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A Review of the Health Act, 2017 from an Access, Quality and Cost Paradigm

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Abstract

The Health Act 2017 was recently enacted to establish a unified health system, to coordinate the interrelationship between the national government and the county government health systems, to provide for regulation of health care service, and health care service providers, health products and health technologies and for connected purposes. The enactment of this Act comes against the backdrop of a health care system that is riddled with structural barriers inhibiting access to health care services with resultant grave consequences. The enactment of the Act is therefore, timely given the constitutional context of the right to the highest attainable standards of health care. However, the key question remains whether the Act sufficiently addresses some of the concerns prevalent in the Kenyan health care system. This paper examines the Act using the lens of access, cost, and quality which are the chief concerns of any health care system. The paper examines the salient issues in the Act under these three broad limbs while examining whether the Act contain provisions that improve access to, reduce costs and improves quality of health care provided in Kenya. The analysis adopted in this paper flows from the understanding of health care as a right with concomitant obligations on the State and its agencies and also within the context of devolved governance adopted by the Constitution in 2010 while also appreciating international best practices and norms.

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1.0 Introduction

Debates on health care reforms have largely revolved around the themes of access, quality and cost of health care while recognizing that holistic approaches to these reforms are imperative.[1] These three themes have been referred by some scholars as the "iron triangle" of health care owing to the fact that among them exist inherent trade-offs hence overly focusing on one leads to a disregard of the other(s) and an attempt to improve all the three elements is also fallacious, though desirable.[2] But before we even embark on this analysis based on the "iron triangle" framework, it is important to point out the normative framework that this paper adopts which is that established by the Constitution which in Article 43. This provision guarantees every person the right to the highest attainable standard of health, which includes the right to health care services, including reproductive health care. This paper reiterates how the constitutional guarantee fits within the "iron triangle" approach forming the main thread linking the three themes.

The import of recognizing access to health care as a human right can be better understood from discussions about the widely accepted set of values that inform the recognition of this right and this includes the principle of equity. The World Health Organization in the 2004 *World Report on Knowledge for Better Health* defines inequity in health as the "systematic and potentially remediable differences in one or more aspects of health across socially, economically, demographically, or geographically defined population groups or subgroups".[3] These differences will only become apparent through an examination on how the three underlying themes of; access, quality and cost inform them.

The philosophical justification of the right to health has been explained through the health capability paradigm which makes the case for the right to health as a meaningful and operational right and underpins these discussions within the context of the justiciability of the right to health and its enforcement as provided for under international law.[4] These discussions are furthered by the norms established under international law through instruments like the International Covenant

[1] Barry Furrow and others, *Health Law: Cases, Materials and Problems* (Seventh, West Academic Publishing 2013) 1.

[2] Aaron Carroll, 'The "Iron Triangle" of Health Care: Access, Cost, and Quality', available at https://newsatjama.jama.com/2012/10/03/jama-forum-the-iron-triangle-of-health-care-access-cost-and-quality/ accessed 18th July 2017.

[3] World Health Organization, 'World Report on Knowledge for better health: strengthening health systems', (2004) World Health Organization available at http://www.who.int/rpc/meetings/world_report_on_knowledge_for_better_health.pdf 140.

[4] Jennifer Prah Ruger, *Health and Social Justice* (Oxford University Press 2010) 118.

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on Economic, Social and Cultural Rights (ICESCR)[5] and the Universal Declaration of Human Rights (UDHR).[6]

Based on the constitutional provisions on health care as a right, it is evident that the State remains the key duty bearer in the provision of health care services. The fulfilment of this duty involves the use of both legal and non-legal instruments with the former being feasible through, among others, the use of legislation that specify respective obligations or duties of each stakeholders and how resources are to be employed in meeting these obligations. The duty-bearer, which is primarily the State, through legislation and other means, creates a framework for respecting, protecting and fulfilling the right to health and this is through the reduction of the broad expression of aspirations contained in international instruments, national constitutions and policy documents into structured obligations with sufficient details.[7] It is in this light that the Health Act, 2017 (hereinafter "the Act") was enacted to breathe life into the guarantees by the Constitution on the right to health and also to recognize the place of devolution of governance in meeting these objectives.

The following parts put the analysis of the Health Act, 2017 within the access, cost and quality framework by interrogating salient provisions in the Act and how they fit within the three themes that form the chief concern of the health care system. What becomes apparent is the failure by the Act to recognize the need for a holistic approach in reforming health care delivery in Kenya. This is evident from the inadequate appreciation of the fact that fulfilling the duty to provide the highest attainable standards of health care requires a concerted effort that links concerns on access to health care, the cost of accessing these services and the quality of the services provided by the relevant entities. On questions such as the cost of health care, I will note that the Act fails to provide direction on initiatives driven towards universal health coverage and that the Act has adopted minimalist approaches when it comes to questions on quality of health care provided notwithstanding the numerous concerns that have recently arisen regarding quality of health care provided in the country.

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[5] The ICESCR in Article 12 provides;

1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:

a. The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
b. The improvement of all aspects of environmental and industrial hygiene;
c. The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
d. The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

[6] Article 25 of the UDHR provides;

> Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

[7] Lawrence Gostin, *Global Health Law* (Harvard University Press 2014) 20.

2.0 Access to health care

Access is the grundnorm of any health care system. It forms the underlying basis of provision of health care in any societal context. The Primary concern of access is distribution of health services and this also leads to the question on availability of these services.[8] This has therefore, lead to the adoption of a definition of access to health care as the geographical availability (in the narrow sense), and from a broader sense that encompasses dimensions such as availability, accessibility, affordability and acceptability.[9] Yet to others, access denotes the opportunity to use health care, while others draw no distinction between access and use.[10] This paper follows the former normative framework that defines access based on the availability, accessibility, affordability and acceptability (4a's) of health care services. It is in this breath that I examine if the Act promotes the constitutive elements of access based on the 4a's identified above.

This paper will not go into the details of the 4a's but will instead focus on section-by-section analysis of whether the Health Act, 2017 guarantees and promotes access to health care. It is important to firstly paint a picture of the state of access to health care in Kenya. In the national census conducted in 2009, the country was found to have a population of approximately 38 million people.[11] The World Bank however approximates that in 2015, the population of Kenya was at 46.05 million.[12] This population is served by approximately 9000 health facilities.[13] This means that a single facility caters for approximately 5,100 persons (this should of course be understood keeping in mind that the facilities, and population, are not evenly distributed across the country). A County like Marsabit which have vast land area (71,905 Sq. Km) has only 89 facilities while Kakamega (3,023 Sq. Km) has 247 facilities.[14] Nairobi (707 Sq. Km) with a population of 3,134,261 in 2009 is said to have 671 facilities.[15]

From the statistical illustrations outlined above, it becomes evident that certain factors such as distance to health center may inhibit access to health care depending on the physical location of a person. The spatial distribution of health care resources contribute significantly in determining their accessibility and the general state of health of individuals.[16] Access has also been inhibited by the fact that there may be inadequate human capacity with a specialization in a given area of medical practice leaving persons suffering from certain ailments without remedies. Experts have lamented that they are more elected officials in the country than there are doctors in public health facilities.[17] The lack of specialized care has particularly seen a rise in the number of patients who

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[8] Owen O'Donnel, 'Access to health care in developing countries: breaking down the demand side barriers', (2007) 23(1) Cad. Saudo Publica, 2820.

[9] Penchansky R, and Thomas JW, 'The concept of access: definition and relationship to consumer satisfaction', (1981) 19(2) Med Care

[10] O'Donnel (n 8) 2821.

[11] Kenya National Bureau of Statistics, 'Statistical Abstract 2016', (KNBS, 2017) 19.

[12] See the World Bank at http://data.worldbank.org/country/kenya

[13] See Kenya Master Health Facility List available at http://kmhfl.health.go.ke/#/facility_filter/results accessed July 19, 2017.

