Kitui County, Nairobi County, Nyeri County, Wajir County, Uasin Gishu County and Isiolo County. (see annexure 1)

4.3. The Ministry also received and considered written submissions on the Regulations from Constitutional Commissions, professional associations, Ministries, Departments and Agencies, Civil Society Organizations and Universities, Kenya Medical Laboratory Technicians and Technologists Board, the 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, the 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. (see annexure 3)

## 5. Guidance

5.1. The Ministry of Health and the Digital Health Agency will conduct stakeholder sensitization for the various stakeholders including Parliament, County Governments and the general public on the provisions of the Digital Health (Data Exchange Component) Regulations, 2025 and the digital health exchange component of the system in order to provide insights on the implementation of the Regulations. This will also ensure that the Regulations serve the purpose for which they have been developed.

## 6. Impact

6.1. **The Impact on Fundamental Rights and Freedoms:** The Regulations promote and facilitate the realization of the right to health by making healthcare services accessible to all, as pronounced by the Constitution. The Regulations therefore do not limit fundamental rights and freedoms.

6.2. **The impact on the Private Sector:** It is expected that all key players including private digital health solution providers, private healthcare providers, private health facilities, academic and research institutions in the private sector will stand to benefit from a better regulated digital health sector and conducive operating environment. They will also be cushioned against fraudsters who purport to offer healthcare services without the requisite qualifications. Privacy of health data and health information shared in the System will also be guaranteed even in private health facilities. The Regulations will further ease access to health information through the provision of e-health solutions that are able to support referrals between private health facilities as well as between private and public health facilities.

6.3. **The impact on the Public Sector:** The Regulations shall have a positive impact by enhancing coherence and ensuring Kenyans receive accessible, affordable and quality health care while safeguarding their rights not to have the information relating to their health unnecessarily disclosed. Public health facilities will reduce the costs of using outdated systems to offer health care systems by adopting more efficient practices to offer services.

## 7. **Monitoring and review**

7.1. The Ministry of Health working together with the Digital Health Agency and the County Governments will work hand in hand to promote research, review, monitoring and evaluation of the effectiveness of the Regulations during implementation through annual reports. The efficiency of the components of the Comprehensive Integrated Health Information System will also be audited by the Digital Health Agency to make them fit for purpose based on the unique needs of the health sector. This monitoring and review will be geared towards the progressive realization of the right to the highest attainable standard of healthcare.

## 8. **Contact Person**

8.1. 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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