

REGULATORY REGIME FOR SOLID ORGAN TRANSPLANTATION IN NIGERIA: A COMPARATIVE ANALYSIS*

Abstract

The right to health is an inclusive right that contains both freedoms and entitlements;¹ solid organ transplantation is a medical intervention that touches directly on the right to health of the donor and the recipient, therefore there is a need for an adequate and efficient framework to regulate solid organ transplantation. The Article undertook a critical appraisal of the provisions of the National Health Act 2014 on organ donation and transplantation and a comparison of these provisions to the Laws governing organ donation and transplantation in the UK and South Africa with the aim of bringing out the strength and weaknesses of the provisions of the National Health Act 2014 on the subject and offered recommendations for possible review.

Keywords: Transplantation, Solid Organ, Donation, Nigeria

1. Introduction

The need for a fit for purpose regulatory/legal framework for solid organ transplantation in Nigeria is underscored by the fact that solid organ transplantation is increasingly becoming an important part of Nigeria's medical culture. In 2014, Nigeria enacted a legislation known as *National Health Act* which became immediately controversial in the area of organ transplant.

However, the Act² has generated a lot of controversy on its certain provisions to the effect that it derogates from the right to personal autonomy of the person from whom an organ is being transplanted³ amongst other issues.

2. The National Health Act 2014

The National Health Act, 2014 is the primary legislation that regulates organ donation and transplantation in the Nigeria. Two sources of organ donation for transplantation are recognised under the Act; living donation and cadaveric donation. The Act provides a general framework for regulating organ donation and transplantation in Nigeria and has made laudable provisions on organ donation and transplantation. Section 51 of the National Health Act provides for the removal and transplantation of Human tissue in hospital thus:

- (1) a person shall not remove tissue from a living person for transplantation in another living person or carry out the transplantation of such tissue except:
 - (a) in a hospital authorised for that purpose and
 - (b) on the written authority of :
 - (i) the medical practitioner in charge of clinical services in that hospital or any other medical practitioner authorised by him or her; or
 - (ii) in the case where there is no medical practitioner in charge of clinical services at that hospital, a medical practitioner authorised thereto by the person in charge of the hospital.⁴

It is clear from the above provision, that the National Health Act permits the removal of a tissue or an organ of a living person for transplantation purposes, also the prohibition of organ transplant services except in a duly authorized hospital and with the written authority of a medical practitioner in charge of clinical services in that hospital, is a laudable initiative by the Act. However, the Act failed to provide for the written consent of the patient or the consent of the relatives in cases where the patient is unable to give consent. The implication of this, is that medical practitioners are by the provision of Section 51 of the Act,⁵ empowered to make decisions on when to remove organs from living persons without the consent of the patient or equally obtained. This lacuna in the provision, creates room for infringement of a patient's right to informed consent, right to self- determination, freedom of thought, conscience and religion. In the case of *Medical and Dental Practitioners Disciplinary Tribunal v. Dr John Emewulu Nicholas Okonkwo*,⁶ the Supreme Court, per Ayoola JSC, upheld and elaborated on these rights thus:

... The right to freedom of thought, conscience and religion implies a right not to be prevented, without lawful justification from choosing the course of one's life, fashioned on what one believes in, and a right not to be coerced into acting contrary to one's life, religious belief. The limits of this freedom as in all cases are where they impinge on the rights of others or where they put the welfare of society or public health in jeopardy. The sum total of the rights of privacy and of freedom of thought conscience or religion which an individual has put in a nutshell, is that an individual should be left alone to choose a course for his life unless a clear and compelling overriding state interest justifies the contrary....

Also, Rule 19 of the Code of Medical Ethics in Nigeria, provides that practitioners involved in procedures requiring the consent of the patient, his relation or appropriate public authority, must ensure the appropriate consent is obtained before such procedures, either for surgery or diagnostic purposes are done be it invasive or non-invasive. The Rule further provides that, consent should be in written form either as a part of case notes or in separate sheets with the institution's name boldly indicated. The National Health Act⁷ also provides for the removal of tissue, blood or blood products from a living person, only with the appropriate consent given by the person. Though the Act provides for consent as a precondition, for the removal of tissue, blood or blood products from a living person, The National

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¹ World Health Organization, 'The Right to Health', <https://www.ohchr.org> accessed on 12/10/2023 at 4:52am.