[14] Kenya Master Health Facility List, available at http://kmhfl.health.go.ke/#/gis/10/ . The 2009 Census indicated that Marsabit had a population of 291,075 while Kakamega had 1,698,576.

[15] Kenya Master Health Facility List, available at http://kmhfl.health.go.ke/#/gis/47/

[16] Nancy Jacqueline Njuhi Kamau, 'Access to Health Care by Inmates in Kenya: A Study of Lang'ata Women's Prison and Nairobi Remand/Allocation', (Masters of Arts Thesis, University of Nairobi, 2006)35.

[17] John Muchangi, 'Kenya has more MCAs than doctors-medic's union', *The Star* May 17th, 2016.

seek treatment in facilities out of the country.[18] Access is also seen to be greatly inhibited when it comes to mental health. There has been slow development of human resource competent to deal with mental health cases with facilities specialized in mental health being also limited in number.[19]

The challenge of access is also evident when it comes to access to essential medicines. Challenges have been faced with regards to access to these medicines which are in some cases not usually available at the facilities that are supposed to be dispensing them or as a result of the financial barriers that may exist hence preventing access.[20] Availability of medicines is particularly a challenge in public health facilities with incidences of stock outs being prevalent.[21] Price constrains have also been noted to be a barrier for access, especially among the poor.[22] This is notwithstanding the fact that most of the medicines obtained by the government are generic and the fact that donor agencies also contribute significantly by providing free medicines. Challenges faced in accessing medicines are as a result of a multiplicity of factors, including stringent protections accorded to these medicines by the patent holders.[23]

Before we look at specific elements of the Act dealing with access, it is important to note that the Act defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity".[24] This is reminiscent of the definition offered by the World Health Organization that defines health in similar wordings.[25] This broad sense of wording is critical in ensuring the adoption of all-inclusive approaches in dealing with the question of access to health care.

2.1 Duties

The Health Act 2017, in its objects gives an indication on how it aims to deal with the question of access to health care.[26] The Act provides that the attainment of the highest standards of health care

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[18] Everlynne Mainnah, 'Factors Influencing Provision of Cancer Treatment in Public Health Facilities in Kenya: The Case of Kenyatta National Teaching and Referral Hospital', (Master of Arts Thesis, University of Nairobi, 2016) 43.

[19] Manohar Dhadphale and J.G. Magu, 'Mental Health Services in Kenya', (1984) 26(1) Indian Journal of Physachiatry 37. See also Maragu E, Sands N, Rolley J, Ndetei D, and Mansouri F, 'Mental healthcare in Kenya: Exploring optimal conditions for capacity building', (2014) 6(1) African Journal of Primary Health Care.

[20] Republic of Kenya, 'Access to Essential Medicines in Kenya: A Health Facility Survey', available at http://apps.who.int/medicinedocs/documents/s18695en/s18695en.pdf accessed July 19, 2017.

[21] Ibid 22.

[22] Ibid 26.

[23] See Smith Ouma, 'Trips Flexibilities and Access to Essential Medicines in Developing Countries', (forthcoming, Strathmore Law Journal).

[24] Health Act, 2017.

[25] See World Health Organization, 'Constitution of WHO: Principles', available at http://www.who.int/about/mission/en/

[26] The Act in Section 3 provides;

The objects of this Act are to-

a. Establish a national health system which encompasses public and private institutions and providers of health services at the national and county levels and facilitate in a progressive and equitable manner, the highest attainable standard of health services;
b. protect, respect, promote and fulfill the health rights of all persons in Kenya to the progressive realization of their right to the highest attainable standard of health, including reproductive health care and the right to emergency medical treatment;

is to be done progressively and in an equitable manner. This is informed by the nature of rights in Article 43 of the Constitution which the Constitution provides are to be achieved progressively.[27] This entails an obligation on the State to take deliberate, concrete and targeted steps aimed at the full realization of the right to health.[28] Progressive realization also requires that the State expends the maximum available resources towards the realization of these rights.[29] The State also ought to establish that it used these maximum available resources in order to fulfil the envisioned rights as was seen in the South African case of *Rail Commuters Action Group v Transnet Ltd t/a Metrorail* that;[30]

> A final consideration will be the relevant human and financial resource constraints that may hamper the organ of state in meeting its obligation. This last criterion will require careful consideration when raised. In particular, an organ of State will not be held to have reasonably performed a duty simply by on the bald assertion of resource constraints. Details of the precise character of the resource constraints, whether human and financial, in the context of the overall resources of the organ of the State will need to be provided.

The Act in Section 4 reiterates the fact that the State is the duty bearer when it comes to the right to health. It is notable that the responsibility assigned to the State in this section extends to the provision of emergency medical treatment. Fulfillment of the right to health under the Act is also seen to go hand in hand with the realization of other health related rights, a duty that the Act vests on the State.[31] The Act provides that the State has the duty to ensure access and realization of these health related rights by every person including the vulnerable groups within the society.[32] The Act further promotes access by establishing that the State has the responsibility of ensuring the provision of a health service package at all levels of the health care system, which shall include services addressing promotion, prevention, curative, palliative and rehabilitation, as well as physical and financial access to healthcare.[33] This is recognition of the fact that barriers to access are not only physical but may also come in financial forms.

Health care users also have certain responsibilities especially arising at the time that they seek to access health care. These duties include the duty to adhere to the treatments provides; to provide accurate information to health care providers; to cooperate with health care providers; and to treat providers and workers with dignity and respect.[34] Interests of health care users are also

c. protect, respect, promote and fulfill the rights of children to basic nutrition and health care services contemplated in Articles 43(1) (c) and 53(l) (c) of the Constitution;
d. protect, respect, promote and fulfill the rights of vulnerable groups as defined in Article 21 of the Constitution in all matters regarding health; and
e. recognize the role of health regulatory bodies established under any written law and to distinguish their regulatory role from the policy making function of the national government.

[27] Constitution of Kenya (2010) Art. 21(2).

[28] Nicholas Orago, 'Limitation of Socio-Economic Rights in the 2010 Kenyan Constitution: A Proposal for the Adoption of a Proportionality Approach in the Judicial Adjudication of Socio-Economic Disputes', (2013) 16(5) 181.

[29] See CESCR General Comment No. 3 (1990) para 12.

[30] 2005 2 SA 359 para 88.

[31] Health Act, S. 4(c).

[32] Ibid.

[33] Ibid S. 4(d).

[34] Health Act, 2017. S. 13

protected as complaints mechanisms are established in the Act. The national and county governments have a duty to publish the complaints procedures which should be displayed in all health facilities.[35]

2.2 Privacy and health information

The Act has also sought to address one key inhibitor to access especially by vulnerable groups like women during maternity care, that is, undignified treatment. The apathy exhibited in certain cases by women against health care facilities results from the fact that most pregnant women are afraid of being subjected to violence and hostile treatment from maternal health service providers which is an iniquity prevalent in many health care facilities.[36] Lack of knowledge of their rights further leaves women vulnerable and also prevent them from seeking appropriate redress whenever their rights are violated.[37] This resultantly lowers confidence in health care systems with devastating effects on the health of women who may need healthcare services.

Health information remains a key determinant of confidence in the health care system even though this is in many cases underappreciated. Properly safeguarded health information systems play a role in improving the quality of health care by restoring trust in the health care system and among consumers, health care professionals, and other stakeholders involved in the delivery of health care services.[38] The question on privacy, which has been addressed by the Act, has also been prevalent when it comes to access to health care by HIV positive individuals. In a directive issued on 23rd February 2015, the President had directed government agencies to collect names of people living with HIV and a case was subsequently instituted challenging the directive, arguing that it amounted to a breach to the right to privacy and confidentiality and was likely to expose these persons to stigma and discrimination.[39] The directive was subsequently declared unconstitutional and the government was directed to codify the names collected.[40]

The provisions of the Act on health information deals with, among others, the duties of a health care provider to the users of health care services.[41] It is however concerning that the

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[35] Ibid, S. 14(3).

