

Nigeria Regulatory Considerations for Telemedicine

Introduction

This paper examines the critical legal considerations for digital healthcare providers, entrepreneurs and patients seeking to harness the diverse benefits of telemedicine in Nigeria. Through a detailed analysis of existing regulations, it highlights the current regulatory landscape and proposes possible ways to address intellectual property, consents, data protection, tax, sector regulatory, licensing and damages concerns relating to the practice of telemedicine in Nigeria including the need for guidelines in Nigeria. The existing regulations largely address some of these concerns except for training, compensation, and practice restrictions. Further regulations are needed to address these concerns. Key points to be addressed by such regulations are set out below.

Key Legal Considerations for the Practice of Telemedicine in Nigeria

Telemedicine is defined as the delivery of healthcare services by health professionals at a distance using Information Communication Technology ("ICT") to exchange valid information for the purposes of diagnosis, treatment, and prevention of disease and injury, with the aim of safeguarding the health of individuals and communities. Simply put, healthcare service providers engage with patients remotely through various digital platforms and with the aid of digital tools enabling patients to have access to diagnosis, treatment, and prescription from the comfort of their homes.

Indeed, there is no specific legal framework dedicated to regulating telemedicine in Nigeria. Despite this, telemedicine intersects with various existing legal frameworks. Some key legal considerations relevant to telemedicine providers in Nigeria to enable them to maximize the opportunities presented by telemedicine in Nigeria include: -

A. Intellectual Property (IP): Telemedicine raises several IP issues due to its association with several innovations and patent applications, including the creation of artificial intelligence and machine learning algorithms for diagnosing and treating medical diseases.² Telemedicine providers and entrepreneurs need to secure their IP rights, trade secrets, and assets, thereby safeguarding proprietary technologies and content that form the basis of their competitive advantage and value creation. In Nigeria, there are laws present to safeguard innovations (industrial property)³ and content (copyright)⁴.

Safeguarding intellectual property rights and assets in telemedicine presents a plethora of opportunities, such as attracting investment, funding for telemedicine projects,

¹ World Health Organisation, "Consolidated Telemedicine Implementation Guide" (2022) https://www.who.int/publications/i/item/9789240059184 (Accessed December 20, 2024); the Code on Medical Ethics in Nigeria, Part A, (the "Code") Rule 22.

² Foster Capital, "Telehealth Intellectual Property: Protecting Telehealth Innovations: A Guide for Enterpreneurs" (2024) in https://fastercapital.com/content/Telehealth-intellectual-property--Protecting-Telehealth-Innovations--A-Guide-for-Entrepreneurs.html (Accessed December 30, 2024).

³ Patents, Trademarks, and Industrial Designs. See Trademarks Act, Chapter T13 LFRN 2004 and Patents and Designs Act Chapter P2 LFRN 2004.

⁴ Literary, Artistic and Musical Works. See Copyright Act Chapter C28 LFRN 2004.

preventing unauthorized infringement, and facilitating the commercialization of telemedicine technologies and services.⁵

B. E-Consent: Consent is a prerequisite for diagnosis and treatment in Nigeria. The National Health Act ("NHA") and the Code mandates that informed consent in written or printed form must be obtained from a patient before any medical procedure including diagnosis, whether invasive or non-invasive. Patients also have the right to refuse health services. This consent can be obtained from the patient, his/her relations, or the public authority (e.g. court order), depending on the circumstances. The Code also provides for an approved format for the purpose of universal application throughout Nigeria. Proper informed consent must include: (i) the benefits and risks of the procedure; (ii) appropriate professional advice on options; (iii) the patient's choice of preferred options; (iv) authorization for the healthcare service provider to commence treatment; and (iv) the particulars of the witness. 8

Indeed, the provision of digital medical services is not exempt from the rule of obtaining informed consent, and this should be strictly construed as personal data is involved. A key aspect of consent is also the capacity to give informed consent. For consent to be valid, it must be shown that the patient has the capacity to consent. The NHA or Code does not expressly provide for electronic consent ("e-consent") or how capacity is to be determined. However, e-consent forms are admissible in evidence in Nigeria, hence consent will not be vitiated on the grounds that it was obtained electronically. Nevertheless, e-consent forms must meet the same standards as the form specified in the Code.

C. Data Privacy and Confidentiality: In the course of in-person medical consultation, it is trite knowledge that patients share much personal information. This is no different in telemedicine, where personal details are passed through the internet, making them susceptible to interception by third parties. This inherently increases the risk of exposure to unauthorized access and illegal disclosure of health data, which is considered sensitive personal data.¹⁰

Often, telemedicine processes involve third parties handling personal data. The healthcare service provider is responsible for ensuring that third parties comply with the law. If a foreign party is involved, the telemedicine provider must ensure that the foreign country where such sensitive data is received has an adequate level of protection and that the patient has given consent through binding corporate rules and contractual clauses.

