



LEGAL NOTICE NO.

THE DIGITAL HEALTH ACT
(No. 15 of 2023)

**THE DIGITAL HEALTH (USE OF E-HEALTH APPLICATIONS AND
TECHNOLOGIES) REGULATIONS, 2024**

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THE DIGITAL HEALTH ACT

(No. 15 of 2023)

IN EXERCISE of the powers conferred by section 60(b) of the Digital Health Act, 2023, the Cabinet Secretary for Health, in consultation with the Board of the Digital Health Agency and the County Governments, makes the following Regulations—

THE DIGITAL HEALTH (USE OF E-HEALTH APPLICATIONS AND TECHNOLOGIES) REGULATIONS, 2024

PART I—PRELIMINARY

Citation. 1. These Regulations may be cited as the (Use of E-Health Applications and Technologies) Regulations, 2024.

Interpretation. 2. In these Regulations, unless the context otherwise requires—

No. 15 of 2023. “Act” means the Digital Health Act, 2023;

“Agency” has the meaning assigned to it under section 2 of the Act;

“Board” has the meaning assigned to it under section 2 of the Act;

“Cabinet Secretary” has the meaning assigned to it under section 2 of the Act;

“certification” means attestation that fulfilment or compliance with the requirements specified by the Agency has been demonstrated in relation to an e-health application or technology;

“Certification Framework” means the Certification Framework developed and published by the Agency to facilitate section 6(m) of the Act;

“Comprehensive Integrated Health Information System” means the Comprehensive Integrated Health Information System established under section 15 of the Act;

“data controller” has the meaning assigned to it under section 2 of the Act;

“data processor” has the meaning assigned to it under section 2 of the Act;

“digital health” means the field of knowledge and

practice that is associated with the development and use of digital technologies to improve health;

“digital health solution” means a digital health application, intervention or initiative and includes digital health technology infrastructure including telehealth systems and electronic health information systems and the provision of education and training support for e-Health initiatives;

“e-Health” has the meaning assigned to it under section 2 of the Act;

“e-health application or technology” includes a digital health solution that provides healthcare services;

“health data” has the meaning assigned to it under section 2 of the Act;

“health data controller” has the meaning assigned to it under section 2 of the Act;

“health data processor” has the meaning assigned to it under section 2 of the Act;

“health information system” has the meaning assigned to it under section 2 of the Act;

“Office of the Data Protection Commissioner” means the office of the Data Protection Commissioner established under section 5 of the Data Protection Act; and

Cap. 411C.

“System” has the meaning assigned to it under section 2 of the Act .

Application of the Regulations.

3. These Regulations shall apply to the provision of e-health through e-health applications and technologies.

PART II—PROVISION OF E-HEALTH

E-health.

4. (1) A healthcare provider and a health facility shall use a digital health solution that has been certified by the Agency in the provision of healthcare services.

(2) A health data controller and a health data processor using or accessing the Comprehensive Integrated Health Information System shall—

(a) use a digital health solution certified by the Agency for service delivery; and

(b) adhere to the digital and physical security

requirements in the Certification Framework.

- (3) The Agency shall—
 - (a) certify all e-health and telemedicine platforms in accordance with the Certification Framework; and
 - (b) give user access to the System to a health data controller of a certified digital health solution.

PART III – CERTIFICATION

Certification
Framework.

5. (1) The Agency shall certify digital health solutions including e-health and telemedicine platforms in accordance with the Certification Framework developed by the Agency.

(2) The Certification Framework to be developed by the Agency shall include—

- (a) define the scope of certification, including the categories of digital health solutions subject to certification;
- (b) specify criteria for certification, including functionality, interoperability, security, and reporting requirements;
- (c) outline the certification process, including application procedures, testing methodologies, re-certification, and audits; and
- (d) provide administrative procedures for addressing non-compliance and timelines for rectification.

(2) The Agency shall, in relation to certification of digital health solutions, —

- (a) manage the certification process;
- (b) ensure that health data controllers and digital health solutions comply with the Certification Framework;
- (c) ensure that the Certification Framework is aligned to digital health standards and guidelines developed and published by the Cabinet Secretary; and
- (d) disseminate the Certification Framework including the digital standards and guidelines.

(3) The Agency may, in collaboration with the relevant institutions, set up and certify laboratory-based testing environments for the purposes of assessing the conformity of digital health solutions with the Certification Framework.

Considerations for certification.