[36] Michael Oriedo, 'Poor Pregnant Women Face Rampant Abuse', *The Standard* March 31st 2011 available at https://www.standardmedia.co.ke/health/article/2000032250/poor-pregnant-women-face-rampant-abuse accessed January 22, 2017. See also Timothy Abuya *et al.,* 'Exploring the Prevalence of Disrespect and Abuse during Childbirth in Kenya', available at http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0123606 accessed January 29, 2017.

[37] Lynn P. Freedman *et al.* 'Defining disrespect and abuse of women in childbirth: a research, policy and rights agenda', available at http://www.who.int/bulletin/volumes/92/12/14-137869.pdf 915.

[38] Furrow and others (n 1) 267.

[39] See High Court Petition 250 of 2015

[40] Ibid.

[41] Section 8 of the Act specifically deals with health information. It thus, provides; 8. (1) Every health care provider shall inform a user or, where the user of the information is a minor or incapacitated, inform the guardian of the— Health information. (a) user's health status except in circumstances where there is substantial evidence that the disclosure of the user's health status would be contrary to the best interests of the user; (b) range of promotive, preventive and diagnostic procedures and treatment options generally available to the user; (c) benefits, risks, costs and consequences generally associated with each option; and (d) user's right to refuse recommended medical options and explain the implications, risks, and legal consequences of such refusal. (2) The health care provider concerned must, where possible, inform the user as contemplated in subsection (1) in a language that the user

provisions of the Act do not comprehensively deal with the question of health information notwithstanding its significance. Firstly, the Act does not mandate health care providers to give patients notice of their privacy practices. This leaves most patients seeking health care services exposed to infringement of privacy of their information as they will not be aware of the obligations that the health care provider has with regards to this information.

Regarding disclosure, which is a key element in patient information concerns,[42] the Act lists the circumstances where patient information may be disclosed and it states thus, that the information may be disclosed where; the user consents to such disclosure in writing in the prescribed form; a court order or any applicable law requires such disclosure; or non-disclosure of the information represents a serious threat to public health.[43] The Act does not however define the mechanisms that are to be employed in enforcing the duty of confidentiality and penalties for non-compliance. This is especially relevant where information is disclosed without the patient's knowledge for research purposes. Questions may also be asked on the nature of rights granted to the entity that has received rights over patient information. Can these entities for example use the information for profit-making ventures and are patients who have disclosed the information entitled to the proceeds of such ventures? This particularly comes in light of the adoption of the District Health Information System (DHIS2) by the Ministry of Health in 2010, which is said to be a free and open-source computer software used to monitor health indicators for a national health system.[44] The System contains vast quantities of information obtained from patients seeking treatment in various health care facilities and such information can be used for research purposes. The Act also speaks of informed consent as a basis for disclosure.[45] The practicality of this may however be difficult especially in the face of illiterate patients or those who may not know the implications of their consent to disclosure.

2.3 Informed Consent

Closely related to the questions on health information is the concern of consent in the health care setup and particularly informed consent. This is a concept that has received much attention as a result of judicial deference towards individual autonomy.[46] Individual autonomy has been justified on the basis that individuals have the right to be free from nonconsensual interference with his or her person and that it is basic moral principle that it is wrong to force another to act against their will.[47] Informed consent is closely related to the right to receive dignified treatment which is

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understands and in a manner which takes into account the user's level of literacy. (3) Where the user exercises the right to refuse a treatment option, the health care provider may at its discretion require the user to confirm such refusal in a formal manner. (4) In this section, the word "user" refers to any person who seeks or intends to seek medical care from a health care provider and the expression "health care provider" includes any health facility.

[42] Joy Pritts *et al.,* 'The State of Health Privacy: A Survey of State Health Privacy Statutes', available at http://sharps.org/wp-content/uploads/PRITTS-REPORT1.pdf iv.

[43] Health Act, 2017.

[44] Yvonne Otieno and Tom Arunga, 'Managing Data with DHIS2: Improving Health Commodities Reporting and Decision Making in Kenya', available at https://www.msh.org/news-events/stories/managing-data-with-dhis2-improving-health-commodities-reporting-and-decision accessed July 20, 2017.

[45] Health Act, S. 11(1).

[46] Furrow and others (n 1) 206.

[47] Ibid. see also Justice Cardozo in *Schloendorff v. Society of New York Hospital* 211 N.Y. 125, 105 N.E. 92(1914) stating "Every human being of adult years and sound mind has a right to determine what shall be done with his own body…"

recognized in the Constitution.[48] The question on informed consent is particularly relevant in the context of a patient base that may not be aware of their rights or the implications of consenting to certain procedures and also due to the skewed power balance in the physician-patient relationship. The right to informed consent will only be effective where the patient possesses enough information to enable an intelligent choice.[49] This is quintessential in the access to health discourse. It has been noted that in many cases that health care providers tend to have the upper hand in influencing decisions, which may inadvertently be abused even with the best intentions based on the fact that only a handful of patients in Kenya even know about it.[50] Questions of informed consent are also relevant during research studies and there is limited evidence on whether researchers in many cases obtain informed consent from their subjects.[51]

Prior to the enactment of the Health Act 2017, the Kenya National Patients' Right Charter 2013, provided for the right to informed consent to treatment by patients.[52] The Act reasserts the importance of informed consent in the health care access debate.[53] Section 9 (c) of the Act is particularly noteworthy as it allows for the provision of health care services without informed

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Professor Alexander Capron lists 6 functions that the doctrine can serve: 1) Protect individual autonomy 2) Protect the patient's status as a human being 3) avoid fraud or duress 4) encourage doctors to carefully consider their decisions; 5) foster rational decision-making by the patient; and 6) involve the public generally in medicine. See Alexander Capron, 'Informed Consent in Catastrophic Disease Research and Treatment', (1974) 123 U.Penn. L. Rev. 365-76. A complete informed consent process is said to consist of seven elements: 1) discussing the patient's role in the decision-making process 2) describing the clinical issue and suggested treatment 3) discussing alternatives to the suggested treatment 4) discussing risks and benefits of the suggested treatment 5) discussing related uncertainties 6) assessing the patient's understanding of the information provided; and 7) eliciting the patient's preference. See Kristina M. Cordasco, 'Obtaining Informed Consent from the Patients: Brief Update Review', in Shekelle PG *et al.,'* Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices', available at https://www.ncbi.nlm.nih.gov/books/NBK133363/pdf/Bookshelf_NBK133363.pdf 461.

[48] Constitution (2010) Art. 28

[49] *Canterbury v. Spence* United States Court of Appels, District of Columbia Circuit, 1972. 464 F. 2d 772.

[50] Nelly Bosire, 'When dealing with children, the matter of informed consent does not apply by virtue of their age', *Daily Nation* 23rd January 2017.

[51] Miriam Carole Atieno *et al.,* 'An audit of the informed consent process in postgraduate dissertation studies at the College of Health Sciences, University of Nairobi, Kenya', (2012) 5(1) The South African Journal of Bioethics & Law.

[52] The Charter provides that every patient has the right " to be given full and accurate information in a language one understands about the nature of one's illness, diagnostic procedures, proposed treatment, alternative treatment and all the costs involved for one to make a decision except in emergency cases and that the decision shall be made willingly and free from duress". See The Kenya National Patient's Rights Charter 2013, available at http://medicalboard.co.ke/resources/PATIENTS_CHARTER_2013.pdf clause 8.

