A CRITICAL OVERVIEW OF THE HEALTH ACT 2017

Maurice Oduor*

1. Introduction
The Constitution of Kenya quite seminally recognizes the right of every person to the highest attainable standard of health encapsulating the right to reproductive health and the right to healthcare services. Moreover, it also guarantees the right of everyone to emergency medical treatment. In themselves, these provisions are not very useful and need to be clarified especially considering the that very Constitution dictates that the provision of health is primarily the function of county governments, with the national government merely formulating policy and providing strategic direction. The job of detailing the exact content of the right to health, the specific obligations of each of the levels of government and the institutions required to implement the right has been done by the Health Act, a piece of legislation that was assented to on 21st June 2017 and expresses to have come into force on 7th July 2017. This paper offers a critical overview of the Act with a view to understanding its core features, what it seeks to achieve and whether indeed it does so. This is a preliminary overview considering that the Act is very new and has yet to be litigated in court where further clarification may indeed render a different meaning from what is represented here.

The Health Act came into being at a time when the country was facing serious challenges in the health sector. One of the key issues had to do with the content of the right to health and an understanding of the role of the state in actualizing that right. The other problem, a huge one, had to do with the definition of functions between the national and county levels of government particularly in relation to the human resource for health as exemplified by rather drawn out and messy strikes by doctors, nurses and clinical officers. In assessing the Act, critical questions revolve around the extent to which the Act effectively clarifies the various components of the right to health and whether such clarification is consistent with established norms on the right to health. Also, one must evaluate the manner in which the Act unbundles the functions of the different levels of government; areas where it creates exclusive jurisdiction and those where it anticipates collaborative approaches.

This preliminary review establishes that there are three types of problems that need to be resolved for the Act to be implemented effectively. One is that some of the obligations arising out of the rights regime under the Act are disproportionately burdensome to some duty bearers, potentially raising weighty constitutional issues. Second is that there may be a case of over-regulation due to the many locales of power potentially in conflict with one another, with the attendant confusion on practitioners and providers. Thirdly, there is a likelihood that the Act will upturn the regulatory balance that has hitherto existed because certain professional supervisory functions are to be exercised by new bodies even though the current regulatory bodies still exist. It is not envisaged that the latter bodies will cease to function thus creating a significant

* LLB | LLM | LLD Candidate | Convenor, Law Society of Kenya Medico-Legal Committee | Lecturer, Moi University School of Law | Advocate of the High Court of Kenya. Views expressed herein are personal and do not purport to represent any of the institutions mentioned here.
interpretative burden on not only courts, but also, and more significantly, on implementing authorities which make day to day decisions on health. Finally, the Act is currently in an incomplete state, a work in progress and requires a whole range of statutes, regulations, norms, standards and rules to be passed to give full effect to many of its provisions. As long as these do not exist, there are significant grey areas. Either way, their development will also call for a careful shepherding process to ensure that Kenyans benefit from the promise that the constitutional and statutory recognition of a right to health portends.

2. General structure
Part I is the preliminary and provides definitions of various terms and concepts found in the legislation. Section 3 sets out the objects of the Act while sections 4 and 5 delineate responsibilities and standards of health expected under the Act. Part II defines rights and duties subsumed under the concept of health as a right and the obligations of the various entities and persons involved as either claimant, provider or guarantor of the right. Part III defines public health facilities setting out the specific functions of the national and county governments in development and maintenance of public health facilities. Parts IV to VI establish the relevant institutional framework that will implement the law, identifying personnel that will make up the institutions while defining their roles. Part VII sets up a regulatory body to be in charge of health products and health technology. Part VIII anticipates what will need to be done to enhance public health and environment health. Part IX deals with mental health and Part X, traditional and alternative medicine. Part XI creates and elaborates rules on donating, harvesting and transfusion of blood, tissue and organs. Part XII makes very critical provisions for health financing, a thorny issue. Part XIII emphasizes private sector involvement and rolls out a framework of licensing and co-operation. Part XIV enacts the rules on research. Part XV introduces the concept of e-health in tandem with developments in medical technology. Part XVI rationalizes interdepartmental collaboration for implementation purposes. Finally Part XVII segues the Act into the existing legal framework by setting out the manner of transition between the new and the old.