² National Health Act 2014.

³F Falana, 'Demand for urgent review of the National Health Act, 2014' (2014) *Nigerian Muse* <<http://www.nigerianmuse.com/20141229144703zg/sections/health/demand-for-urgent-review-of-the-national-health-act-2014-by-femi-falana/>> accessed 16 September 2021.

⁴ National Health Act, 2014.

⁵ *Ibid.*

⁶ *Op.Cit.* P. 26.

⁷ National Health Act, 2014.

Health Act has been criticized for not prescribing the process of obtaining and recording consent for that purpose in the light of international ethical standards.

Again, the Act failed to specifically mention 'organ' in its provision for informed consent under Section 48(1)(a). Informed consent was mentioned only in relation to tissues, blood or blood vessels. There is also no clear distinction between organ and tissue under the Act, the Act under its interpretation section, interpreted tissue to include organs, though tissue was also defined in the act. This interpretation with respect is wrong as biologically tissues are not organs. Organs are biologically defined as a collection of tissues that structurally form a functional unit specialized to perform a particular function example, the kidney, heart, lung,⁸ tissues on the other hand, are groups of cells that have a similar structure and act together to perform a specific function.⁹

Still on informed consent, the Act provides in Section 48(1) (b) and (c) that the consent clause may be waived for medical investigations and treatment in emergency cases and in accordance with prescribed protocols by the appropriate authority.

By the provisions of section 48 of the Act, the need for consent may be waived in cases of emergency, investigation and treatment of diseases. The implication therefore is that once any available personnel is satisfied that there is a case of emergency or any related issue, he can act for the purposes provided by the law. This is worrisome as consent to medical treatment is an issue of human right. In the case of *Denloye v. Medical & Dental Practitioners Disciplinary Tribunal*¹⁰ the Court held that failure to seek and obtain a patient's informed consent before administering a blood transfusion on him constituted a violation of his fundamental human rights to privacy and right to freedom of religion and conscience. Also, the Act failed to define emergency situations in relation to its provision in Section 48, the implication of this, is that it is left at the discretion of the medical practitioner to decide whether there exists an emergency and consequently authorise the removal of a patient's organ without consent. Again, though the Act aims at protecting children from being exploited, the Act equally failed to make provision for donation of organ for transplantation by a person under the age of 18, thereby excluding donation of organ by a minor.

Section 49 of the Act¹¹ prohibits the use of 'tissue removed or blood or a blood product withdrawn from a living person for a purpose other than medical or dental purpose as may be prescribed. Similarly, the Act provides that human organs obtained from deceased persons for transplantation or treatment, or medical or dental training or research, shall only be used in the prescribed manner and also authorized the National Tertiary Health Institutions Standards Committee to develop guidelines for the approval of organ transplant facilities and the procedure for such approval to be obtained. Clearly, from the provisions of Sections 49 and 54 of the NHA, the Act recognizes and permits living and cadaveric donations for transplantation. However, although the Act has made remarkable provisions in that regard, the Act does not provide for confidentiality in a situation where the donor or the family of a cadaveric donor wishes to be anonymous. There is no provision for non-disclosure of information or personal details of either the donor or the recipient. Also, with regards to cadaveric donation, there is no clarity as to the meaning of brain death under the Act, thereby leaving room for uncertainty in the provision as to when a person can be proclaimed brain dead.

Furthermore, Section 53 of the Act prohibits any form of commercialization of human organs. Therefore, it is an offence punishable with imprisonment or fine or both for a person who has donated tissue, to receive any form of financial or other reward for such donation or sell or trade tissues. However, there is an exception to this provision. The Act exempts reimbursements for reasonable costs incurred by a donor to provide such donation.¹² This implies that the prohibition of financial gain does not prevent living donors from being compensated for loss of earnings and other justifiable expenses incurred as a result of the removal or related medical examination thereof. The National Health Act, equally provides for the capacity of deceased donors to consent to donation before death. By the provisions of Section 55 of the Act, a deceased who is competent to make a will, can show his or her consent through a Will or in a document signed by him or her in the presence of two competent witnesses or in a written statement made in the presence of two competent witnesses. However, the Act does not make provision for persons who died intestate but were willing to donate their organs, tissues, or blood products before they died. Again in outlining the purposes for which the deceased may donate his or her body or any specified tissue thereof to be used after his or her death under the Act, donation for transplantation purposes was not clearly mentioned in the Act.