6. (1) The Agency shall certify digital health solutions based on considerations determined by the Board including—

- (a) functionality as set out in the Certification Framework including the system and data quality;
- (b) compliance with reporting and alerts as required by the prevailing policies and guidelines in the health sector;
- (c) compliance with the Information Security, Privacy and Confidentiality standards provided in the Kenya Health Data Governance Framework established under section 21(1) of the Act; and
- (d) capacity to perform information exchange and interoperability in accordance with the Interoperability Framework developed by the Cabinet Secretary pursuant to section 21(2)(b) of the Act

(2) The Agency shall assess a digital health solution submitted for certification in accordance with the—

- (a) functionality test for each type of digital health solution as specified by the Agency; and
- (b) standards and guidelines for each type of digital health solution set by the Cabinet Secretary.

PART IV – CERTIFICATION PROCESS

Certification process.

7. The process of certifying a digital health solution shall involve—

- (a) self-attestation and application;
- (b) document review;
- (c) scheduling and testing;
- (d) certification;
- (e) re-certification and ad hoc audit; and

(f) review or appeals.

Self-attestation,
application and
document review.

8. (1) A digital health solution provider shall apply for the certification of a digital health solution to the Agency using the Form set out in the First Schedule.

(2) A digital health solution provider shall, prior to applying for certification under subregulation (1), undertake self-attestation on the digital health solution to be submitted for certification.

(3) A digital health solution provider who makes an application under subregulation (1) shall submit documents for review by the Agency including—

- (a) a self-attestation report;
- (b) proof of payment of the certification fees set out in the Second Schedule;
- (c) incorporation certificates of the health data controller;
- (d) the particulars of the health data controller;
- (e) a system manual and requirements specification;
- (f) evidence of registration with the office of the Data Protection Commissioner as a data controller and data processor
- (g) the security, privacy and confidentiality policy of the health data controller;
- (h) the system back-up and recovery policy of the health data controller; and
- (i) the Cyber Security Assessment Report of the digital health solution.

Scheduling and
testing.

9. (1) The Agency shall schedule and undertake testing of the digital health solution submitted to the Agency for certification.

(2) The Agency shall, on completion of the testing under subregulation (1), notify the digital health solution provider of the results of the testing within five days from the date of the adoption of the testing report by the Board.

(3) The digital health solution provider shall comply with the requirements given by the Agency in the testing report.

(4) The digital health solution provider may, on receipt of the testing report, submit further evidence of compliance to the Agency including the corrective actions taken to comply with the requirements given by the Agency.

(5) Where the Agency finds that the corrective actions taken by the digital health solution provider—

(a) sufficiently resolves the non-compliance, the Agency shall issue a certificate of compliance for the digital health solution; or

(b) does not sufficiently resolve the non-compliance, the Agency shall refuse to certify the digital health solution.

(6) Where the Agency refuses to certify the digital health solution, the digital health solution provider may resubmit the application for certification in the manner set out in these Regulations and the certification framework.

(7) A digital health solution provider dissatisfied by the decision of the Agency in relation to the certification process may apply to the Complaints Committee for a review of the decision.

(8) The Complaints Committee shall consider the application for review within fourteen days from the date of the application for review.

Certification.

10. (1) The Agency shall notify the digital health solution provider of the outcome of their application for certification within thirty days from the date of the completion of the testing under regulation 9.

(2) The Agency shall, where the digital health solution complies with Certification Framework, —

(a) issue a certificate of compliance for the digital health solution; and

(b) enter the digital health solution into Certification Register maintained by the Agency.

(3) The certificate of compliance issued under this regulation shall be valid for a period of two years from the date of issue.

(4) A digital health solution provider shall, on the expiry of the period under subregulation (3), submit their digital

health solution for re-certification in the manner specified under these Regulations.

Ad hoc audit.

11. (1) A digital health solution provider or health data controller shall comply with the Certification Framework set out in the Schedule for purposes of maintaining the certification of the digital health solution issued pursuant to section 6(m) of the Act and these Regulations and shall, in particular—

- (a) perform the necessary updates and bug fixes;
- (b) ensure that the certified digital health solution documents any change logs;
- (c) ensure that data generated through the certified digital health solution is accurate, timely, complete, consistent, valid and in conformity to the needs of the health sector;
- (d) perform regular data quality assessments of their systems using standards, protocols and tools defined by the Agency and maintain records of the assessments for review by the Agency;
- (e) notify the Agency in the event of system changes affecting security, functionality, reporting or interoperability of the digital health solution upon which the Agency shall conduct a fresh audit of the digital health solution; and
- (f) notify the Agency, in the event of system breaches, on the nature of the breach and the solution implemented to resolve the breach.