3. On a substantive right to health
It seems that the Act has taken a broad view on the concept of the right to health. Peppered in its various sections are references to entitlements, freedoms, and access to goods, facilities and services that make up the system of health rights. The intention is to avail a wide range of health promoting and disease preventing services from both the public and private health sectors. Thus it is that section 5 reiterates the provisions of article 43(1)(a) of the Constitution but also goes further and adds that the right to health includes the right to access for provision of promotive, preventive, curative, palliative and rehabilitative services, and hence emphasizing the expansive nature of the right. Moreover, the section situates dignity, respect and privacy as core to the realization of the right to health. In addition, the law specifies that maternal and child health as part of the right to health and obliges the national and county governments to provide free and compulsory services in that regard. S 6 expounds on the right to reproductive health, which it states to include, the right to information about and, access to reproductive health services, including family planning services that are safe, effective and acceptable. This also includes safe motherhood for expectant mothers-which is a guarantee for safe pregnancy, childbirth and post-
partum period. Further, reproductive health is expressed to include “access to treatment by a trained health professional for conditions occurring during pregnancy.” Not only must such treatment be done by “a health professional with formal medical training” with a valid licence, but it must be in “a legally recognized health facility with an enabling environment consisting of minimum human resources, infrastructure, commodities and supplies...”\(^1\)

Section 7 of the Act elaborates the article 43 (2) edict that “a person shall not be denied emergency medical treatment”. In terms of Section 7 (1) “every person has the right to emergency medical treatment”, which includes pre-hospital care; stabilizing the health status of the individual or arranging for referral where the health provider of first call does not have facilities or capability to stabilize the health status of the individual.\(^2\) Failure to provide emergency medical treatment despite ability, if by an institution, amounts to a criminal offence.\(^3\) Further, all licensed healthcare providers i.e. doctors, nurses etc have a duty under Section 12(1) to provide the emergency medical treatment defined in section 7(2).

The Act has now legislated the doctrine of informed consent, hitherto only defined in common law, policy documents and ethical standards. Informed consent is at the core of healthcare and s.8 of the Act reiterates this by obligating a healthcare provider to inform a patient or, a prospective patient of their health status (unless where a therapeutic expectation applies), options available for treatment, risks of all of those options including, the costs and consequences and, also, their right to refuse any of the proposed regimes of treatment and implications of such refusal.\(^4\) It is only when such information has been availed and a patient so empowered can treatment be said to be consensual. No treatment should be rendered without the informed consent of the patient unless otherwise allowed under the exceptions in Section 9. The right to information goes beyond episodic interaction between provider and user. It also has wider policy implications on both levels of government so far as they are obligated under Section 11 to establish a system that ensures that “appropriate, adequate and comprehensive information is disseminated in the health functions for which they are responsible.” The constitutional right to information under article 35(1) is thus called into play. Citizens are therefore, entitled to know:

(a) The types, availability and cost if any of the health services  
(b) The organization of the health services  
(c) Operating schedules and timetables of visits.  
(d) Procedures for access to the health services.  
(e) Procedures for laying complaints and  
(f) The rights and duties of users and healthcare providers under this Act and as provided for in the applicable service charters;  
(g) and management of environmental risk factors to safeguard public health.

Both levels of government must therefore institute measures to disseminate this information to as wide a reach of people as possible. Under Section 11, information generated in the course of

\(^1\) S 6(2) and (3)  
\(^2\) S 7(2)  
\(^3\) S 7(3)  
\(^4\) S 8
treatment must be kept confidential unless lawfully released under the exceptions created in the Act and pursuant to relevant regulations passed by the Cabinet Secretary.