2. The United Kingdom

In the United Kingdom, the Human Tissue Act¹³ and the Human Tissue (Scotland)¹⁴ regulate the removal, storage and use of organs, tissues and cells for transplantation. The Human Tissue Act applies to England, Wales and Northern Ireland and provides for organ and tissue transplantation from living and cadaveric or deceased donors.

Human Tissue Act 2004

The Human Tissue Act¹⁵ regulates organ and tissue donation and transplantation in England, Wales and Northern Ireland. The Act recognises and makes provision for organ and tissue transplantation from living and cadaveric or deceased donors.

The provisions of the Human Tissue Act on removal, storage and use of organs and tissues from the body of living or deceased persons are governed by the underlying principle of 'appropriate consent'. Compared to the provisions of the National Health Act¹⁶ on consent, appropriate consent under the Human Tissue Act differs. The HTA clearly distinguished appropriate consent where the person concerned

⁸ National Human Genome Research Institute, <https://www.genome.gov> accessed on 13/10/2023 at 4:47am.

⁹ Biology Dictionary, <https://biologydictionary.net> accessed on 13/10/2023 at 4:49am.

¹⁰ [2002] AHRLR 159

¹¹ National Health Act, 2014.

¹² Ibid, Section 53(1) (a).

¹³ Human Tissue Act 2004.

¹⁴ Human Tissue (Scotland) Act 2006.

¹⁵ Human Tissue Act 2004.

¹⁶ National Health Act, 2014.

is alive and is an adult or a child, where the person concerned is deceased or a cadaveric and in the case of a deceased appropriate consent depends on whether the deceased is a child or an adult.

The Human Tissue Act¹⁷ provides for the consent of a child with regards to the removal, storage and use of organ or tissue. The National Health Act 2014 on the other hand omitted children in its provisions on organ and tissue removal and transplantation. By the provisions of the Human Tissue Act, where the child concerned is alive appropriate consent means his consent.¹⁸ The Act went further to provide for how consent can be determined where the child concerned is dead. Though the English age of Majority is eighteen years, *Gillick v Norfolk and Wisbech Area Health Authority*,¹⁹ established the principle that children under the age of 16 years are deemed to be capable of giving valid consent to advise or treatment without parental knowledge or agreement provided they have sufficient understanding to appreciate the nature, purpose and hazards of the proposed treatment. Compared to the provisions of the National Health Act, it is clear that the HTA does not only make provision for donation and transplantation of organs and tissues with regards to children but also stipulates the mode of establishing consent for that purpose as well as offers a clear interpretation of the term 'appropriate consent'. The National Health Act 2014 does not make provision for donation and transplantation in relation to children. The Act merely provides that a person shall not remove tissue which is not replaceable by natural processes from a person younger than 18 years.²⁰

The Human Tissue Act²¹ equally provides for 'appropriate consent' with respect to an adult. Where the person concerned is an adult who is alive, appropriate consent means his consent under the Act²², where the adult concerned has died, appropriate consent under the Human Tissue Act, means his consent in writing²³ and by the provisions of the Act, the consent of the deceased in writing is only valid if it is signed by the person concerned in the presence of at least one witness who attests the signature, if it is signed at the direction of the person concerned in the presence of at least one witness who attests the signature, or it is contained in a will of the person concerned made in accordance with the requirements of section 9 of the Wills Act 1837 or Article 5 of the Wills and Administration Proceedings (Northern Ireland) Order 1994.²⁴ Compared to the provisions of the National Health Act 2014, the Human Tissue Act²⁵ contains detailed provisions on the interpretation of what appropriate consent with respect to the removal or the use of an organ or body part of an adult entails and how this can be said to have been obtained and where consent by an adult is expressed in writing; the validity or otherwise of such consent in writing. Section 48(1) of the National Health Act on the other hand, provides that a person shall not remove tissue, blood or blood product from the body of another living person for any purpose except with the informed consent of the person from whom the tissue blood or blood product is removed, granted in the prescribed manner. This provision leaves a lot to chance as it creates room for consent to be inferred in different circumstances.

