



MINISTRY OF HEALTH

PUBLIC NOTICE: INVITATION TO MEMBERS OF THE PUBLIC AND ALL STAKEHOLDERS FOR PUBLIC PARTICIPATION AND STAKEHOLDER ENGAGEMENT ON DRAFT REGULATIONS FOR THE DIGITAL HEALTH ACT, 2023 AND THE DRAFT REGULATORY IMPACT STATEMENT

The Digital Health Act No. 15 of 2023 was enacted on the 19th October, 2023. The Act confers upon the Cabinet Secretary for Health, in consultation with the Digital Health Agency and the County Governments, the power to make Regulations under section 60 for various matters required to be prescribed under the Act, in particular, health information management policies and procedures, the use of e-Health applications and technologies, medical devices and innovations, data quality and data protection audits and the establishment and implementation of the data exchange component as per the Kenya Health Enterprise Architecture. To this end and pursuant to section 60 of the Digital Health Act;

IT IS NOTIFIED for information of the general public that the Cabinet Secretary for Health, in consultation with the Digital Health Agency and the County Governments, through a Technical Working Group comprised of officers from the Ministry of Health, the Council of Governors, County Governments, the Digital Health Agency, the Office of the Attorney General and Department of Justice, the Kenya Law Reform Commission and the National Assembly, has developed the following three (3) sets of draft regulations to the Digital Health Act:

- a) **The Digital Health (Health Information Management) Regulations, 2024**
- b) **The Digital Health (Data Exchange) Regulations, 2024**
- c) **The Digital Health (Use of e-Health Applications and Technologies) Regulations, 2024**

FURTHER in compliance with Section 6 of the Statutory Instruments Act No. 23 of 2013 which require the regulation making authority to, prepare a Regulatory Impact Statement about the proposed Regulations, the Cabinet Secretary for Health has in consultation with the Digital Health Agency and the County Governments, through the Technical Working Group, prepared a Regulatory Impact Statement for the proposed Regulations.

FURTHER AWARE THAT Article 10 of the Constitution as read with section 5 of the Statutory Instruments Act No. 23 of 2013 require a regulation-making authority to undertake public participation and make appropriate consultations with persons who are likely to be affected by proposed regulations. The provisions of section

5 further provide that the consultations envisaged under the Statutory Instruments Act No. 23 of 2013 shall involve notification, by advertisement, of bodies that, or of organizations representative of persons who, are likely to be affected by the proposed instrument or invite submissions or participation in public hearings to be held concerning the proposed instruments.

NOW THEREFORE, pursuant to Article 10 of the Constitution and section 5 and 6 of the Statutory Instruments Act No. 23 of 2013, the Cabinet Secretary, in consultation with the Digital Health Agency Board, invites interested members of the public, stakeholders and organizations to submit any comments, views or make representations regarding the three (3) draft regulations and the draft Regulatory Impact Statement.

The comments, views, representation and any written memoranda may be forwarded to the Office of the Principal Secretary, State Department for Medical Services, Nairobi; hand-delivered to the Office of the Principal Secretary, State Department for Medical Services on **Afya House 6th Floor, Nairobi**; or emailed to dharegulations@dha.go.ke; to be received on or before, 19th December, 2024, at 5:00 pm. The three (3) sets of draft regulations and the draft Regulatory Impact Statement are available at the following links: - <https://www.health.go.ke>

Additionally, and pursuant to the Statutory Instruments Act, 2013, the Cabinet Secretary and the Digital Health Agency plans to engage members of the public and stakeholders on the same through public hearings in two (2) sessions. The purpose of the hearings shall be to:

- a) **9.00 a.m. - 12.00 p.m.** - Sensitize the members of the public and stakeholders on the provisions of the Digital Health Act, the three (3) sets of draft Regulations and the draft Regulatory Impact Statement; and
- b) **2.00 p.m. - 5.00 p.m.** - Get oral submissions on the draft Regulations and the Regulatory Impact Statement to ensure that persons likely to be affected by the Statutory Instruments have adequate opportunity to give their views on the Instruments.

We therefore invite all stakeholders and members of the public for stakeholders' engagement meetings which shall be held as follows: -

REGION (CLUSTERED COUNTIES)	MEETING VENUE	DATE	TIME
UPPER EASTERN REGION Embu, Marsabit, Isiolo, Meru, Tharaka Nithi	Isiolo – Catholic Diocese of Isiolo Hall	9 th December, 2024	9.00 am – 12.00 pm 2.00 pm – 5.00 pm
NYANZA REGION Homa Bay, Siaya, Kisumu, Kisii, Migori, Nyamira	Kisumu – Mama Grace Onyango Cultural and Social Centre	9 th December, 2024	9.00 am – 12.00 pm 2.00 pm – 5.00 pm
CENTRAL REGION Nyandarua, Nyeri, Kirinyaga, Muranga	Nyeri – Nyeri Cultural Centre Hall	11 th December, 2024	9.00 am – 12.00 pm 2.00 pm – 5.00 pm
WESTERN REGION Kakamega, Vihiga, Bungoma, Busia	Kakamega – Magharibi Hall	11 th December, 2024	9.00 am – 12.00 pm 2.00 pm – 5.00 pm
SOUTH RIFT VALLEY REGION Nakuru, Narok, Bomet, Kericho, Baringo, Samburu, Laikipia	Nakuru – Regional Commissioners Hall	13 th December, 2024	9.00 am – 12.00 pm 2.00 pm – 5.00 pm
NORTH RIFT VALLEY REGION Turkana, Nandi, Uasin-Gishu, Elgeyo– Marakwet, Transzoia, West Pokot	Eldoret – Eldoret County Hall	13 th December, 2024	9.00 am – 12.00 pm 2.00 pm – 5.00 pm
COAST REGION Mombasa, Taita Taveta, Kwale, Kilifi, Lamu, Tana River	Mombasa – Technical University of Mombasa (TUM)	17 th December, 2024	9.00 am – 12.00 pm 2.00 pm – 5.00 pm
NORTH EASTERN REGION Garissa, Wajir, Mandera	Wajir – ICT Hall Wajir Town	17 th December, 2024	9.00 am – 12.00 pm 2.00 pm – 5.00 pm
NAIROBI REGION Nairobi, Kiambu, Kajiado	Nairobi – KICC	19 th December, 2024	9.00 am – 12.00 pm 2.00 pm – 5.00 pm
LOWER EASTERN REGION Machakos, Kitui, Makueni	Kitui – Kitui Multi-Purpose Hall	19 th December, 2024	9.00 am – 12.00 pm 2.00 pm – 5.00 pm

All interested persons should submit written comments on the draft Regulations and draft Regulatory Impact Statement in the prescribed format as follows;

TEMPLATE TO SUBMIT COMMENTS

NAME OF ORGANIZATION/INDIVIDUAL PERSON				
S/No.	Regulation/Clause	Issue of Concern	Justification	Recommendations
1.				
2.				

DR DEBORAH BARASA
CABINET SECRETARY/MINISTRY OF HEALTH