The Act, quite uniquely, also recognizes rights and obligations from the healthcare providers’ perspective. A healthcare provider is entitled: not to be discriminated against on any of the grounds recognized in the constitution; to a safe working environment with minimal risk of disease transmission and injury or damage; to refuse to treat a physically or verbally abusive patient or one who sexually harasses him/her except under emergency situations; and the right to seek and accept employment in both the public and private sector. The duties binding healthcare providers include the duty to do their best; the duty to provide emergency care; and the duty to inform a user of their health status; except where such information would be detrimental to the patient (under the therapeutic exception doctrine). S 13 sets out the duties of users of a healthcare service. Under s 14, the Act allows any person to file a complaint about the manner in which they were treated at a health facility. It is not said where these complaints would be filed but it is contemplated that the national and county governments will institute the necessary procedures to be used in both private and public healthcare facilities to deal with complaints arising in the areas they are responsible for. It seems that the procedures for the complaints are supplemental to those that exist under the various regulatory regimes for the different cadres of healthcare providers, and is perhaps in the nature of an ombudsman. However, sooner or later, the question as to who has jurisdiction to deal with such complaints and issue sanctions is one that will have to be confronted.

4. Delineating powers and functions in the context of devolution

The Constitution disperses sovereign powers and functions between two levels of government: national and county. While these two levels are distinct in the sense that each exists separately and has its own competencies, they are at the same time interdependent and must conduct their relations on the basis of consultation and cooperation. Counties enjoy some degree of autonomy and while the national government has some supervening role, this is very limited and exercisable rather sparingly. Counties enjoy the competence to establish offices and appoint officers. They can determine and structure their own administrative or public offices and, because the Constitution, while limiting the number of members that can make up the county executive committee, and does not dictate which specific offices must exist, Counties do enjoy some level of discretion in this regard. This raises the question whether legislation can compel

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5 S 12(1)
6 S 12(2)
7 These are the duty to: (a) to adhere to the rules of a health facility when receiving treatment or using the health services provided by the establishment; (b) to adhere to the medical advice and treatment provided by the establishment; (c) to supply the healthcare provider with accurate information pertaining to his or her health status; (d) to cooperate with the healthcare provider; (e) to treat healthcare providers and health workers with dignity and respect; (f) if so requested, to sign a discharge certificate or release of liability if he or she refuses to accept or implement recommended treatment.
8 Constitution Art 1(4),
9 Ibid Art 6(2)
10 Ibid Art 192
11 County Governments Act No 17 of 2012, s 5(f)
12 Ibid s 30(2)(d) County Governments Act
a county to create a specific executive committee docket as indeed the Health Act has done.\textsuperscript{13}

With regard to health, the \textit{Constitution} in its Schedule 4 disperses the health function between the national and county governments in the following manner: the former is responsible for “National referral health facilities” and the “health policy”, while the latter is responsible for:

- County health services, including, in particular-
  - (a) county health facilities and pharmacies;
  - (b) ambulance services;
  - (c) promotion of primary health care;
  - (d) licensing and control of undertakings that sell food to the public;
  - (e) veterinary services (excluding regulation of the profession);
  - (f) cemeteries, funeral parlours and crematoria; and
  - (g) refuse removal, refuse dumps and solid waste disposal.

Section 4 provides that it is the fundamental duty of the state observe, respect, promote and fulfill the right to the highest attainable standard of health including reproductive healthcare and emergency medical treatment by doing a number of things including:

(a) Developing policies, laws and other measures necessary to protect, promote, improve and maintain the health and well-being of every person.
(b) Ensuring the prioritization and adequate investment in research for health to promote technology and innovation in health care delivery.
(c) Ensuring the realization of the health related rights and interests of vulnerable groups within society; including women, older members of society, persons with disabilities, children, youth, members of minority or marginalized communities and members of particular ethnic, religious or cultural communities.
(d) Ensuring the provision of a health service package at all levels of the healthcare system which shall include services addressing prevention, curative palliative and rehabilitation, as well as physical and financial access to health care.
(e) Ensuring adequate investment in research for health to promote technology and innovation in the healthcare delivery.