⁵ Foster Capital, "Telehealth Intellectual Property: Protecting Telehealth Innovations: A Guide for Entrepreneurs" (2024) in https://fastercapital.com/content/Telehealth-intellectual-property--Protecting-Telehealth-Innovations--A-Guide-for-Entrepreneurs.html (Accessed December 30, 2024).

⁶ In Medical and Dental Practitioner Disciplinary Tribunal v Okonkwo (2001) 7 NWLR (Pt. 711) 205, the court held that a patient's consent is paramount in doctor/patient relationship and the choice of a competent adult with a sound mind should be respected. See also Okekearu v Tanko (2002) 15 NWLR (Pt. 791) 657.

⁷ National Health Act 2014, s. 23; the Code, Rule 19.

⁸ The Code, Rule 19; Form MDCN/COMEIN/R19.

⁹ Evidence Act, 2011 (as amended), s. 84.

¹⁰ Nigeria Data Protection Act, 2023, ("NDPA"), s. 65.

¹¹ NDPA s. 29.

The personal data of Nigerian citizens is protected by law.¹² There are established guidelines and standards for the collection, processing, storage, and transfer of personal data in Nigeria.¹³ The NDPA recognizes that personal data can be processed where consent has been given by the data subject (patient), and mandates that such data be secured against foreseeable hazards and breaches.¹⁴ The guidelines and standards apply to all data controllers and processors who collect, process or store personal data in Nigeria, including healthcare service providers.¹⁵ They owe a duty to patients to employ appropriate measures to ensure all data is kept and transmitted in a safe and confidential manner.¹⁶ This duty extends to being held accountable for acts and omissions in data processing by way of claims for injunctions and damages.¹⁷

Furthermore, the NDPR requires healthcare service providers, as data controllers to have a simple and conspicuous privacy policy displayed on any medium (e.g., apps, websites) through which personal data is being collected.¹⁸

The Nigerian Data Protection Act prescribes a remedial or penalty fee for non-compliance with the regulation and permits patients who suffer injury, loss, or harm from a breach of data protection rights to recover damages in civil proceedings.¹⁹ It is essential that healthcare service providers performing telemedicine services adopt best-practice security measures including multifactor authentication, encryption of data, and antivirus software.

D. Taxation: In Nigeria, companies generally are liable to pay Companies Income Tax ("**CIT**") on their profits "accruing in, derived from, brought into, or received in Nigeria" at rates between twenty per cent (20%) and thirty per cent (30%), depending on the turnover of the company.²⁰ However, telemedicine hospitals formed of a public character or formed for ecclesiastical, charitable or educational purposes are CIT-exempt.²¹

Additionally, a digital healthcare service provider resident in Nigeria will be liable to remit personal income tax based on the earned income.²² Non-resident telemedicine providers and those physically present in Nigeria are required to pay personal income tax and/or CIT if their services create a significant economic presence in Nigeria in accordance with the law.²³ However, income earned by individuals relating to the performance of ecclesiastical, charitable, or educational functions which are of a public character are tax-

¹² CFRN 1999, s. 37.

¹³ NDPA and the Nigeria Data Protection Regulation, 2019 ("NDPR"). The NDPR will only apply in so far as its provisions are not inconsistent with any provisions of the NDPA; NDPA, s. 63.

¹⁴ NDPA s. 25(1) (a); s. 39.

¹⁵ NDPA s. 2.

¹⁶ NDPA s. 24(2), s. 39 and the Patient Bill of Rights, 2018 (Accessed February 24, 2025).

¹⁷ NDPA s. 24(3).

¹⁸ NDPR, Part.2.5.

¹⁹ NDPA s. 51.

²⁰ Companies Income Tax Act, Chapter C21, Laws of the Federation of Nigeria ("LFN"), 2004 (as amended) ("CITA") s. 9.

²¹ This includes any registered organisation of institution in Nigeria that does not distribute or share its profit in any manner to members or promoters. CITA s. 23 and s. 105.

²² Personal Income Tax Act, Cap P8, LFN, 2004 ("PITA") s. 3 as amended by PITA (Amendment Act, 2011, s. 3).