[53] The Act in Section 9 provides; No Specified health service may be provided to a patient without the patient's informed consent unless- (a) the patient is unable to give informed consent and such consent is given by a person- (i) mandated by the patient in writing to grant consent on his or her behalf; or (ii) authorized to give such consent in terms of any law or court order; (b) the patient is unable to give informed consent and no person is mandated or authorized to give such consent, but the consent is given by the next of kin (c) the provision of a health service without informed consent is authorized by an applicable law or court order; (d) the patient is being treated in an emergency situation; (e) failure to treat the user, or a group of people which includes the user, will result in a serious risk to public health; or (f) any delay in the provision of the health service to the patient might result in his or her death or irreversible damage to his or her health and the patient has not expressly, or by implication or by conduct refused that service. (2) A health care provider must take all reasonable steps to obtain the user's informed consent. (3) For the purposes of this section "informed consent" means consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as provided for in section 8 of this Act.

consent where an applicable law or court order has authorized the provision of the services. This clearly flies in the face of patient autonomy considerations. Concerns may particularly arise where a patient refuses to receive treatment as it may expose physicians and surgeons to liability as a result of battery. This is based on the fact that any action by medical professionals where a patient has not consented to a procedure will amount to unwanted bodily contact as the plaintiff will need only to show that a nonconsensual touching occurred.[54]

Section 9 (1)(c) of the Act also waives the requirement for informed consent where the delay in the provision of the health service may result in the death or irreversible damage to the patient and that the patient has not expressly, by conduct or implication refused that service. This leads to a question on whether health care providers can assume the existence of informed consent where there is none. The Act itself defines informed consent as "consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as provided in section 8 of this Act".[55] The practical difficulty in obtaining informed consent in an emergency situation is clear. The situation anticipated in Section 11 (1)(f) may however pose difficulties since the concept of informed consent is largely understood as a positive initiative to be taken by the patient which comes to fruition where a patient expressly, impliedly or through their actions agreeing to undergo as specific medical intervention.[56] An illustrative case where these concerns have played out is *C.N.M v. The Karen Hospital Limited*[57]where the claimant, who was suffering from severe diarrhea, visited the respondent hospital to seek treatment and was later subjected to a HIV test without her informed consent which test indicated that she was HIV positive. The information was subsequently shared with her insurance company. Upon her discharge she filed a claim against the Hospital for breach of confidentiality and privacy for having been tested by the respondent without her consent. The HIV Tribunal held that the claimant's rights had been violated as a result of failure by the hospital's failure to obtain her informed consent. The claimant was awarded Kshs. 2,500,000/= general damages for the testing without her informed consent and breach of confidentiality.

This notwithstanding, the right to informed consent may be waived where failure to treat the user, or a group of people which includes the user, will result in serious risk to public health.[58] This is in recognition of the fact that the State has a wider obligation to protect the health of the general public. This obligation is met within the public health framework where the State is vested with certain legal powers and duties to assure the conditions for people to be healthy and the limitation of individual autonomy for the common good.[59] This also furthers the duty bestowed on the State in Article 43 of the Constitution and also Section 4 of the Act which provides that it is a fundamental duty of the State to observe, respect, promote and fulfil the right to the highest attainable standards of health.

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[54] Furrow and others (n 1) 208.
[55] Health Act 2017, S. 9 (3).
[56] See The Joint Commission, 'Informed consent: More than getting a signature', available at https://www.jointcommission.org/assets/1/23/Quick_Safety_Issue_Twenty-One_February_2016.pdf
[57] Case No. HAT 008 of 2015
[58] Health Act 2017, S. 9 (1) (f).
[59] Lawrence Gostin and Lindsay Wiley, *Public Health Law: Power, Dduty, Restraint* (Third, University of California Press 2016) 4.

Disclosure of information relating to a patient's condition which may be material to the decision on whether or not to undergo a treatment is also considered to be a central constituent of the doctrine of informed consent.[60] This has been reiterated in Section 8 of the Act which outlines the disclosure duties of a health care provider. This is particularly relevant in light of the numerous reported cases of unnecessary referrals to seek treatment abroad.[61] A health care provider who refers their patient elsewhere for treatment that may be unnecessary is therefore liable for breach of informed consent by a patient.

Access also denotes the right to refuse treatment in the context of informed consent. The Act recognizes the right of a patient to refuse a treatment option.[62] The relevance of this provision may be seen in situations of end-of-life treatment decision-making. Can an adult with competent decision-making exercise the right to refuse treatment where such refusal may lead to their death? This should be looked at within the constitutional framework providing for the right to life. The Constitution guarantees the right to life which is not to be intentionally deprived except to the extent authorized by the Constitution or other written law.[63] An analysis of this constitutional provision reveals that the right to life may be deprived where it is permitted by the law, for example, by the Penal Code[64] or any other law such as the Health Act. It is clear that the manner in which the provisions of section 8 of the Act are phrased leaves wide room for a person to refuse treatment which may lead to their death. this should also been looked at within the context of the State's interest in 1) preserving life 2) preventing suicide 3) protecting innocent third parties, and 4) maintaining the ethical standards of the medical profession.[65]

Questions however arise on whether the right to refuse treatment may be exercised on a patient's behalf where the patient lacks competence to make the decision. This may particularly arise where the patient is a minor or a person in a vegetative state. As recently seen in Britain in the Charlie Gard case, the question of who has the final say when treating a critically ill child has elucidated hotly contested debates.[66] The wordings of the Act seem to suggest that this option is not exercisable on behalf of a user. The definition of user (who is given the right to exercise the option of refusing treatment) in the Act is "any person who seeks or intends to seek medical care from a health care provider".[67] Questions may therefore, arise on whether "seeking medical care" as used in the Act can also be interpreted as seeking medical care on behalf of others. The word "seek" assumes presence of capacity to do an act and it may be interpreted to mean authority to act by a guardian or legal representative where a party is incapacitated or is a minor. In such a case, it would be important that the State institutes a claim in Court on behalf of the minor or the

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[60] *Arato v. Avedon* Supreme Court of California, 1993. 5 Cal. 4th 1172, 23 Cal.Rptr.2d 131,858 P. 2d 598.

[61] See All East Africa, 'Kenya: New rule to prevent unnecessary referral of patients abroad', January 31st 2017. Available at https://www.alleastafrica.com/2017/01/31/kenyanew-rule-to-prevent-unnecessary-referral-of-patients-abroad/ accessed July 20, 2017.

[62] Health Act, 2017 s. 8 (4).

[63] Constitution (2010) Art. 26.

[64] See *John Kaberia Kahinga and 11 others v The Honourable Attorney General* Petition No. 618 of 2010, stating that the right to life may be limited where the law provides for a death sentence.

[65] See *Bouvia v. Superior Court* California Court of Appeal, Second District, 1986. 179 Cal. App.3d 1127,225 Cal.Rptr.297.

[66] Steve Inskeep, 'The Case of Charlie Gard Divides Doctors and Parents', *NPR News* July 20th 2017.

[67] Health Act, S. 8(4)

incapacitated person in order to protect their interests whenever a party seeks to make a decision on their behalf that may result in death of a patient.[68] It is important that the Act establishes regulations to guide how the right provided for in Section 8(3) may be exercised where a patient lacks decision-making capacity. Models like the use of advance directives/ individual's instructions, decisions by surrogates and powers of attorney have been used in some jurisdictions.[69]

2.4 Access to mental health

With regards to mental health, the Act missed an opportune moment to comprehensively deal with prevalent concerns but instead deferred the matter to Parliament to enact another legislation to provide for mental health.[70] Until such a law is enacted, the Mental Health Act which was enacted in 1989 will be the guiding legislation. It is notable that the Mental Health Policy 2015-2030 also provides some guidance when it comes to mental health concerns. The Policy seeks to address the systemic challenges, emerging trends and mitigate the burden of mental health problems and disorders.[71] The Policy recognizes mental health as a key determinant of overall health and socio-economic development and also notes that there is inadequate data and information on the prevalence of mental health, neurological, and substance use (MNS) in Kenya.[72] This observation is also reminiscent of the fact that numerous barriers exist that bar access to mental health services in the country which range from shortage of mental health specialists and neurologists.[73] It has been noted with concern that there are about 100 psychiatrists in the entire country with only 12 neurologists in the country.[74] These challenges are exacerbated by the fact that there exist stereotypes and stigma associated with mental illness and this further inhibits access to care by the mentally ill.[75] The Act ought to have provided tangible gauges to be used as a basis for the enactment of the legislation envisioned in Section 73 of the Act. One particular area that the Act failed to appreciate is the need for the envisioned Act to put in place mechanisms to ensure promotion of mental health care through the establishment of awareness programmes. This is key in dismantling the stereotypes that exist in the society that make access to mental health services a challenge.