Again, by the provisions of Section 4 of the Human Tissue Act, an adult can appoint one or more persons to give consent on his behalf after his death. From the provisions of section 4 of the Act, it is clear that the Human Tissue Act permits nominated representatives in relation to consent after the death of an adult. On the other hand, the National Health Act in its provision on donation of human bodies and tissue of deceased persons merely states that the person who makes the donation may nominate an institution or a person as donee, there is no provision for consent after the death under the Act.²⁶

The Human Tissue Act also prohibits commercial dealings in human material for transplantation. Section 32 of the Act²⁷, contains a series of offences connected with dealings with organ for reward. Compared to the provisions of Section 53 of the National Health Act, the Human Tissue Act contains broader and more detailed provisions as the Human Tissue Act,²⁸ extends to commercial dealing involving third parties, including advertisements as well the provision of an exception to the offence where payment is made for defraying or reimbursing any liability incurred in respect of expenses incurred by a third party in the connection with transporting removing e.tc of the organ or tissue.

Furthermore, Section 33 of the Human Tissue Act, places a number of restriction on transplants involving a live donor as well as constitute as an offence, for a person to remove or use transplantable material removed from the body of a living person, with the intention that the material be used for the purpose of transplantation, knowing or reasonably expected to know that the person from whose body he removes the material is alive, for commercial purposes and without compliance with the conditions specified in the regulation. The Act²⁹ places a restriction on the person or persons who performed the actual act of the removal and use for transplantation. Although the Act does not specifically mention medical practitioners, it can be deduced from its provisions that this provision directly relates to medical practitioners. The National Health Act on the other hand only places a restriction on the removal and use of tissue, blood or blood products removed or withdrawn from living persons and not on the person who removes or uses the materials so removed for transplantation.³⁰ Section 49 of the National Health Act, provides that a person shall use tissue removed or blood or blood product withdrawn from a living person only for such medical or dental purposes prescribed. This provision of section 49 is subject to Section

¹⁷ Ibid.

¹⁸ Human Tissue Act, Section 2(2).

¹⁹ [1985] 2 All ER 402.

²⁰ National Health Act 2014, Section 48(2) (a).

²¹ Human Tissue Act 2004, Section 3.

²² Ibid, Section 3(2).

²³ Ibid, Section 3(3).

²⁴ Ibid, Section 3(5).

²⁵ Ibid, Section 3.

²⁶ National Health Act 2014, Section 55(b).

²⁷ Human Tissue Act 2004, Section 32.

²⁸ Ibid.

²⁹ Ibid.

³⁰ National Health Act 2014, Section 49.

52 of the Act which provides that only a registered medical practitioner or dentist may remove any tissue from a living person, use tissue so removed for any of the purposes stated in the Act or transplant tissue so removed into another living person.³¹

As a solution to shortage of organs for transplantation in the UK, the Deemed Consent Act came into force in England on May 20, 2020. The Act³² amended the Human Tissue Act 2004, to introduce provisions that would allow consent for organ and tissue donation from deceased donors to be deemed in certain circumstances. The Act, introduced what is referred to as an 'opt out' system, which assumes every adult to have agreed to donate their organs at death for the purpose of transplantation unless a person who stood in a qualifying relationship to the person concerned immediately before death provides information that would lead a reasonable person to conclude that the person concerned, would not have consented.

This implies that after death, a person would be considered to have consented to organ donation in their life time unless they made specific provision to the contrary in their life time and appointed someone to make the decision on their behalf of information that would lead a reasonable person to conclude that they would not have consented.³³ This is often referred to as an 'opt -out' system of consent as people may 'opt-out' of becoming an organ donor if they do not consent.³⁴ However, this provision excludes an adult who has died and who had not been ordinarily resident in England for a period of at least 12 months immediately before dying, or an adult who has died and who for a significant period before dying lacked capacity to understand the effect of the deemed consent. The Act defined 'significant period' for this purpose to mean a sufficient long period as to lead a reasonable person to conclude that it would be inappropriate for consent to be deemed to be given.³⁵ Children under the age of 18 years are also excluded from the application of this provision.³⁶ Deemed consent does not apply to all organs and tissues, organs and tissues that are to be excluded are those that will cover transplants that are currently rare or novel and many may not regard as normal to donate; set out in regulations made by the Secretary of State. In Nigeria, though the National Health Act recognises and makes provisions for cadaveric or deceased organ donation for transplantation, there is no provision in the Act that allows for consent to organ or tissue to be deemed to have been given by a potential adult organ donor before their death.