The importance of these provisions is that they create a wide collaborative framework for policy formulation and implementation. Generally, the national government would be responsible for policy formulation and the development of guidelines save for national referral hospitals, which are in its exclusive docket. The Act elaborates more than 26 other functions in Section 15 (1) (a) to (z). The critical point here is that these functions are in the domain of policy or law making or administrative processes. Other functions call for the provision of technical support coordination, mobilization of resources, promotion of specific activities, facilitation and so on. Outside of these, the national government has the important function of harnessing resources to ensure uninterrupted access to quality health services countrywide. It also has the mandate to establish an emergency medical treatment fund to provide for unforeseen circumstances. Moreover, the national government is responsible for developing standards of training as well as maintaining the relevant training institutions. Also, in relation to personnel, the national government develops and ensures compliance with professional standards on registration and licensing of individuals in the health sector. Further, under Section 24, the national government

\textsuperscript{13} See \textit{Health Act}, s 19 with respect to establishment of the county executive department of health and a county director for health.
manages and is responsible for national referral facilities and institutions that rely on shared expertise, laboratories of a national nature and regulation of health products. ¹⁴

Section 20 of the Act elaborates the County health functions. The major thrust of county government functions is that they relate to implementation and delivery in accordance with the policy established by the national government; thus, counties implement the national health policy and standards laid down by the national government. They are required to: deliver services; facilitate registration of healthcare workers and facilities; develop staffing policies especially with regards to marginalized areas; procure health supplies; implement monitoring standards; developing supplementary sources of income; develop criteria for compensation of hospitals that have provided services but have not been paid because the patient was indigent; disseminating information to the public; reporting on activities, development and the state of finance within a particular county, implementing public participation in the government of health services among others. ¹⁵ While Act emphasizes the national government’s policy and strategy roles, there seems to be a great deal of interweaving of roles, perhaps within the context the intention to develop a “unified” health system. Thus it is possible to find that counties are responsible for a certain albeit limited degree of policy formulation, just like the national government may be liable for certain cross-cutting functions. While this arrangement may instigate a unified approach to solving problems, it at the same time makes it difficult to hold any of the governments liable because the buck can be passed around easily. For example, during the strike by doctors, there was confusion, perhaps deliberate when the Ministry of Health sought to shoulder blame on counties, not to mention that their representatives quite often spoke at cross-purposes. ¹⁶ Again, as was seen during the strikes, healthcare workers’ union were forced to negotiate with both the national and county governments out of extreme caution that failure to involve all of them might result in an agreement that was not enforceable. ¹⁷

5. Institutional framework
While the Act establishes a number of institutions to facilitate its implementation, and while an attempt has been made to respect the principle of devolution, there are many instances where conflicts may arise, usually to the detriment of the health sector.

5.1 The Kenya Health Sector Intergovernmental Consultative Forum
This body is established under s 26 of the Act, with the mandate to facilitate cooperation between the two levels of government in matters of health. In its pursuit of cooperation, it can determine

¹⁴ Health Act s 24(b) and (c)
¹⁵ Ibid, s 20(a)-(p)
criteria for consultations between the national and county governments, develop agreements for joint implementation of activities governance to health delivery and provide a platform for coordination and collaborations. The Forum is made up of the Director General (or a designated representative), and all County Directors of health (or their designated representatives).  

**5.2 The Kenya Health Human Resource Advisory Council**

This body, made up of persons representing a wide cross-section of interests in the healthcare arena is a potentially powerful one in the context of development of a human resource for health. Its members are: the principal secretary in charge of health or a designate; a person representing the council of governors (not being a governor); the Attorney General or a designate; the Director General for Health (who under s 16 is appointed by the Cabinet Secretary for Health) or a designate; a person representing the Public Service Commission; a person nominated by county directors of health; a person nominated by the county public service boards; and three persons representing public universities, private universities and mid-level institutions. The Council is to be headed by a chairperson appointed by the Cabinet Secretary and shall have a Chief Executive Officer who shall be its secretary.