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[68] See *Bouvia v. Superior Court* California Court of Appeal, Second District, 1986. 179 Cal. App.3d 1127,225 Cal.Rptr.297.

[69] Furrow and others (n 1) 1582–93.

[70] Health Act, S. 73. The Act provides in this Section that; There shall be established by an Act of Parliament, legislation to— (a) protect the rights of any individual suffering from any mental disorder or condition; (b) ensure the custody of such persons and the management of their estates as necessary; (c) establish, manage and control mental hospitals having sufficient capacity to serve all parts of the country at the national and county levels; (d) advance the implementation of other measures introduced by specific legislation in the field of mental health; and (e) ensure research is conducted to identify the factors associated with mental health.

[71] Ministry of Health, 'Kenya Mental Health Policy 2015-2030', (Ministry of Health, 2015) foreword.

[72] Ibid 5.

[73] Ana-Claire Meyer and David Ndetei, 'Providing Sustainable Mental Health Care in Kenya: A Demonstration Project', available at https://www.ncbi.nlm.nih.gov/books/NBK350312/ accessed July 20, 2017.

[74] See Kakuma R *et al.,* 'Human resources for mental health care: Current situation and strategies for action', (2011) 378 Lancet.

[75] Sandy Hausman, 'Affordable Mental Health in Kenya: Frugal Innovations with Global Implications', available at http://www.commonwealthfund.org/~/media/files/multimedia/podcasts/basic-needs-final.pdf?la=en accessed July 20, 2017.

2.5 Access to reproductive health

The Act recognizes the right of every person to reproductive health care which includes the right to be informed about and have access to reproductive health care including the right to safe, effective, affordable and acceptable family planning services.[76] The Act further mandates that any procedure carried out to enable access to reproductive health care shall only be carried out in a legally recognized health facility with an enabling environment and competent staff.[77] These provisions do not speak much on access to abortion as a family planning service but guidance on this can be obtained from the Constitution in Article 26(4) which prohibits abortion except in the opinion of a trained health professional, there is need for emergency treatment, or the life of the mother is in danger, or if permitted by any other law. This provision by the Constitution therefore, envisions a situation where permission can expressly be granted by any other law. Since the Act is silent on the same, a claim of the right to access abortion cannot be founded on the Act since there is no express permission as envisioned by the Constitution. The Act missed an opportune moment to deal with the question of abortion whose prohibition continues to lead to insurmountable injustices on women.[78] The reproductive services envisioned in the Act must also be acceptable to the consumers of these services. This provision is important in dealing with cases where certain family planning methods have been forcefully administered on women especially those living with HIV.[79] It is not however, clear what penalties are to be imposed on persons and institutions that violate these provisions. Claims on battery will therefore, be useful in instituting proceedings against violators of these provisions.

2.6 Access to emergency treatment

The Constitution in Article 43(2) provides that a person shall not be denied emergency medical treatment. The Health Act has gone further to define what amounts to emergency medical treatment.[80] Punitive measures are also established against violators.[81] The provision on access to emergency medical treatment was long overdue given the reported cases of constant violations by health care providers with grave consequences to Kenyans.[82] This has further been exacerbated by

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[76] Health Act, 2017 S. 6(1) (a).

[77] Ibid, S. 6(3).

[78] See Smith Otieno, 'Commentary on Reproductive Justice in Kenya and the State's Human Rights Obligations', (2016) 10(1) Asia Pacific Journal of Health Law and Ethics.

[79] See Tabitha Griffith Saoyo, 'Breaking the Silence on Forced Sterilization of Women Living with HIV', *KELIN Kenya* December 1st 2016 available at http://www.kelinkenya.org/2016/12/breaking-silence-forced-sterilization-women-living-hiv/ accessed July 23, 2017.

[80] Health Act 2017, S. 7(2): For the purposes of this section, emergency medical treatment shall include-

a. pre-hospital care
b. stabilizing the health status of the individual; or
c. arranging for referral in cases where the health provider of first call does not have facilities or capability to stabilize the health status of the victim.

What constitutes emergency medical treatment has also been dealt with in *Luco Njagi & 21 Others v Ministry of Health & 2 Others* Petition No. 218 of 2013.

[81] Ibid, S. 7(3) Any medical institution that fails to provide emergency medical treatment while having ability to do so commits an offence and is liable upon conviction to a fine not exceeding three million.

[82] Maurice Oduor and Dan Wafula Simiyu, 'The right to emergency medical treatment in Kenya', available at https://poseidon01.ssrn.com/delivery.php?ID=731070114084106029112028089021094127058062071092084057031005126078009006125025102099057029023099109125023091101027005125093126040057062033063081112

the numerous barriers faced by persons seeking to access emergency medical treatment such as costs and transportation.[83] The right to emergency medical treatment is closely tied to the right to human dignity which is considered to be a foundation for recognition of human rights as was held in *A.N.N v Attorney General*[84] thus;

> It is thus apparent that human dignity is the foundation for recognition and protection of human rights, which, as provided at Article 19(3) (a), 'belong to each individual and are not granted by the State.' Regardless of one's status or position, or mental or physical condition, one is, by virtue of being human, worthy of having his or her dignity or worth respected. Consequently, doing certain things or acts in relation to a human being, which have the effect of humiliating him or her, or subjecting him or her to ridicule is, in my view, a violation of the right to dignity protected under Article 28.

Duties to treat in emergency situations have been considered to be core in health care service provisions in jurisdictions such as the U.S. where it is said that physicians have an obligation to provide medical treatment where necessity arises and that this is a continuing obligation.[85] This obligation has however been looked at from a contractual perspective that warrants such a duty only when a physician undertakes to provide care to a patient.[86] Exceptions however exist that have been established by the Emergency Medical Treatment and Labor Act which requires a hospital having an emergency department to provide appropriate medical screening examination to determine whether or not it is an emergency medical condition and to provide necessary stabilizing treatment for the emergency condition.[87] The Act further restricts the transfer of patients in such conditions until they have been stabilized.[88] The position in Kenya based on the Constitution and the Act seems to be that the duty will arise immediately a patient presents themselves to a health care provider for treatment. Regarding the penalties provided for in the Act, a glaring omission is evident where a case of patient dumping occurs. This practice is rife in Kenya with one of the notable cases being that of Alex Madaga, who was an accident victim in critical condition who spent 18 hours in an ambulance oscillating between hospitals that didn't want to admit him claiming that they lacked ICU beds while the real issue was that they did not want to admit him before he made some payments.[89] It is laudable that the Act requires for provision of treatment to stabilize a patient in emergency situations. The Act however ought to have established punitive measures for health care providers who transfer patients to other institutions in emergency

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[83] Morgan Broccoli *et al.,* Perceptions of emergency care in Kenyan communities lacking access to formalized emergency medical systems: a qualitative study', (2015) 5 BMJ Open, available at http://bmjopen.bmj.com/content/bmjopen/5/11/e009208.full.pdf accessed July 23, 2017.