3. South Africa

South Africa has the most advanced solid organ transplantation programmes in Africa.³⁷ Some of her solid organ transplantation programmes are the liver programme which has existed for about two decades and presently offers living-related liver transplantation and the combined kidney-pancreas and lung transplantation.³⁸ South Africa operates the 'opt-in' system of organ and tissue donation. This system requires an individual to express his or her consent to become a potential donor. The 'opt-in' system offers prospective organ and tissue donors the freedom in their life time, to indicate their wish to voluntarily donate their organs and tissues upon their death for transplantation.³⁹ The National Health Act, 2003⁴⁰ contains detailed provisions on organ donation and transplantation, compared to the National Health Act 2014 of Nigeria. The National Health Act, 2003⁴¹ prohibits the removal of tissue, blood, a blood product or gamete by a person from the body of another living person for transplantation purposes except with the written consent of the person from whom the tissue, blood, blood product or gametes are removed granted in the prescribed manner and in accordance with prescribed conditions.

In contrast to the above provision, in Nigeria, the National Health Act⁴² merely provides that a person shall not remove tissue from a living person for transplantation in another living person or carry out the transplantation of such tissue except in a hospital authorised for that purpose and on the written authority of the medical practitioner in charge of clinical services in that hospital or any other medical practitioner authorised by him or her or in the case where there is no medical practitioner in charge of the clinical services at that hospital, a medical practitioner authorised by the person in charge of the hospital. By implication therefore, the medical doctor and not the individual is empowered to make decision under the Act.⁴³

The Act⁴⁴ further provides that the removal and transplantation of organs or tissues of a living person should be done in a hospital or an authorised institution. Section 58 of the Act⁴⁵, provides that a person may not remove tissue from a living person for transplantation in another living person or carry out the transplantation of such tissue except in a hospital or an authorised practitioner authorised by him or her; or in the case where there is no medical practitioner in charge of the clinical services at that hospital or authorised institution, a medical practitioner authorised thereto by the person in charge of the hospital or authorised institution.

The provision of Section 58 of the National Health Act, 2003 is similar to the provision of section 51 of the National Health Act 2014. However the National Health Act, 2003 is more detailed and clearly separated and defined the right of the patient to give consent for the removal of an organ or tissue from his or her body for transplantation, from the authority given to a medical practitioner in charge of the

³¹ Ibid, Section 52(1).

³² Organ Donation (Deemed Consent) Act 2019.

³³ Organ Donation (Deemed Consent) Act 2019, Explanatory Notes, <https://www.legislation.gov.uk> accessed on 15/10/2023 at 5:14am.

³⁴ Ibid.

³⁵ Ibid.

³⁶ Ibid.

³⁷ I Ulasi, C Ijoma, N Ifebunandu, E Arodiwe, U Ijoma, J Okoye, U Onu, C Okwuonu, S Alhassan and O Onodugo, 'Organ Donation and Transplantation in Sub-Saharan Africa: Opportunities and Challenges', <https://www.intechopen.com> accessed 16/10/2023 at 3:37am.

³⁸ Ibid.

³⁹ P M Dimo, 'Participating in Organ Donation: Issues among Black South Africans' *Global Journal of Health Science* (2019) Vol. 11, No.1, 72.

⁴⁰ The National Health Act, 2003 (Act No. 61 of 2003).

⁴¹ Ibid, Section 55.

⁴² National Health Act 2014, Section 51.

⁴³ Ibid.

⁴⁴ Ibid, National Health Act, 2003.

⁴⁵ Ibid.

hospital or authorised institution where transplantation is carried out. The Act⁴⁶ also provides that the medical practitioner, contemplated in the provision may not participate in a transplant for which he or she has granted authorisation. Again, under the National Health Act, 2003 it is an offence to receive any financial consideration or other reward in exchange for the donation of blood, organs, tissues or gametes except for the reimbursement of reasonable costs incurred by him or her to provide such donation; and to sell or trade in tissue, gametes, blood or blood product except as provided in the Act. Any person who is convicted of this offence is liable to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment.⁴⁷ The above provision of Section 60 of the Act on payment in connection with the importation, acquisition or supply of tissue, blood, blood products or gametes is similar to the provision of Section 53 of the National Health Act 2014 on payment in connection with the importation, acquisition or supply of tissue, blood or blood products. However the South African regulation is more detailed in its provisions and unlike the National Health Act 2014, the Act allows a health care provider registered with a statutory health professional council to receive remuneration for any professional service rendered.⁴⁸