The functions of the Council are a myriad but focused on human resource for health (HRH), albeit in the context of policy. Thus, the Council has the mandate of reviewing policy and establishing norms and standards for posting of interns to all government facilities in the country vertical and horizontal movement of staff across the facilities. The Council also sets up norms and standards on staff welfare and schemes of service clearly evidencing its responsibility on labour rights and human resource issues affecting health professionals. It is for this reason that the Council has the mandate to develop policies for management and rotation of the cadre of healthcare professions known as specialists and to maintain a master register for all health professionals in the counties. These functions make the Council the human resource policy organ for the health sector and it appears that its jurisdiction cuts across all levels of government. The importance attached to the Council is evident not only from its elaborate composition, but also from the powers donated to it by statute. It is headed by a Chairperson and also has a Chief Executive Officer, a registered a medical doctor, who runs the day to day operations of the Council. The Council has a budget of its own that is approved by the Cabinet Secretary and funded by Parliament, and by the Council (from funds it raises while performing its functions) and from donations or credits to it. To enable it perform its functions, the Council is expressed to be a body corporate with powers to sue and be sued; acquire, hold or dispose of property and to do all that which a body corporate might do lawfully.

**5.3 The Kenya Health Professions Oversight Authority**

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18 *Health Act* s 26-29  
19 Ibid s 30(1)  
20 Ibid s 30(1)(j)  
21 *Health Act* s 31  
22 Ibid s 32  
23 Ibid s 33  
24 Ibid s 32  
25 Ibid
This body, established under Part VI as a body corporate, is to be run by a board consisting of: a Chairperson who is a health professional appointed by the Cabinet Secretary; the Principal Secretary for health or a designated representative; the Director General for health or a designated representative; the Attorney General or a designated representative; two representatives nominated by the health regulatory bodies; two representatives nominated by the Council of Governors; two representatives nominated by registered health professional associations that are not regulated or registered by any regulatory bodies; one representative from the private sector appointed by the Cabinet Secretary; one representative from consumer rights bodies appointed by the Cabinet Secretary; and a Chief Executive Officer appointed by the Authority through a competitive process. The Chief Executive Officer shall be the secretary of the Authority. Many of the members of the Authority are also members of the Human Resources Advisory Council; the Principal Secretary; the Director General, Attorney General and the representatives of the Council of Governors.

Under the Act, the Authority has the mandate to maintain a duplicate register of all health professionals in the national and county health system. While this is contrasted with the Council’s role of maintaining a master register of all health practitioners in the counties, it is not clear how this list will be generated. It also promotes and regulates relationships between statutory regulatory bodies, co-ordinates joint inspections with all regulatory bodies; receives and facilities resolution of complaints from patients, aggrieved parties and regulatory bodies; play an oversight role over regulatory bodies and arbitrate disputes among them and among the various boards and councils; and ensure maintenance of standards for health professionals. The Authority can propose regulations for approval by the Cabinet Secretary for the carrying out of its functions. Such regulations may prescribe the procedures for coordination of joint inspections with all regulatory bodies; procedure for receipt and facilitation of complaints from patients or even regulatory bodies; monitoring the execution of the functions of the various regulatory bodies; procedures for arbitration and dispute resolution amongst regulatory bodies including conflicts among Boards and Authorities; procedures for ensuring standards are maintained. Equally, the Authority is granted elaborate powers to ensure it performs its functions effectively. The Public Service Commission recruits the Chief Executive Officer, who should by law be a health practitioner registered by the respective regulatory body and having at least ten (10) years experience in the practice of medicine. The Board is allowed to recruit such staff as may be necessary for the efficient performance of its functions.