[84] Petition No. 240 of 2012.

[85] See *Ricks v. Budge* 91 Utah 307, 64 P. 2d 208.

[86] See *Childs v. Weis* Court of Civil Appeals of Texas, 1969. 440 S. W. 2d 104.

[87] Emergency Medical Treatment and Labor Act 42 U.S.C. §.

[88] Ibid.

[89] Eunice Kilonzo, 'Car accident survivor spends over 18 hours waiting in ambulance', *Daily Nation* October 7th 2015.

situations even though they have facilities and capability to attend to the patients. This will go a long way in curbing patient dumping especially by private hospitals.

2.7 Access to medicines

Often overlooked in the access to health care discourse are concerns on access to medicines. As noted earlier, challenges in accessing medicines spring from a number of factors key among them being the numerous I.P. protections accorded to manufacturers. Developed countries have particularly continuously exerted pressure on developing countries to reform their intellectual property regimes to offer more protection for the pharmaceutical companies.[90] It is in this light that most developing countries are realizing the significance of traditional medicines in remedying any gaps in access to medicines. The practice of traditional medicines has largely been informal and unregulated.[91] The Act mandates the national government with formulation of policies to guide the practice of alternative medicines.[92] It is also provided that a body shall be established to regulate the practice of traditional medicine and alternative medicine.[93] The establishment of these regulations will be important in safeguarding the interests of health care service users from exploitation by rogue providers. This notwithstanding, challenges are still rife that bar many from accessing essential medicines and some of these are attributed to corrupt practices that see essential medicines availed by donors for free ending up in markets where they are offered for sale by rogue providers.[94]

2.8 Public and environmental health

Access to health care also denotes certain duties by the government to promote and advance public health and environmental health. In this regard, the Act states that the government is required to establish interventions to reduce the burden imposed by communicable and non-communicable diseases and neglected diseases especially among marginalized and indigent populations.[95] The government is further required to put in place interventions to promote healthy lifestyles including those aimed at countering excessive use of alcohol products, reduce us of tobacco and other addictive substances.[96] It is notable that the government, through initiatives like tobacco regulations in the Tobacco Control Act 2007, has attempted to meet some of these obligations notwithstanding strong opposition by tobacco companies.[97] The government can also meet such goals through initiatives like increasing taxes on sugary drinks which has been hailed as one

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[90] John Harrington, 'Access to Essential Medicines in Kenya: Intellectual Property, Anti-Counterfeiting, and the Right to Health', in Michael Freeman *et al., Law and Global Health: Current Legal Issues* (2014, Oxford University Press) 95.

[91] John Harrington, 'Kenya: Traditional Medicine and the Law', available at https://www.africaresearchinstitute.org/blog/kenya-traditional-medicine-and-the-law/ accessed July 23, 2017.

[92] Health Act, 2017 S. 74(1).

[93] Ibid, S. 75(1).

[94] Stellar Murumba, 'Kemsa in a spot over free HIV medicines fraud', *Business Daily* July 24th 2017.

[95] Health Act, 2017 S. 68(1) (a).

[96] Ibid, S. 68(1) (b).

[97] See World Health Organization, 'WHO Report on the Global Tobacco Epidemic, 2017: Monitoring tobacco use and prevention policies', (WHO, 2017) 49. See also James Gathii and Cynthia Ho, 'Regime Shifting of IP Law Making and Enforcement from the WTO to the International Investment Regime', (2017) 18 Minnesota Journal of Law, Science & Technology.

approach to promoting healthy lifestyles.[98] Promotion of public health also means establishing proper safeguards at border entry points to ensure effective detection and response to communicable diseases especially in the wake of the push for a visa-free Africa.[99]

2.9 Human organs, blood, blood products, tissues and gametes

Often overlooked is the question on how organ transplants are to be done especially in situations of scarcity. This grim state of affairs has been compounded by the myths and misconceptions that many people hold against organ donation.[100] The law has historically forbidden donation of body parts from dead people and doctors have lamented that these barriers have inhibited access to health care by persons in dire need of these organs.[101] The Act is clearly transformative when it comes to issues on organ transplant as it allows for human organ transplantation.[102] The provisions of the Act dealing with organ transplantation recognize patient autonomy and recognize patients as the decision makers when it comes to questions on organ transplant.[103] A person can therefore, through a will, or through consent from close relatives in the absence of a will, or through a directive by the Cabinet Secretary, have their body parts donated to an institution after their death.[104] The Act has however, not outlined the criteria to be followed by the institution contemplated in Section 81 in using or donating to a recipient the body parts extracted from a deceased person. Since charging a fee during the harvesting and transplant process is prohibited, it is not clear whether the donated organs will be availed on a first-come first-serve basis to recipients or what criteria will be used. The Act also imposes a penalty of ten million shillings or imprisonment for a period not exceeding ten years or both where there is contravention of the provision barring charging of fees for human organs.[105] Some scholars have argued that the wording of the Act leaves room for exploitation and haphazard organ harvesting, especially the provision allowing the Cabinet Secretary to allow for donation of a deceased's body parts where there is no will or traceable relatives.[106] These arguments should also be looked at within the bigger debate on whether corpses have rights. Some scholars have argued that rights over corpses vest on the surviving relatives, and by extension the State, if these relatives cannot be found.[107]

2.10 E-health

The recognition of e-health by the Act is also a step in the right direction in improving access to health care. The concept recognizes that physical access to health care services may not necessarily be possible in all cases. The use of e-health has particularly been seen to be useful in

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[98] Gostin and Wiley (n 57) 475.
[99] See Smith Ouma and Oyeniyi Abe, 'Regional Integration, Public Health Capabilities and the Place of the World Health Organization in Africa', (forthcoming) Albany Law Journal of Science & Technology.
[100] See Sarah Ooko, 'Negative beliefs stand in the way of Kenya's drive to legalize body organs harvesting', *Business Daily* May 4th 2016.
[101] Verah Okeyo, 'Dying for organs: A Case for Transplants', *Daily Nation* February 28th 2015.
[102] Health Act, 2017 Part XI.
[103] Ibid, S. 80(1) (iii).
[104] Ibid, S. 81.
[105] Ibid, S. 80(4).
[106] Luis Franceschi, 'Problematic health bill could spur organ trafficking', *Daily Nation* June 10th 2017.
[107] Peter Nemeth, 'Legal Rights and Obligations to a Corpse', (1943(19)1 Notre Dame Law Review 70.

the provision of maternal health care where pregnant women have, through the use of cellphone applications. Advances in medicine and technology promises a new dawn in the realization of the expected health outcomes by patients especially by pregnant women. Technology has been harnessed to facilitate strengthening of health systems and improve the quality of health care being delivered.[108] As we will see later on, the use of mobile technology has also been very successful in health financing where patients have been able to pay health care bills using their mobile phones or make insurance contributions using mobile phones.[109]

3.0 Quality of health care

Closely related to concerns on access to health care is the question of the quality of health care delivered. Concerns on quality particularly arise from the fact that health care is concerned with the wellbeing of individuals hence the need to ensure the best practice possible when availing health care resources to individuals. The Institute of Medicine defines quality of care as;

> "Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."[110]

This definition illustrates that quality in health care is concerned with the meeting of certain goals that are mainly measured in the form of outcomes derived from health procedures.[111] The anticipated outcomes are also based on current technical and scientific knowledge and this alludes to the fact that quality is a dynamic factor that may change based on new discoveries. As identified in the definition of quality offered above, health care quality is measurable based on certain benchmarks.[112] Campbell *et al* on the other hand look at quality of health care from the dimension of individual patient (which is concerned with access and effectiveness) and from a population perspective.[113] Notwithstanding these, defining quality remains an uphill task in light of resource differences and differences in priority areas. Nevertheless, looking at quality of health care warrants an examination of how a health care system is structured (i.e. the availability of human

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[108] See CDC Foundation, 'Mobile Health: How Phones are Reshaping Health in Africa', available at http://www.cdcfoundation.org/content/mobile-health-how-phones-are-reshaping-healthcare-africa

[109] See Daily Nation, 'Mobile phone health saving plan launched for low-income Kenyans', *Daily Nation* October 21st 2016.