The National Health Act 2003 also provides for cadaveric or deceased organ and tissue donation. Section 62 of the Act provides that a person who is competent to make a will may in the will; in a document signed by him or her and at least two competent witnesses; or in an oral statement made in the presence of at least two competent witnesses, donate his or her body or any specified tissue thereof to be used after his death. Such a donor must nominate an institution or a person contemplated as donee.⁴⁹ The Act in contrast to the National Health Act 2014,⁵⁰ further provides that in the absence of a donation or a contrary direction given by a person whilst alive, the spouse, partner, major child, parent, guardian, major brother or major sister of that person, in the specific order mentioned, may after that person's death, donate the body or any specific tissue of that person to an institution or a person for transplantation purposes. Again, the Act⁵¹ provides that the Director-General may after the death of a person and if none of the persons mentioned can be located, donate any specific tissue of that person to an institution or a person for the purposes contemplated in the Act. The Director-General may only donate the specific tissue if all the prescribed steps have been taken to locate the persons mentioned in the Act.⁵² Also, Section 61 of the National Health Act 2003 provides that human organs obtained from deceased persons for the purpose of transplantation or treatment or medical or dental training or research may only be used in the prescribed manner; and must be allocated in accordance with the prescribed procedure.⁵³ The Minister is empowered to prescribe the criteria for the approval of organ transplant facilities; and procedural measures to be applied for such approval.⁵⁴ Any person who contravenes the Provision of Section 61 of the Act or fails to comply therewith or who charges a fee for a human organ is guilty of an offence and upon conviction is liable to a fine or to imprisonment for a period not exceeding five years or to both a fine and such imprisonment.⁵⁵

It is worthy of note that compared to the National Health Act 2014⁵⁶, the National Health Act 2003⁵⁷ does not provide a specific amount to be fined upon the conviction of an offender. The implication of this is that it is at the discretion of the Court to decide taking into consideration inflation and other related factors at the time. Section 65 of the Act⁵⁸ provides for the revocation of donation. By virtue of that provision, a donor may prior to the transplantation of the relevant organ into the donee, revoke a donation in the same way in which it was made or in the case of a donation by way of a will or other document, also by the intentional destruction of that will or document. The foregoing provision is similar to the provision of the National Health Act 2014 on the procedure for revocation of any donation.⁵⁹ Furthermore, Section 61(3) of the National Health Act 2003 provides that an organ may not be transplanted into a person who is not a South African citizen or a permanent resident of the Republic without the Minister's authorisation in writing. This provision will contribute hugely in regulating transplant tourism and curbing illegal transplant tourism and organ trafficking in the country. The National Health Act 2014 on the other hand, does not contain specific provisions regulating organ transplantation respect to a non - Nigerian citizen or permanent resident.

4. Conclusion

The National Health Act has no doubt made laudable provisions on organ donation and transplantation in Nigeria, however a critical perusal of the provisions of the Act, reveals a number of limitations and lacunas which calls for further and urgent review. It is recommended that the provisions of the National Health Act 2014 on organ donation be amended to incorporate relevant provisions on organ donation and transplantation as well as fill up existing lacunas in the Act in that regard so as to adequately equip the Act towards the effective implementation of quality standards for organ donation and transplantation in Nigeria.

⁴⁶ Ibid, Section 58(2).

⁴⁷ Ibid, Section 60(5).

⁴⁸ Ibid, Section 60(3).

⁴⁹ Ibid, Section 62(1) (b).

⁵⁰ National Health Act 2014, Section 55.

⁵¹ National Health Act 2003, Section 62 (3) (a).

⁵² Ibid, Section 62(3) (b).

⁵³ Ibid, Section 61(1) & (2).

⁵⁴ Ibid, Section 61(4).

⁵⁵ Ibid, Section 61(5).

⁵⁶ National Health Act 2014, Section 48(3), Section 49(2), Section 53(2).

⁵⁷ National Health Act 2003, Section 60(5), Section 61(5).

⁵⁸ Ibid.

⁵⁹ National Health Act, 2014, Section 57.