

DRAFT NATIONAL eHEALTH POLICY

Prepared by

Technical Working Group (TWG) (for Legislation, Policy & Compliance) towards the implementation of National eHealth Strategy

Submitted to

eHealth Project Management Office (PMO) Federal Ministry of Health New Federal Secretariat Abuja



Facilitated by NITDA in collaboration with the Federal Ministries of Health and Communications

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Foreword

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Important Definitions

- **eHealth** refers to use of information and communication technology (ICT) in support of health and health-related fields, including health care services; health surveillance; health literature; and health education, knowledge, and research.
- **Information Technology** is all forms of technology used to create, store, exchange and use information in its various forms (source NITDA Act).
- **Personal Health Information (PHI)**is demographic information, medical histories, test/laboratory results, mental health conditions, insurance information, and other data that a healthcare professional collects to identify an individual.
- Universal Health Coverage (UHC) is defined as ensuring that all people have access to needed healthservices (including prevention, promotion, treatment, rehabilitation and palliation) of sufficient quality to be effective while also ensuring that the use of these services does not expose user to financial hardship.

Acronyms and Abbreviations

CPC Consumer Protection Council

CVRS Civil and Vital Registration Statistics

ICT Information, Communication Technology

FMOH Federal Ministry of Health

HRORBN Health Records Officers Registration Board of Nigeria

NAFDAC National Agency for Food and Drug Administration and Control

NHA National Health Act

NHIS National Health Insurance Scheme

NHMIS National Health Management Information Systems

NITDA National Information Technology Development Agency

MDCN Medical and Dental Council of Nigeria

MLSCN Medical Laboratory Science Council of Nigeria

PCN Pharmaceutical Council of Nigeria

PHI Personal Health Information

PMO Project Management Office

SDG Sustainable Development Goals

SON Standards Organization of Nigeria

TWG Technical Working Group

UHC Universal Health Coverage

MDA Ministry Department and Agency

USPF Universal Social Provision Fund

MAC Media Access Control

IP Internet Protocol

IMEI International Mobile Equipment Identity

IMSI International Mobile Subscriber Identities

SIM Subscriber Identification Module

1.0 Introduction

1.1 Background

The World Health Assembly in 2005 recognized the widespread use of ICT in the health sector. However, it observed that coordination was limited and thus, passed resolution 58.28 on the adoption of eHealth where member states were urged to draw up long-term strategic plans for development and implementation of digital health services to strengthen their health systems. Similarly, in 2010 the WHO regional committee meeting for Africa further urged member states to strengthen their health systems through the creation of the appropriate enabling environment for digital health governance through effective regulations; human resource development; adoption of standards to facilitate interoperability; the provision of the requisite infrastructure together with promotion and use of the appropriate services and applications.

Universal Health Coverage (UHC) is a principal goal of Nigeria's health policy. UHC is a foundational strategy for the country's attainment of the Sustainable Development Goals (SDGs) by the year 2030.ICT is a key instrument to achieve the goal of UHC.From providing easier enrollment and coverage of persons through ICT platforms for health insurance programmes to provision of services through telemedicine, eHealth is essential to achieving universal health coverage. With this background, in 2016, the National Health ICT Strategic Framework 2015-2020 was developed by the Federal Ministry of Health.It acknowledged the burgeoning but uncoordinated deployment of eHealth strategies and products, manifested amongst different stakeholders in the health sector. It aimed to facilitate better coordination of the use of ICT in order to produce effective and sustainable solutions for the achievement of UHC.

The need for a unifying policy is well acknowledged in eHealth literature and in the WHO-ITU eHealth Strategy Toolkit. An inadequate policy and regulatory environment for eHealth has been noted as a key challenge for encouraging and sustaining innovation and uptake of existing and emerging eHealth products. There are a myriad policies and regulations which touch upon the use and application of eHealth. However, the fragmentation in policies and regulations on eHealth remains another key challenge. A policy that addresses key issues and provides a basis for an enabling environment for eHealth and standards for its management, and which may eventually form the basis of legislation is thus essential. Matters relating to legislation, policy and compliance therefore constitute a major component of the ICT strategy and covers national policies and legislation for Health ICT in terms of development, alignment and regular review.