²³ CITA s. 13(2)(c), Personal Income Tax Act, Cap.P8, LFN, 2004 (as amended), s. 6(6a) as amended by Finance Act, 2020 s. 25, Companies Income Tax (Significant Economic Presence) Order, 2020, s. 1; SEP is determined by factors such as (a) earning revenue of NGN25 million or more from Nigeria; (b) using domain name (.ng) or registers a website address in Nigeria or (c) customizing digital platform by a foreign entity or person for Nigerian users by showing prices and providing payment options in Nigerian currency.

exempt.²⁴ Telemedicine companies are also obliged to file appropriate tax returns with the Federal Inland Revenue Services (FIRS).²⁵

However, a telemedicine company that is less than ten (10) years in existence and renders its services through digital platforms can apply to be labelled a start-up.²⁶ This designation allows the company to enjoy various benefits, such as tax incentives²⁷ and seed funding from the Nigeria Sovereign Investment Authority subject to the approval of the National Council for Digital Innovation and Entrepreneurship.²⁸

E. Regulatory Requirements: These requirements include the incorporation of a company in Nigeria, registration and licensing with the appropriate regulatory body and registration of the acquisition and/or transfer of foreign technology if any.

Digital healthcare service providers must possess the necessary qualifications, professional licences and registrations to provide healthcare services in Nigeria. Depending on the structure chosen by the parties, incorporating a company might be essential.²⁹ It is an offence for a person not registered as a medical practitioner in Nigeria, to practise for or in expectation of reward. If found guilty, such person, will be liable on summary conviction to a fine not exceeding \(\pm\)5,000, and on conviction or indictment will be liable to a fine not exceeding \(\pm\)10,000 or imprisonment for a term not exceeding five years or both.³⁰ Given the current economic reality, there is a pressing need to review these fines. They are now far too small to make sense. Medical practitioners are also required to register and pay practising fees annually to maintain their licences to practice in Nigeria.³¹ The digital nature of telemedicine necessitates training requirements beyond initial licensing to understand virtual care protectors, use technology tools and effectively translate traditional healthcare skills to an online environment.

The territorial nature of practising medicine in Nigeria raises jurisdictional concerns for the practise of telemedicine. The practise of telemedicine inherently transcends geographical boundaries, potentially extending beyond Nigeria's jurisdiction. Scenarios still exist where a foreign doctor, not registered in Nigeria provides medical services to a patient residing in Nigeria or *vice versa*, which becomes a concern. To mitigate this concern, telemedicine providers or entrepreneurs should consider establishing partnerships with locally-licensed entities and, if licensed in Nigeria should display their registration numbers on the various platforms utilised. This approach, in addition to

²⁴ PITA Act, s. 19 and Third Schedule.

²⁵ CITA s. 55.

²⁶ Nigeria Startup Act, 2022 ("**NSA**"), See generally, s. 13.

²⁷ This includes (a) exemption from the payment of income tax or any other tax chargeable on income or revenue for a period of five years (three years initially and renewable for an additional two years); (b) deduction of any expenses on research and development wholly incurred in Nigeria from taxable income; and (c) exemption from contributions to the industrial training fund, provided the labelled startup facilitates in-house training for its employees. See NSA, s. 25.

²⁸ NSA, s. 19.

²⁹For instance, establishing a telemedicine hospital in Nigeria. Additional licenses and registration may also be required e.g Certificate of Standards from the Federal Ministry of Health, Health Facility Accreditation present in States, National Health Insurance Scheme (NHIS) and Environmental Health Permits.

 $^{^{\}rm 30}\text{MDPA},$ Cap. M8, LFN, 2004, (as amended), s.17(4) and 18.

³¹ MDPA s. 14.

fulfilling licensing requirements, will help ensure that the quality of patient care is not compromised due to distance.

Furthermore, foreign contracts and agreements for the transfer of healthcare technologies must be registered with the National Office for Technology Acquisition and Promotion ("NOTAP").³²

F. Liability: The adoption of telemedicine in Nigeria is not without risks. These liabilities can be civil, criminal, or both.³³ Civil liabilities can arise from medical negligence as a telemedicine provider owes a duty to his patient to exercise due caution, diligence, care, knowledge, and skill in administering treatment.³⁴ Medical negligence would arise where the action of the healthcare service provider falls short of the standard of a reasonably skilful medical professional.³⁵

Also, patients may suffer loss or damage as a result of defective hardware or software.³⁶ Determining liability can be complex. A well-drafted contract (such as a click-wrap agreement) containing disclaimer, indemnity and/or representation and warranty clauses will be useful to address such circumstances. Furthermore, a digital healthcare service provider should be mandated to take out professional indemnity insurance to cover liabilities that may arise.³⁷ Often, the question of liability is addressed in contracts. It is pertinent that the healthcare service provider ensures that notices or documents relating to liability, which are to be assumed by the patient, are either issued directly to the patient or published conspicuously on the platform where the telemedicine service is to be rendered.³⁸

Criminal liability can arise from the failure of a digital healthcare service provider to make appropriate provisions to ensure that patient health records are protected and to set up measures to prevent unauthorised access.³⁹ The Criminal Code prescribes that a healthcare service provider should exercise reasonable care and skill in rendering services.⁴⁰ It also prescribes that any person who, in a manner so rash or negligent as to endanger human life or to be likely to cause harm to any person, either by giving medical or surgical treatment to any person whom he undertakes to treat or dispenses, supplies, sells, administers, or gives away, any medicine or poisonous or dangerous matter, is guilty of a misdemeanour and is liable to imprisonment for one year.⁴¹

³² NOTAP Act, Cap. N62 LFN, 2004, s. 4(d) and s. 5.