[110] Institute of Medicine, 'Medicare: A Strategy for Quality Assurance', (1990, National Academy Press) 42.

[111] Ibid.

[112] In the U.S. the Affordable Care Act lists a set of factors to be used in measuring quality as;
'(A) health outcomes and functional status of patients; ''(B) the management and coordination of health care across episodes of care and care transitions for patients across the continuum of providers, health care settings, and health plans; ''(C) the experience, quality, and use of information provided to and used by patients, caregivers, and authorized representatives to inform decision making about treatment options, including the use of shared decision making tools and preference sensitive care (as defined in section 936); ''(D) the meaningful use of health information technology; ''(E) the safety, effectiveness, patient-centeredness, appropriateness, and timeliness of care; ''(F) the efficiency of care; ''(G) the equity of health services and health disparities across health disparity populations (as defined in section 485E) and geographic areas; ''(H) patient experience and satisfaction; ''(I) the use of innovative strategies and methodologies identified under section 933; and ''(J) other areas determined appropriate by the Secretary.
See The Patient Protection and Affordable Care Act § 3013.

[113] See S.M. Campbell *et al.,* 'Defining quality of care', (2000) 51(11) Social Science & Medicine.

and financial resources), the processes involved in the delivery of health care (here we consider what is actually done in giving and receiving care), and outcome of health care on the status of patients and populations.[114]

The Health Act does not define quality. The definition of "health care services" in the Act will therefore prove useful in identifying what needs to be looked at in measuring health care quality as envisioned by the Act.[115] The definition tells us that the concern of the Act with regards to quality is the establishment of mechanisms that ensure prevention, promotion, management and alleviation of diseases and impairments. The Act also recognizes the role of regulatory bodies in meeting the objectives outlined and these bodies are also established to promote access to quality health care.[116]

Firstly, the obligation on the State to fulfill the highest attainable standards of health that has been outlined in the Act envisions the establishment of standards from which the State's duty will be measured against. This entails an examination of both the processes and outcomes employed in the delivery of health care services.[117] The U.N. Committee on Economic, Social and Cultural Rights has also recognized the importance of States establishing benchmarks to monitor the realization of the right to health.[118] This is in recognition of the fact that the right to the highest attainable standards of health will only be realized based on some established standards that are measurable.

The Act further recognizes that provision of health care services, such as maternal treatment, is only to be provided by "a trained health professional" who is defined in the Act as a health professional with formal medical training at the proficiency in the skills needed to manage pregnancy-related complications in women, and who has a valid license from the recognized regulatory authorities to carry out that procedure.[119] This definition also brings out the aspect that health care professions in the country need to be licensed by the established regulatory agencies. Persons who are not licensed to provide services cannot therefore purportedly provide the services reserved to be provided by licensed providers. Licensure is considered to be one component of the quality control array in health care with the rationale for licensure being the fact that most health care service consumers lack information to make proper decisions hence the need for licensing bodies to actively monitor quality through licensure.[120] Like in many countries, the professional licensure in Kenya is that of professional self-regulation based on the fact that standards are established by established Boards that are mainly composed of members of the licensed health

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[114] Avedis Donabedian, 'The Quality of Care: How can it be Assessed?', (1988) 260(12) JAMA 1745. Donabedian further identifies seven pillars that he considers critical in measuring quality as; 1) efficacy 2) effectiveness 3) efficiency 4) optimality 5) acceptability 6) legitimacy, and 7) equity. See Donabedian A., 'The seven pillars of quality', (1990) 114(11) Archives of Pathology and Laboratory Medicine.

[115] The Act in Section 2 defines "health care services" as the prevention, promotion, management or alleviation of disease, illness, injury, and other physical and mental impairments in individuals, delivered by health care professionals through the health care system's routine health services, or its emergency health services.

[116] Health Act, 2017 S. 3(e).

[117] Paul Hunt and Gunilla Backman, 'Health Systems and the Right to the Highest Attainable Standard of Health', available at https://nesri.org/sites/default/files/Health_Systems_and_the_Rights_Backman_Hunt.pdf 43.

[118] CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art 12) para. 57.

[119] Health Act, 2017 S. 6(2).

[120] Furrow and others (n 1) 88–89.

profession.[121] Licensure in the Act also extends to health care facilities which has to meet the standards established by the Act.[122]

Health care providers also have certain duties established in the Act that relate to quality of health care. An example of this is the duty to provide health care conscientiously and to the best of their knowledge within their scope of practice and ability, to every person entrusted to their care or seeking their support.[123] This means that health care providers are required to uphold certain standards when providing health care services and the services ought to be provided by competent persons.

The Government also has the responsibility of developing health policies, laws and administrative procedures to enable the realization of the right to health and this includes the duty to develop and maintain organizational structures at the Ministry and at the national level.[124] Apart from the development of organizational structures, the Government also has a duty to provide technical support that are aimed at strengthening the health system.[125] The technical support that the government is required to provide also extends to the development of standards of training and institutions providing education to meet the needs of service delivery.[126] Key among the regulatory measures to be undertaken by the government is the duty to develop and ensure compliance with professional standards on registration and licensing of individuals in the health sector and the duty to coordinate development of standards for quality health service delivery.[127]

The Act also establishes certain offices, like that of the Director-General, which are tasked with certain responsibilities that are key in ensuring that quality health care is provided in the country.[128] At the County level, the Act provides for the establishment of county executive departments responsible for health and the office of the County Director of Health.[129] County governments have further been vested with responsibilities of "facilitating registration, licensing and accreditation of providers and health facilities respectively according to standards set nationally by the national government department responsible for health and relevant regulatory bodies."[130] The provisions of the Act dealing with licensure of health care providers however fails to provide for the duty of the licensed institutions to report any cases of adverse outcomes of medical procedures that occur within their facilities. Lack of these provisions disregard the fact that injuries arising from procedures and services in health care facilities is the inverse of quality medicine.[131] In Kenya, adverse events arising from medical negligence have become the norm

[121] The Medical Practitioners and Dentists Board is one such body that is tasked with the registration, licensing and discipline of medical and dental practitioners in Kenya. See Medical Practitioners and Dentists Act (Cap 253, Laws of Kenya).
[122] Health Act, 2017 S. 6(3).
[123] Ibid, S. 12 (2) (a).
[124] Ibid, S. 15.
[125] Ibid, S. 15(1) (e).
[126] Ibid, S. 15(1) (j).
[127] Ibid, S. 15(1) (l) & (m).
[128] Ibid. S. 17.
[129] Ibid, S. 19(1)-(3).
[130] Ibid, S. 20(d).
[131] Furrow and others (n 1) 39. The U.S. Agency for Healthcare Research and Quality (AHRQ) defines an adverse event as "Any negative or unwanted effect from any drug, device, or medical test".

with those culpable often not being held to account.[132] The Act recognizes the duty of providers of private health services to permit and facilitate inspection at any time by relevant authorities.[133] Reliance of inspection as a quality-assurance tool has however, been discredited as being ineffective.[134] The Act ought to have established mechanisms to ensure the institutionalization of safety by health care providers through among others requiring the full disclosure of any adverse events that occur in the health care facility and proper investigation and redressing of the same. Tracking of these events will also ensure that the provider knows how it is performing with regards to safety and quality of procedures in their facilities.