The Technical Working Group (TWG) for Legislation, Policy and Compliance was established in line with National Health ICT Strategic Framework and is chaired by NITDA. The mandate of this TWG being two-fold:

- 1. Develop a National eHealth Policy taking into accounts the National Health Policy, The National Health Act, The National ICT Policy, and other relevant health or ICT policies.
- 2. Develop and recommend regulatory/compliance guidelines for the National eHealth Policy and other guidelines.

This draft document is the result of deliberations of the TWG for Legislature, Policy and Compliance. It provides a framework that draws from the disparate policies and pieces of legislation relevant to eHealth in Nigeria which going forward will provide a unified policy for Nigeria. For the purposes of would be policy and for consistency across policies, the definition of eHealth provided in the Health ICT Framework is adopted. It also adopts the approach already set out by the National Health and ICT Strategic Framework in emphasizing eHealth as beneficial and requiring a positive enabling environment.

1.2 Situation Report

Nigeria as a developing country has consistently ranked poorly on global health indices. For instance, the National Health ICT Strategic Framework (2015 - 2020) stated inter-alia: "...Despite the country's economic gains, the overall health status of the Nigerian population is poor (as defined by the 2013 Nigeria Demographic and Health Survey); infectious and noncommunicable diseases remain among the leading causes of morbidity and mortality, ...; and health coverage and financing remains low. Over 46% of the population continues to live in poverty (2010 estimate); ...; Maternal and under-five mortality rates remain high at 576 deaths per 100,000 live births and 201 deaths per 1,000 live births, respectively; ...; Nigeria is second to South Africa in the number of people living with HIV/AIDs worldwide; This represent 9% of Global burden of the disease" and a declining prevalence rate of 4.1 as of 2010. (NDHS 2013, page 224); Malaria is the leading cause of infant and child mortality; Diseases such as hypertension, diabetes and coronary heart disease also represent an increasing share of Nigerians' burden of disease; As of 2013, fewer than 5% of the population were insured; Nigeria is among the 23 African nations that spends more than USD44 per capita on health care, however, the government expenditure on health is 6.1% of the gross domestic product - below the Abuja Declaration's target of 15%....".

Nigerian government at-all-times have recognized these shortcomings and has prioritized health as a critical essential social service and placed health matters on the concurrent legislative list. The health components of all National Development Plans and health policies have acknowledged these issues and have always proffered strategies, plans and programmes to overcome the observed challenges. Also, Nigeria as a state member has always adopted WHO guidelines, strategies, action plans and programmes

in order to solve Nigeria's health challenges. Presently, Nigeria's government is committed to attaining UHC through the SDGs by 2030.

Globally, digital technology, due to its' numerous advantages has gained unprecedented acceptance and usage in all spheres of life including governance, defense, engineering, education, commerce and health. In this regard, the WHO established the Global Observatory for eHealth (GOe) in 2005. The WHO's eHealth resolution adopted in 2005 focused on strengthening health systems in countries through the use of eHealth; building public-private partnerships in ICT development and deployment for health; supporting capacity building for the application of eHealth in member states; and the development and adoption of standards.

Accordingly, following the GOe action plans and survey reports of (2005) and (2009; 2013; 2015) respectively, the WHO and ITU developed eHealth strategy Toolkit for member states.

In 2005, all WHO Member States (*including Nigeria*) made the commitment to strive for universal health coverage (UHC). Pursuant to Nigeria's commitment to attain UHC by 2030, the FMOH in collaboration with other MDAs developed the National Health ICT Strategic Framework 2015 – 2020. This Framework, published in March, 2016, was adapted from WHO/ITU eHealth Strategy Toolkit (2012) with seven (7) components – Leadership & Governance; Strategy & Investment; Architecture, Standards & Interoperability; Solutions (Services & Applications); Capacity Building; Infrastructure; Legislation, Policy and Compliance. Furthermore, the FMOH has put in place different Technical Working Groups (TWGs) to develop all the components of the National Health ICT Strategic Framework. The TWG on Policy, Legislation and Compliance; made up of participants from critical sectors is chaired by NITDA and has been mandated to develop a draft National eHealth Policy together with its accompanying regulatory guidelines.

