

COMMENTS BY THE NATIONAL ASSEMBLY DEPARTMENTAL COMMITTEE ON DELEGATED LEGISLATION

(a) THE DIGITAL HEALTH (HEALTH INFORMATION MANAGEMENT PROCEDURES) REGULATIONS, 2025

NO	REGULATION	ISSUE	TECHNICAL WORKING GROUP RESOLUTION
1	2	<p>(a) Define the following terms:</p> <ul style="list-style-type: none"> • Agency • Health data controller • Health data processor • Data subject • Digital Health Solution Provider • Certification Framework • Data Quality Standards and Protocols • Health Sector Information Security Operations Centre • Health Facility Information Security Operations Centre <p>(b) Import the definitions of the terms that is <i>emergency treatment, healthcare provider, healthcare services, sensitive personal data and System</i>, as they are used in the laws within which they are defined instead of using the words “has the meaning assigned to it”.</p> <p>(c) In the definition of the term “Information Security Operations Center”, delete the words “cutting edge”.</p>	<p>Adopted:</p> <p>(a) The terms proposed defined in regulation 2.</p> <p>(b) The definitions imported from the Health Act, Cap. 241 and the Data Protection Act, CAP. 411C.</p> <p>(c) The words “cutting edge” deleted In the definition of the term “Information Security Operations Center”.</p>
2	3	<p>Redraft the Regulation to state as follows:</p> <p>“The purpose of these Regulations is to—</p> <p>(a) ensure safe management of health information; and</p> <p>(b) provide for e-health through e-health applications and technologies.”</p>	<p>Adopted. Regulation 3 redrafted as recommended.</p>

3	4	Delete Regulation 4 as the Ministry may develop the Kenya Health Data Governance Framework separately pursuant to section 21(1) of the Digital Health Act, 2023.	Adopted. Regulation 4 deleted as recommended.
4	6	Delete the words “collaboration and cooperation with”.	Adopted. The words deleted in regulation 6.
5	11	In Regulation 11(3), delete the words “whichever is relevant” and substitute therefor the words “where applicable”.	Adopted. Regulation 11(3) redrafted to incorporate the words “where applicable”.
6	17	In Regulation 17(7), delete the words “within fourteen days from the date of the decision of the Agency” in light of the High Court Rules.	Adopted. The words deleted in regulation 17(7)
7	21	(a) In Regulation 21(1), define the term “de-identified”; (b) In Regulation 21(4), delete the words “the requirements of section 27 of the Act, and”.	Adopted. The term “de-identified” defined in regulation 2 in line with the Digital Health Act, No. 15 of 2023. The words “the requirements of section 27 of the Act” deleted in Regulation 24(1).
8	22	In Regulation 22(4), delete the words “within fourteen days from the date of the decision of the Agency”.	Adopted. The words deleted in regulation 22(4)
9	27	(a) In Regulation 27(2)(a), address how the oral complaint is to be recorded for purposes of ensuring practicality. (b) Provide for lodging a complaint through posting by mail. (c) Delete Regulation 27(3)(c).	Adopted. The issue of recording of complaints addressed by making reference to written complaints only. Regulation 27(2) further amended to make provision for the lodging a complaint through posting by mail. Regulation 27(3)(c) deleted as recommended.
10	29	Delete 29(b).	Adopted. Paragraph (b) deleted as recommended.
11	30	Rearrange the paragraphs under Regulation 30(1) to simulate the legal processes relating to the conduct of investigations.	Adopted. The paragraphs re-arranged to read:- <i>“(a) issue summons requiring the attendance of any person at a specified date, time and place for examination.</i> <i>(b) require any person to produce any document or</i>

			<p>information from a person or institution;</p> <p>(c) administer an oath or affirmation on any person during the proceedings;</p> <p>(d) examine any person in relation to a complaint; and</p> <p>(e) upon obtaining warrants from the court, enter into any establishment or premises and conduct a search and may seize any material relevant to the investigation.”</p>
12	40	<p>(a) Revise Regulation 40(9) as it is too long and wordy.</p> <p>(b) In Regulation 40(10), delete the words “with conditions’ so as to comply with section 13(m) of the Statutory Instruments Act, Cap. 2A on further delegation.</p> <p>(c) The Regulation to provide for appeal from the decision of the Agency in relation to the certification process.</p>	<p>Adopted. Regulation 40(9) amended to read-</p> <p>“40. (9) Where the Agency is satisfied with the outcome of the testing under this regulation, the Agency may—</p> <p>(a) issue a certificate of compliance for the digital health solution; and</p> <p>(b) notify the digital health solution provider within thirty days from the date of the completion of the testing.”</p> <p>The issuance of a certificate by the Agency with conditions deleted and regulation 40(10) amended to provide for appeal from the decision of the Agency in relation to the certification process.</p>
13	44	<p>(a) There is no provision for review or appeal in relation to revocation of a certification of a digital health solution.</p> <p>(b) Renumber Regulation 45 on transitional and saving provisions as Regulation 46 so as to cure the repetition in numbering.</p>	<p>Adopted. Regulation 44(4) amended to provide for the review and appeal mechanism as recommended.</p> <p>The error in numbering corrected.</p>
(b) THE DIGITAL HEALTH (DATA EXCHANGE COMPONENT) REGULATIONS, 2025			
1	2	<p>Define the following terms:</p> <ul style="list-style-type: none"> • Enterprise Service Bus • Agency 	<p>Adopted. The terms proposed defined in regulation 2.</p>

		<ul style="list-style-type: none"> • Shared resources • Shared Health Record 	
2	11	In Regulation 11(3), add the Data Protection Act in addition to the Computer Misuse and Cybercrimes Act.	Adopted. The Data Protection Act, Cap. 411c incorporated in regulation 11(3).
2	22	<p>(a) Is Regulation 22 necessary and yet the Digital Health Act is required to comply with all laws including Fair Administrative Action Act, Cap. 7J.</p> <p>(b) Provide for specific offences for breach of the Regulations and the commensurate penalties.</p>	Adopted. Regulation 22 deleted and recommended. A regulation on general offences introduced as regulation 22.
3	General	Provide timelines for uploading of health data on patients by a health facility.	Adopted. The uploading of health data provided in regulation 19(4).