6. Other salient provisions of the Act
   6.1 Regulation for health products and health technologies
The Act requires the establishment of a single regulatory body through an Act of Parliament to regulate health products and health technologies. The term “health product” is not defined.
but “health technology” is stated to refer to “the application organized knowledge and skills in the form of devices, medicine, vaccines, procedures and systems developed to solve a health problem and improve the quality of life”. This is fairly broad. Health products may be those outputs that are not directly used to treat or are not necessarily therapeutic; they could be nutritional. The relevant regulating body is given the function of licensing health products and health technologies; licensing manufacturers and distributors of health products; conducting laboratory testing and inspection of manufacturing, storage and distribution facilities of health products and technologies; control of clinical trials; conduct advertising and promotion, post marketing surveillance for quality, safety and disposal of health products and health technologies; regulating contractors for medical devices and physical security for product including radioactive material and biological products. Under Section 63(2), the Act extends this regulation to therapeutic feeds and nutritional products. Section 64 states that the legislation contemplated under Section 62 shall also provide for granting of marketing approval by a technically competent body after appropriate assessments. Section 66 establishes the criteria upon which a license would be granted by the single regulatory body. No “medicine, vaccine or other health product and technology intended for sale to members of the public shall be eligible for licensing” unless it meets the set criteria.

6.2 Promotion and advancement of public and environmental health

Public health and environmental concerns are also the crosscutting issues that fall in the mandate of the Act. A holistic national health system should devise and implement measures to promote health and to counter influence having an adverse effect on the health of the people such as communicable, non communicable and neglected diseases, alcohol and tobacco use and also abuse, safe foodstuffs etc. The Act requires interventions in these areas to be initiated by the national government. It also calls for a comprehensive program to advance reproductive health, focusing on family planning, unsafe sexual practices, female genital mutilation, maternal and neo-natal health and nutrition. Generally, the mandate of the relevant national department for health should aim at dealing with known public health and environmental concerns, displaying a deliberate good faith effort to respond to the set parameters as further indicated in Section 69 of the Act.

6.3 Mental health

The Act calls for legislation to be passed with the express purpose of; protecting rights of persons suffering from mental disorders or condition; ensuring the custody of such persons and management of their estates where necessary; establishment, management and control of mental hospitals and their distribution evenly at national and county levels; implementation of other measures introduced by specific legislation in the field of mental health; and ensuring research is conducted to identify factors associated with mental health.

33 Ibid s 2
34 Ibid s 63
35 Ibid s 66
36 Ibid Part VIII
37 Ibid s 68(1)
38 Ibid s 68(1)(c)
39 Ibid Part IX
6.4 Traditional and alternative medicine
The Act incorporates unconventional medicine as part of the available health alternatives, perhaps a nod the reality that people do seek other methods of treatment despite existence of contemporary medicine. However, the Act requires that policies be formulated by the national government department of health to guide the practice of traditional and alternative medicine. Such policies are to be implemented by the county executive department for health. Moreover, the Act requires that legislation be passed to establish a body to regulate this practice whose mandate would be to register, license and enforce standards for practitioners in this field. Also, the body should set the minimum criteria of practice. While integration of traditional and alternative medicine into conventional medicine practice is the contemplated outcome, it is obvious that the former is deemed somewhat inferior. For example, the national government is required to develop policy guidelines for referral from traditional practitioners to conventional hospitals. However, no reverse referral is contemplated.

6.5 Human organs, Human blood, blood products, other tissues and gametes
Harvesting of tissue or gametes for purposes of transplantation can only occur under the circumstances specified in Section 80. It has to be done in a facility authorized for that purpose, and there must be written authority of a medical practitioner in charge of clinical services or by with the consent of the donor. The Act empowers the Cabinet Secretary to develop regulations prescribing criteria for approval of organ transplants and procedures thereof. The Act further provides for the harvesting of organs for research or teaching purposes or for post-mortem pathology. It also sets up an institutional framework to govern donation of blood for transfusion purposes; which is to be regulated by an Act of Parliament which shall establish a body to be known as the Kenya National Blood Transfusion Service.