1.3 Vision and Mission

Vision

The vision of this policy is in alignment with that of the national eHealth strategy which states: "By 2020, Health ICT will help enable and deliver Universal Health Coverage"

Mission

To revolutionize the delivery of effective and efficient health care services through the use of information communication technology.

2.0 Policy Context

2.1 eHealth Strategy

This policy is being developed in line with the principles outlined in existing national eHealth strategy document which presents UHC as its central goal. The successful use of Health ICTs to achieve UHC in Nigeria will achieve:

- Improved access to health services through the effective use of telemedicine and other ICTs for health worker training and support;
- Improved coverage of health services through the effective use of Civil Registration and Vital Statistics (CRVS), National Identity Management System (NIMS), Human Resource Management Information Systems (HRIS), National Health Management Information System (NHMIS) and Logistic Management Information System (LMIS) for tracking demand and supply of health services and commodities;
- •Increased uptake of health services through the effective use of mobile messaging and cash transfer incentives for demand creation;
- •Improved quality of care through the effective use of ICT for decision support within the continuum of care;
- •Increased financial coverage for health care services through effective use of ICT for the national health insurance scheme (NHIS) and other health-related financial transactions and;
- •Increased equity in access to and quality of health services, information, and financing through effective use of ICTs for delivering appropriate health services for those who need them.

2.2 Applicable Laws and Legal Framework

The legal underpinning for eHealth in Nigeria is located in different pieces of legislation. Principal among these is the Constitution of the Federal Republic of Nigeria 1999 (as amended) which provides for a right to privacy. This right has been interpreted in judicial cases as including the right to privacy in the health sphere. In addition, the National Health Act of 2014 ("NHA"), a comprehensive health statute in Nigeria establishes amongst other things the national health system, which is required to provide the best possible health services within the limits of available resources for persons living in Nigeria; and to protect, promote and fulfill the rights of the people of Nigeria to access health care services. Its provisions underpin health delivery, including eHealth innovations and practices implicated in health care delivery. With respect to health information systems management, a key component of eHealth, the National Health Act mandates the Federal Ministry of Health (FMOH) to facilitate and co-ordinate the

establishment, implementation and maintenance by State Ministries, Local Government Health Authorities and the private health sector of the health information systems at the national, state and local government levels in order to create a comprehensive National Health Management Information System. As the National Health Management and Information System cannot be set up and managed without the utilization of ICT, the reasons the National Health Act envisaged the use of ICT in healthcare delivery and in the management of health information becomes clear. Health Management Information System is particularly essential as States enact and operationalize their Health Insurance Scheme laws. Some States have also enacted legislation to manage health information systems. In addition to the National Health Act's provisions on health information systems management, it also provides for relevant standards including the right to privacy and confidentiality of health information, patient privacy and the secure capture, processing, storage, and transfer of personal health information. It establishes offences relating to the misuse of personal health information.

The other significant legal framework in this regard is the *Health Records Officers* (*Registration, etc.*) (*HRORBN*) *Act*, which establishes a Board to oversee the profession of health records management. It defines health record broadly to include "all technical and clerical procedures associated with management of patients from primary health care to tertiary levels of care." It regulates health records management, including the "logistics of admission and discharge routines, reception and registration, efficient appointment system, coding and classification of morbidity and mortality dates, maintenance of waiting lists, preservation of health medical records and provision of medical secretariat services."

Ethical and Professional Codes of Conduct issued and enforced by professional regulatory bodies would, to the extent that they touch on eHealth, provide guidance to practitioners on how eHealth matters are to be dealt within their respective fields and create the standard of conduct required of their professionals. The existence of these subsidiary legislations, create avenues for the management of various eHealth issues. A case in point is the Code of Medical Ethics in Nigeria, 2008, made pursuant to the Medical and Dental Practitioner's Act, which recognizes telemedicine and acknowledges its existence in Nigeria and provides some practice guidance in that regard to members of the medical and dental profession in Nigeria.