(2) The Agency shall, during the validity period of the certificate of compliance, undertake ad hoc audits including site visits to—

- (a) assess compliance with certification requirements; and
- (b) verify corrective actions in the event of non-conformity with the certification requirements.

(3) Despite subregulation (2), the Agency shall conduct a fresh audit in the event of a breach of the certificate of compliance.

PART V – MONITORING IN CERTIFICATION

Monitoring of compliance by the Agency.

12. (1) The Agency shall monitor compliance with the Certification Framework by digital solution providers or health data controllers and, in particular, shall—

- (a) review the data quality assessments submitted by health data controllers to ensure compliance with the digital health standards and guidelines; and
- (b) schedule and conduct annual audits and checks, using the tools and procedures in the Data Quality Assessment Standards, to assess adherence and compliance to Data Quality Protocols by the System and the certified digital health solutions

(2) A digital health solution provider or health data controller shall comply with a change in the digital health standards and guidelines within six months from date of the change.

(3) The Cabinet Secretary shall, in consultation with the Agency, continuously revise and update Data Quality Protocols.

(4) A digital health solution provider who fails to maintain the certification status shall migrate health data in the enterprise service bus in accordance with the data migration guidelines issued by the Agency.

Revocation of certification.

13. The Agency shall revoke the certification of a digital health solution where—

- (a) the digital solution provider or health data controller fails to adhere to the certification requirements; or
- (b) a major system security breach has occurred.

Transitional and saving provisions.

14. (1) A digital health solution provider who, subject to subregulation (2) and (3), immediately before the commencement of these Regulations was providing a digital health solution shall continue to provide that digital health solution.

(2) A digital health solution provider referred to in subregulation (1) shall make an application using the Form set out in the First Schedule within six months of the coming into force of these Regulations for the certification of a digital

health solution to the Agency under regulation 9.

(3) Where the Board rejects an application for certification of a digital health solution applied for under this regulation, the digital health solution provider shall cease to provide that digital health solution from the date of the rejection of the application.

<ul style="list-style-type: none"> • PROPOSED USAGE: 	
<input type="checkbox"/> HEALTH FACILITY-WIDE	<input type="checkbox"/> COMPONENT
COMPONENT (Tick appropriately)	
<input checked="" type="checkbox"/> LABORATORY MANAGEMENT	<input type="checkbox"/> OUTPATIENT
<input type="checkbox"/> PHARMACY	<input checked="" type="checkbox"/> FINANCE
<input type="checkbox"/> CHRONIC DISEASE MANAGEMENT AND PROMOTION	<input type="checkbox"/> PREVENTION
<input type="checkbox"/> SURVEILLANCE & REPORTING	<input type="checkbox"/> OTHER
IF OTHER SPECIFY:	
REQUISITE DOCUMENTS (Attach the following documents)	
• Certificate of Incorporation	
• Tax Compliance Certificate	
• Evidence of Registration with the ODPC	
• Data Protection Impact Assessment Report	
• System Manual & Requirements Specification	
• Self-attestation Report	
• Security, Privacy and Confidentiality Policy	
• System Backup and recovery policy	
• Cybersecurity Assessment Report	
• Proof of payment of the prescribed fee	
DECLARATION	
I hereby attest that the information provided, including the attached documents, is true and accurate to the best of my knowledge. I authorize the DHA to validate and verify for legitimate purposes.	
Signature:	Date:

SECOND SCHEDULE
(r. 8(3)(b))

REPUBLIC OF KENYA
DIGITAL HEALTH ACT, NO. 15 OF 2023
THE DIGITAL HEALTH (USE OF E-HEALTH APPLICATIONS AND
TECHNOLOGIES) REGULATIONS, 2024

FEES

	Component	Fees
	CERTIFICATION Paid by the Digital Health Solution Vendor	<ol style="list-style-type: none">1. Application fees – KES. 20,0002. Testing of the PoC, Hospital-wide HMIS – KES. 500,0003. Mhealth solution – KES. 50,0004. Telemedicine – KES. 250,000 <hr/> <ol style="list-style-type: none">1. Innovators, Students and innovator system testing up to a maximum of KES.10,000

Made on the, 2024.

DR. DEBORAH M. BARASA,
Cabinet Secretary for Health.