6.6 Health financing
Financing of health is critical for the success of the regime under the Act. Section 86 contemplates that the national government shall ensure progressive financial access to universal healthcare through the development of an insurance scheme for health. The national government should develop policies and strategies for ensuring the realization of universal health coverage, develop a framework for public financing of healthcare including financing healthcare providers who respond to emergencies. It should also monitor pricing of pharmaceutical and non-pharmaceutical products and develop a standard health package to be financed through prepayment mechanisms. The ministry should also develop a framework for collaboration among all the relevant ministries and departments as well as private healthcare providers.

6.7 Private sector participation
In recognition of the deficiencies in the public health system, the Act requires that the input of private practitioners be deliberately harnessed and conditions created to enable them contribute

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40 Ibid Part X
41 Ibid Part XI
42 Ibid s 86(1)
43 Ibid s 86(2)
to lessening the burden on public resources. Thus, the Cabinet Secretary is to pursue strategies that actualize this goal by incentivizing development and regulations of private health services in a manner that makes them responsive to the needs of the population. Private and public facilities are required to play complementary roles. While the law demands that every healthcare practitioner and facility provide emergency treatment even in the absence of payment, the Act contemplates that measures will be implemented to create a system of compensation.

6.8 Research for health

The Act empowers the Cabinet Secretary to establish a technical committee known as the National Health Research Committee. Not more than eleven members can be appointed to this committee and who shall constitute: a chairperson (who should be a distinguished health researcher and renowned in a health discipline); a representative from Kenya Medical Research Institute; head of the research directorate in the Ministry of health; a representative from the National Commission for Science and Innovation; a representative from the Authority; two representatives from public university and one from private universities; a research expert on traditional and alternative medicine; a research expert in clinical trials and a bio-medical researcher. The Committee has a myriad of functions related to the development of research in health such as making recommendations on national health research policy and identifying priority areas for health research while taking a number of factors into account as specified in Section 96 (2). The Committee works together with the Kenya Medical Research Institute, which in itself is directed to attune its research mandate to accord with the health interest of the population and the overall programme of health research. The Committee is mandated to approve various forms of health research on humans including minors on the basis of standards it shall set. The Act highlights the importance of scientific and policy research in the field of health and as such requires that not less than 30% of the National Research Fund be allocated for health research. Moreover the committee is required to reach out and cooperate with other bodies involved in research for health such as universities, non-governmental and informational organizations as well as the Kenya Medical Research Institute. This is important since the committee itself does not conduct research and must be seen to be playing only a facilitative role.

6.9 e-Health

The Act calls for the recognition and incorporation of e-Health as a mode of health delivery. It defines e-health as the combined use of electronic communication and information technology

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44 Ibid; also s 88-92
45 Ibid s 88(1)
46 Ibid s 91(1)(b) as read with s 15(1)(x) and s 20(1)
47 Ibid s 93
48 Ibid s 94 (wrongly numbered as s 94(1))
49 Ibid s 97
50 Ibid s 100
51 Ibid s 101
52 Ibid 2 102
53 Ibid s 104
in the health sector including telemedicine.\textsuperscript{54} Telemedicine is in turn said to refer to “the provision of healthcare services and sharing medical knowledge over distance using telecommunications and it includes consultative diagnostic and treatment services.”\textsuperscript{55} There can be no doubt that technological development in health is fast paced and is assuming an ever-increasing significance in the delivery of health services. It is important that any legal regime on health recognizes this fact and creates a mechanism for enhancing the system to interact in useful ways with new technological developments and also provides some certainty in its regulation. The Act requires that the Cabinet Secretary to ensure that relevant legislation is passed within 3 years to elaborate on e-health. Such legislation must provide for, among others: administration of health information banks, including inter-operability, framework, data interchange and security; collection and use of personal health information; management of disclosure of personal information; protection of privacy; business continuity, emergency and disaster preparedness; health service delivery through M-health, E-learning and telemedicine; E-waste disposal; and health tourism.\textsuperscript{56} The contemplated legislation will be highly significant and must anticipate all these areas. E-Health raises serious questions on fundamental rights related to personal autonomy, use of private data, disclosure of personal information among others, which must be structured to comply with the Constitution. These are factors that must be reflected upon even as the Ministry discharges its mandate of facilitating the establishment and maintenance of a comprehensive integrated health information system and as the Cabinet Secretary prescribes policy guidelines in terms of Section 105 of the Act.