The NITDA Act 2007 establishes the National Information Technology Development Agency and charges it with the responsibility to develop IT and enforce IT standards across the economy, including the health sector. The reach of NITDA's regulatory authority extends to eHealth and is reflected in its data protection policies and regulation. This eHealth Policy will draw from the standards set out in various NITDA guidelines and regulations, especially those relating to collection, storage and protection

of personal data of Nigerians. Other relevant statutes whose provisions would significantly impact this policy includes the Cybercrimes (Prohibition, Prevention, etc) Act 2015, the Nigerian Communications Act 2003; the National Identity Management Commission (NIMC) Act; and regulations promulgated by the institutions established under those laws, like the Nigerian Communications Commissions' Registration of Telephone Subscribers (RTS) Regulations.

While the eHealth Policy acknowledges the foregoing pieces of legislation as forming part of the foundational legal framework from which standards can be drawn for the guidance of stakeholders, and for the regulation of eHealth in Nigeria, several gaps however, remain. These gaps include but are not limited to the definition of personal health information; what constitutes "health record"; the entities obligated to comply with data processing requirements; the conditions for the lawful processing of data, for example, the procedure for obtaining consent from the patient; patient information disclosure management; data quality; whether patient or health data can be stored in a Cloud and whether the cloud service can be off premises and outside the country, etc are some of the issues which are not fully addressed. This Policy will focus on these gaps and point stakeholders towards the direction of addressing them. It is anticipated that in the future, eHealth focused legislation will consider positions adopted in this policy after due consultation with key stakeholders.

A summary of relevant legal instruments includes but may not be limited to:

- (i) National Health Act
- (ii) Health Records Officers Registration Board of Nigeria Act
- (iii) NITDA Act 2007
- (iv) Cybercrimes (Prohibition, Prevention, etc) Act 2015
- (v) Nigeria Communications Act 2003
- (vi) National Identity Management Commission Act
- (vii) Freedom of Information Act
- (viii) Consumer Protection Council Act

3.0 Policy Development Process, Thrust, Direction and Statements

3.1 Policy Development Process

The policy development process was initiated and commissioned by the Federal Ministry of Health (FMOH). Under the direct supervision of the Project Management Office (PMO), the Technical Working Group (TWG) for Legislation, Policy and Compliance, (chaired by NITDA) in collaboration with the relevant stakeholders and consistent with the National Health ICT Framework will meet as many times as may be required to develop the first draft which will be sent to the FMOH (through the PMO) for review and final ratification. Stakeholder collaboration/engagement here may include workshops, townhall meetings, etc.

3.2 Policy Thrust

Policy addresses the application of ICT to health care delivery in Nigeria and will articulate Government's commitment to providing an enabling environment for all aspects of digital health and particularly telemedicine, Health Information Management System (HMIS)/electronic health records, teleconsultation, telepathology, telemonitoring, tele-radiology, tele-dermatology, tele-ophthalmology, tele-surgery, e-prescribing, e-referrals, electronic transmission of results, emailing of drugs/medication, e-counselling, consumer health informatics, m-Health, emergency medical response system, enlightenment/awareness, e-payment, disease outbreak, e-surveillance and monitoring.

3.3 Policy Direction

Policy is developed around the policy thrusts identified. It was drafted after due consultation with stakeholders and a careful consideration of eHealth policies and laws in other jurisdictions. The Policy will significantly strengthen and improve the Nigerian health system and enhance universal health coverage for Nigerians.

3.4 Policy Statements

In order to ensure ownership by the populace and thus enable broad-based compliance, the process of developing a national eHealth policy for Nigeria will need to be farreaching, multi-sectorial and cross-cutting. The *Policy Statements* served to give direction to policy development process and therefore constitute the soul of this Policy. Enabled by the WHO/ITU tool kit, the *Policy Statements* together with their adjoining objectives and strategies have been adapted from the 7 component areas of the Health ICT Strategic Framework as follows:

Leadership & Governance

Government at all levels shall engage and create awareness on eHealth adoption
while the private sector shall be encouraged to increase participation in the
implementation of eHealth strategies and projects.

Objective:

To ensure that the oversight and coordinating role of government at all levels is maintained thus better guarantee sustainability in the implementation of Nigeria's eHealth strategy whilst also better aligning our national health goals and priorities amongst stakeholders (private sector inclusive).

Strategies:

- 1. Educate the various government actors (especially at the state level) of their role in this value chain using workshops and capacity building programmes (with private sector players in attendance).
- 2. Publish Nigeria's governance structure for eHealth deployment and distribute widely amongst stakeholders.