³³ Okonta N., "An Analysis of Telemedical Liabilities under the Nigerian Laws" *Nigerian Bar Journal* (2023) in https://www.ajol.info/index.php/nba/article/view/254144 (Accessed January 2, 2025).

³⁴ R v Bateman (1925) 19 Cr. App. R 8.

³⁵ Alex Otti v Excel-C Medical Centre Limited et al. (2019) LCN.13457(CA); (2019) LPELR-47699(CA).

³⁶ Okonta N., *supra note* 33. In Lagos State, a producer is liable for damages caused by a defective product; Law Reform (Torts) Law 2013, s. 20.

³⁷ The Code, rule 10(f). This was a mandatory requirement in National Health Insurance Scheme ("NHIS") Act s.45; However, the NHIS Act has been repealed by the National Health Insurance Authority Act, 2022, s.58 without replicating this provision.

³⁸ Federal Competition and Consumer Protection, Act, 2018, s. 128.

³⁹ Failure to do so, such institution will be liable on conviction to imprisonment for a period not exceeding two years or to a fine of N250,000; National Health Act, 2014 s. 29.

⁴⁰ Criminal Code Act, Cap C38 LFN 2004, s. 303.

⁴¹ *ibid*, s. 343 (e) and (f). See also *Akerele v R* (1942) LJR WACA, where a medical practitioner was charged with manslaughter after administering injections of a drug known as sobita to children as a cure for yaws, resulting in several deaths. *The State Of Lagos V. Dr. Ejike Ferdinand Orji* [Unreported Decision In Suit LD/8963C/2019].

Maintaining the level of care, diligence and standard as in traditional in-person consultations is essential to reduce malpractice claims and manage various liabilities. Additionally, introducing practice restrictions in Nigeria is necessary to limit the scope of telemedicine including the diagnosis, treatment and prescription that can be provided.

A Case for a More Robust Legal Framework for Telemedicine in Nigeria

To enhance the existing legislation and equip telemedicine providers, it is essential to develop a supportive guideline or policy framework for telemedicine.⁴² Nigeria's healthcare system currently has a significant gap in telemedicine regulation, with no clear operational guidelines to govern how providers should deliver services, protect patient rights, or maintain quality standards. While legislation exists, the lack of comprehensive guidelines leaves the system vulnerable to potential misuse and compromised care quality. Several countries have pioneered effective frameworks. India requires practitioners to display registration numbers and complete mandatory training.⁴³ Ethiopia has established specific technological standards and protocols for emergency situations,⁴⁴ and Singapore maintains detailed requirements for clinical care standards and provider qualifications.⁴⁵

These international frameworks demonstrate how comprehensive guidelines can create a secure foundation for telemedicine services. Their frameworks cover essential aspects like practitioner licensing, technological requirements, practice limitations, emergency protocols, and quality assurance measures. Nigeria needs to develop similar detailed guidelines that address training standards, compensation structures, and practice restrictions while ensuring both commercial viability and exceptional healthcare delivery standards.

Conclusion

The integration of digital interventions in Nigeria's healthcare system particularly through telemedicine presents a variety of opportunities including but not limited to accessible, quality healthcare, increased commercialisation and potential investment in the healthcare sector. While advocating for a comprehensive regulatory framework, healthcare service providers engaging or intending to engage in the practice of telemedicine in Nigeria must comply with the existing legal landscape as well as ensure necessary documentation such as privacy policies, contracts, terms and conditions, consent documentation and data protection protocols.

⁴² WHO, "Consultation Telemedicine Implementation Guide"

https://iris.who.int/bitstream/handle/10665/364221/9789240059184-eng.pdf?sequence=1 (Accessed January 21, 2025.

⁴³ See generally, Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2020, in https://ruraltelemedicine.in/telemedicine-guideline/ (Accessed January 27, 2025).

⁴⁴ Ethiopia Telehealth Implementation Guideline Practical Tips, 2020 in https://www.coursehero.com/file/155767713/Telehealth-Guide-final2pdf/ (Accessed 27/01/2024).

⁴⁵ the National Telemedicine Guidelines, 2015 published by Academy of Medicine, Singapore https://www.hpp.moh.gov.sg/docs/librariesprovider4/guidelines/2015-national-telemedicine-guidelines.pdf?sfvrsn=65418f43 1 (Accessed January 27, 2024).

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