The Act establishes the Kenya Health Professions Oversight Authority which is tasked with; maintaining a duplicate health register of all health professionals working within the national and county government; promote liaison between statutory bodies; coordinate joint inspections with all regulatory bodies; receive and resolve complaints by aggrieved parties; monitor execution of mandates by relevant bodies; arbitrate disputes between statutory bodies; and ensure that the necessary standards for health professionals are not compromised by the regulatory bodies.[135] The wordings of the Act seem to suggest that the Kenya Professional Oversight Authority shall be deemed the ultimate authority when it comes to regulation of the health profession and quality oversight questions. The obligation to monitor and evaluate standards of performance of health professionals shall however remain with the respective regulatory bodies established while ensuring that these functions are not in conflict with those of the Authority established in Section 45 of the Act.[136]

The Act further provides for the establishment by an Act of Parliament a body that shall be tasked with regulation of health products and health technologies.[137] Licensing of medicines, vaccines or other health products is to be done only after assessments establishing that it achieves the therapeutic of intended effects, when the safety has been determined and if it is made and packaged according to satisfactory standards.[138] It is however, not clear from the Act how far and for how long the assessments are to be done before their sale is permitted. This is particularly relevant when it comes to newly developed medicines and vaccines which in numerous occasions have been tested on patients in developing countries without their consent.[139] Mechanisms therefore, ought to be placed to ensure safeguarding of the interests of patients where such medicines and vaccines are introduced.

A National Health Research Committee is established by the Act and tasked with identifying research for health priorities.[140] The Act requires that research dealing with human subjects must be in accordance with regulations articulated under the Commission for Science,

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[132] See Smith Ouma, Cynthia Amutete and Mbori Otieno, 'Engendering Rule of Law in Healthcare Delivery in Kenya', (forthcoming, 2017) Wisconsin International Law Journal.
[133] Health Act, 2017. S. 91(1) (a).
[134] Furrow and others (n 1) 46.
[135] Health Act 2017, S. 45, 48.
[136] Ibid, S. 60(1).
[137] Ibid, S. 62.
[138] Ibid, S. 66.
[139] Furrow and others (n 1) 1746.
[140] Health Act, S. 93,96

Technology and Innovation established under the Science and Technology Act.[141] Such research must also be conducted in accordance with the ethical standards established by the Committee.[142] The Act requires the obtaining of informed consent of the parent or guardian where research or experimentation is to be conducted on a minor.[143] These provisions of the Act do not however speak to research dealing with subjects that are not minors. Guidance on this can therefore be obtained from the National Commission for Science, Technology and Innovation *Legal Notice No. 106 of 2014* and *108 of 2013* which grants the Commission powers to among others, register, license and regulate researchers. Directions can also be obtained from The World Medical Association in its *Declaration of Helsinki-Ethical Principles for Medical Research Involving Human Subjects*[144] which provides in paragraph 7 that medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights. The *Principles* further provide that it is the duty of physicians involved in medical research to protect life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.[145]

The heightened requirements established by the *Principles* came against considerable controversies over drug trials by multinational pharmaceutical companies and United States federal agencies in African countries.[146] The provisions of the Health Act dealing with rights of patients and the requirement for informed consent are therefore helpful in determining what duties are owed to human subjects during a medical research. The Act also ought to have established more clarity on where the line should be drawn between patient-assistance programmes and health care research since many of the later may be cloaked in the name of the former. The Act also lacks clarity on cases where pharmaceutical companies engaged in research unduly influence health care providers to prescribe their products without taking due regard to the interest of the patient.

4.0 Cost of Health Care

Cost of health care has been debated on numerous occasions based on the fact that it is intricately related to the access discourse. The question of cost has been pervasive in health care sector in the country and remains a key inhibitor to access to health care by many in the country.[147] This has particularly been attributed to the fact that most Kenyans rely on out-of-pocket payments which is responsible for pushing many households below the poverty line.[148] Interventions like the adoption of a national health insurance scheme have not completely resolved the question of cost as this

[141] Ibid, S. 99(1).
[142] Ibid, S. 99(2).
[143] Ibid, S. 100.
[144] Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 with subsequent amendments in 1975,1983,1989,1996,2000,2002,2004,2008 and 2013.
[145] Ibid, para. 9.
[146] Furrow and others (n 1) 1747.
[147] See Smith Ouma, 'Structural Impediments to Access to Health Care in Kenya and the Promises of the New Constitutional Order', (forthcoming) Suffolk Transnational Law Review 11.
[148] Health Policy Project, 'Healthcare Costs Continue to Impoverish Millions of Kenyans', available at http://www.healthpolicyproject.com/index.cfm?ID=KenyaCHE accessed July 25, 2017.

scheme remains largely inaccessible to the poor and those working in the informal sector.[149] It has also been established that a close relation exists between lack of insurance, lack of health care and poor health.[150] Different views have subsequently emerged on who between the government and private providers is best placed to provide health insurance services.[151] Consensus has emerged that government-run insurance schemes are likely to be less costly compared to privately-run schemes which are associated with a number of costs such as advertising costs that make them more expensive.[152] The government however, remains a key stakeholder in the provision of health insurance services to its populace and this has further been propelled by arguments on universal health coverage.

The Act contains certain provisions that are directed at addressing questions of cost in health care. The Act particularly recognizes the role of county governments in developing supplementary incomes for the provision of services in as long as they are compatible with applicable laws.[153] Regarding the practice of traditional medicine, the Act stipulates that the charges to be levied shall be approved by the relevant authority.[154] This provision is important in ensuring that health care consumers are not exploited by those practicing in traditional medicine due to lack of regulations as has previously been the case.[155]

The Act further recognized the need for the progressive realization of universal health coverage and it mandates the department of health to among others provides mechanisms for the realization of social health protection, provide for regulation of health insurance providers and the development of policies and strategies aimed towards the realization of universal health coverage.[156] The Act further recognizes the importance of collaboration between the national and county governments in meeting costs associated with the provision of health care services.[157] The Act however, needed to shed more light on how such collaborations between the national and county governments will facilitate the goal of universal health care which is critical in dealing with cost as a barrier to access.

5.0 Conclusion

In this paper, I have attempted to provide a holistic analysis of the recently enacted Health Act by looking at its provisions under the broad bases of access, quality and cost. What emerges from these discussions is the fact that the Act contains a raft of provisions that are meant to promote access to health care, improve the quality of health care providers and also deal with issues of costs. Notwithstanding this, and as noted in the paper, the Act missed an opportune moment to

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[149] See Mukhwana Eugine Sundays *et al,* 'Determinants of Uptake and Utilization of National Hospital Insurance Fund Medical Cover by People in the Informal Sector in Kakamega County, Kenya', (2015) 3(4) Universal Journal of Public Health 169-76.
[150] Furrow and others (n 1) 526.
[151] Atul Gawande, 'The Cost Conundrum: What a Texas town can teach us about health care', *The New Yorker* June 1st, 2009 available at http://www.newyorker.com/magazine/2009/06/01/the-cost-conundrum accessed July 25, 2017.
[152] Furrow and others (n 1) 536.
[153] Health Act, 2017. S. 20(k).
[154] Ibid, S. 78.
[155] See Amos Kareithi, 'How con herbalists con Kenyans', *The Standard* February 11th 2009.
[156] Health Act, 2017. S. 86(1).
[157] Ibid, S. 86(1) (c).

comprehensively deal with certain questions on access especially concerns on informed consent and how to deal with breaches of the duty to provide emergency treatment among other concerns noted in the paper. With regards to quality, the Act ought to have heightened obligations on health care providers to guarantee quality of services and products offered and to impose punitive measures where breaches of the same occurred. Concerns have also been noted regarding the provisions of the Act dealing with costs as it is not clear how the Act contributes to the goal of universal health coverage. A raft of recommendations have been noted in the paper borrowing from best practices in various jurisdictions and from international bodies and these could inform amendments to the Act to guarantee achieving the triple goal of improving access, guaranteeing quality and lowering costs.