Strategy & Investment

- Government shall institutionalize the provision of a dedicated budget line item for the implementation of eHealth in relevant MDAs;
- Government shall encourage incentives for private sector investment in eHealth.

Objective:

To ensure that the enabling environment needed to position eHealth as a viable investment in Nigeria is provided.

Strategies:

- 1. Embark on robust advocacy for budgetary inclusion for eHealth.
- 2. Develop incentives to encourage private sector participation.
- 3. Ensure full implementation of our local content laws.

Architecture, Standards & Interoperability

Government shall promote unifying standards for use by practitioners/consumers
across the healthcare value chain whilst also ensuring that the standards are
enforceable.

Objective:

To promote cyber security and ensure interoperability amongst operators within the Health ICT value chain.

Strategy:

1. Regulate and possibly streamline usage of IT software and hardware.

Solutions (Services & Applications)

• Government shall periodically publish national priority areas for eHealth innovations/interventions whilst ensuring alignment with local content policies.

Objective:

To ensure that devices and tools promoted for end-user consumption take into consideration the peculiarities and dynamism of Nigeria's healthcare system especially as it concerns on-going changes in our priority areas (or areas of focus).

Strategies:

- 1. Strengthen the relevant regulatory body to act as central clearing house for all prospective solutions.
- 2. Develop and deploy a very agile data collection and dissemination infrastructure within the healthcare system.

Capacity Building

- Government shall make basic ICT training mandatory in all health training institutions;
- Government shall provide a national e-Learning platform for the healthcare workforce (public and private sectors).

Objective:

To ensure that adequate capacity in ICT is built amongst Nigeria's healthcare workforce.

Strategy:

1. Collaborate with the relevant bodies to introduce basic IT into the training curriculum of healthcare workers in Nigeria.

Infrastructure

- Government shall prioritize and promote the availability of sustainable alternative sources of power in all healthcare facilities;
- Government through USPF and other relevant Agencies shall provide internet access /connectivity for health facilities in underserved areas.

Objective:

To ensure that the physical facilities and related assets that form the foundation for Health ICT implementations are made available.

Strategy:

- 1. Provide strong advocacy for legislation to make mandatory the provision of alternative sources of power in all healthcare facilities.
- 2. Provide strong advocacy to ensure underserved communities have internet access.

Legislation, Policy & Compliance

- Government at all levels shall direct its Agencies to exercise their latent powers for the promotion and regulation of digital health services;
- Government shall through legislation provide a level playing field for local and international healthcare providers thus mitigating economic losses and unwholesome health practices.

Objective:

Provide constitutional backing for all future eHealth initiatives and thus better assure its sustainability whilst also ensuring that regular reviews and updates are done at the prescribed intervals.

Strategy:

1. Facilitate regular workshops and knowledge sharing sessions where capacity is built amongst regulators within the ecosystem.

3.5 Policy Review

eHealth is an emerging area in health care service delivery. ICT in itself is dynamic and new inventions are coming up which can change the face of healthcare delivery. It is therefore imperative that this policy is reviewed periodically to reflect continuing changes in eHealth and technological advancements. This Policy shall be reviewed every three (3) years.

4.0 Monitoring and Evaluation

The Project Management Office (PMO) in the Federal Ministry of Health in collaboration with relevant agencies shall be responsible for monitoring and evaluating the implementation of this Policy in line with indicators that shall be developed in the action plan. It is expected that baseline survey will be carried out at the onset of the implementation, and will be followed by subsequent surveys which will collect relevant information on eHealth adoption and the impact of the implementation of this Policy.

5.0 Conclusion

Policy when fully operational will seek to achieve the following:

- 1. Ensure adequate resource allocation (finance, human resources and logistics support) for health information system at all levels.
- 2. Strengthen mechanisms to ensure accuracy, timeliness and completeness of health data-reporting from both public and private health facilities.
- Build up capacity in routine data-collection, analysis and interpretation for decision making.
- 4. Strengthen coordination mechanisms and platforms for effective collaboration, harmonization and integration of data-collection, reporting and management systems of both state and non-state actors to ensure adequate and complete information for decision making in health care delivery.
- 5. Strengthen mechanisms for translating health evidence into policy, decision making and resource allocation.
- 6. Collaborate with relevant Agencies to strengthen civil registration and harnessing of vital statistics.
- 7. Strengthen and integrate existing surveillance systems and registries into the overall health information system.
- 8. Strengthen both data and ICT infrastructure at all levels within the healthcare value chain.
- 9. Strengthen mechanisms to ensure data protection, confidentiality and security, in line with the provisions of the *National Health Act* 2014.
- 10. Establish a national health observatory for appropriate knowledge management.
- 11. Develop and implement mechanisms to ensure collaboration, harmonization and integration of data-collection, analysis, storage and dissemination of activities of state and non-state actors to ensure adequate and complete information sharing for decision making in the health sector.
- 12. Strengthen mechanisms that ensure accuracy, timeliness, and completeness of health information from the general population and from health facilities.

Appendix

RELEVANT LAWS, REGULATIONS AND STANDARDS APPLICABLE TO IMPLEMENTATION OF E-HEALTH IN NIGERIA

INSTRUMENT	CORE PURPOSE	APPLICABILITY TO E-HEALTH	COMMENT
1999 Constitution	defines rights and core	S. 17(3)c, d- State Policies to be	
	national institutions	directed to improving health of	
		persons	
		S. 37 Privacy right is guaranteed	
Health Records	An Act to establish a	The Board can by its powers in S.	determining what
Officers	Board for the control	1(2)a prescribe digital literacy as	standards of knowledge
(Registration etc.)	and practice of the	minimum qualification for entry or	and skill shall be attained
Act	profession of health	continuation in the profession	by a person seeking to
	records management		become a member of the
	and matters relating		profession of health records
	thereto.		management and
			improving those standards
			from time to time as
			circumstances may permit
Primary	To make healthcare	S.3(a)I the Agency shall support	
Healthcare	accessible at all locations	National Health Policy by	
Development	and for all Nigerians	reviewing existing health policies	
Board Act		particularly as to their relevance to	
		the development of primary health	
		care and to the integrated	
		development of health services	
		and health manpower and propose	
		changes when necessary;	
National Health	To provide healthcare	S.6(g) advising on the continuous	NHIS can issue
Insurance Scheme	services for all at	improvement of quality of services	regulation, promotion
Act	reasonable prices and	provided under the Scheme	and adoption of eHealth
	efficiently	through guidelines issued by the	platforms and products
		Standard Committee established	in health institutions.
		under section 45 of this Decree;	This would make the
			services more efficient
Evidence Act	Determines admissible	S. 84 admits electronic and	This gives vent to the
2011	evidence in court	computer evidence	development of digital
	proceedings		health as it is now
			statutorily recognized as
			an enforceable means of
			transaction

NITDA Act	Regulation, Development and Advisory on IT	S.6© Develop guidelines for electronic governance and monitor the use of electronic data interchange and other forms of electronic communication transactions as an alternative to paper-based methods in government, commerce, education, the private and public sectors, labour, and other fields, where the use of electronic communication may improve the exchange of data and information.	The Agency clears IT projects in the public sector and gives advice to MDAs. Its standards and Guidelines would also help to develop eHealth
National Enterprise Network Architecture	The Standards makes provision for vertical and horizontal communications amongst MDAs. It seeks to establish a nationwide Network that seeks to connect Government IT infrastructure		It is advised that the eHealth Architecture aligns with this and provide further specialization where necessary
National Information Systems and Network security standards and Guidelines	This standard provides for Network Security measures and principles for Government Agencies		This Standard would provide a base for the design of eHealth network security.
Data Interoperability Standards	This standard defines basic schema for establishing data interoperability between databases and systems		This Standard enumerates basic data sets that users are to ensure interoperability. It gives room for sector specific additional standards
Data Protection Guideline	Prescribes obligations of Data Controllers, processors and protects data owners from abuse	Personal Data means any information relating to an identified or identifiable natural person ("data subject"); information relating to an individual, whether it relates to his	

	or her private, professional or	
	public life. It can be anything from	
	a name, address, a photo, an email	
	address, bank details, posts on	
	social networking websites,	
	medical information, and other	
	unique identifier such as but not	
	limited to MAC address, IP	
	address, IMEI number, IMSI	
	number, SIM and others.	