7. **Salient issues on the Health Act**

7.1 Devolution

7.1.1 Human resource for health

Under the\textsuperscript{57} Constitution, the national government is responsible for developing national health policy and managing national referral hospitals. One of the biggest challenges facing health care currently has been the unclear manner in which the health function was devolved. It has been said time and again that counties were never really prepared to handle the health function and that it is one of those areas that should have devolved gradually.\textsuperscript{57} Health was one if the functions that were devolved soon after the General Election under the current Constitution. This transfer of functions to the counties was marred with confusion particularly in terms of the management of the existing human resource. It was soon realized that county governments lacked capacity to manage the health sector effectively partly because they were ill-prepared and ill-equipped and also lacked the resources to absorb these very new responsibilities. While efforts to craft the relevant implementing legislation started reasonably early, as early as the year 2011, there were considerable delays in clarifying how the health function was to be carried out. On the face of it, the Health Act is premised on the ideals of devolution there being a very deliberate effort to foster collaboration operation and consultation between the two levels of

\textsuperscript{54} Ibid s 2

\textsuperscript{55} Ibid

\textsuperscript{56} Ibid s 104

\textsuperscript{57} Presentation by Mohammed Kuti, Chairperson of the Health Committee, Council of Governors during the Kenya Healthcare Federation Multi-stakeholders Meeting 26\textsuperscript{th} January 2018, Hotel Radisson Blue
government and among the various bodies and institutions involved in the provision of health. That is why in the preamble a unified health system is stated to be an objective of the Act. Moreover, there is the declared purpose of coordinating the inter-relationship between the national government and the county government. Further, section 3 depicts the national health system as encompassing “public and private institutions and providers of health services at the national and county levels.” Delivery of health is seen as a structured singular object that is to be pursued through concerted efforts where national government institutions develop policies, and county level institutions implement them. So, in terms of obligations it may be difficult to rationalize a clean division of functions seeing as each level’s role depends on the others. In fact, on a strict interpretation, the national government has a very prominent role even if couched in policy formulation terms. It is hardly conceivable that the national government will hazard delayed implementation of set policies by county governments. But the counties themselves may not be too comfortable if it appears that the national government is encroaching on their turf. Any grey areas will merely sharpen conflicts between the two levels of government. Devolution conflicts are not new in the health sector. Not too long ago, the national government conjured a programme for leasing equipment to the counties. Very few counties signed off on the project with most of them ascribing to the position advanced by the Council of Governors that the national government had no business in health and could not coerce them into getting into those agreements.

Beyond possible jurisdictional conflicts, the risk of self-serving institutional lethargy is quite high, especially where politically unpalatable or economically burdensome decisions have to be made, like enhanced remuneration of health care workers. As was seen during the protracted industrial action by doctors, legal lacuna may be used to defer or avoid, undesirable but critical outcomes. During the strike, the national government claimed it had no authority to negotiate with doctors because health was a devolved function. Now that the national government has taken on such a prominent role county authorities may feel elbowed out and hence unable to commit to certain positions. For example, the lack of a common position during the health care workers’ strikes may have unduly prolonged the dispute. The legal framework therefore needed to have established the responsibilities of all the relevant institutions with certainty. Instead, what we have is a dispersal of functions in a manner that mixes up both policy formulation and implementation, particularly with reference to the national government. Take the Director General for Health, a national government official, who is said to be responsible for internship programme for health workers.\(^\text{58}\) This means that every matter relating to interns including placement and welfare is squarely a national function, to be done in accordance with norms and standards set by the Council. At this level, trainee health workers are under the national government but as soon as their training is complete, the national government washes its hands off them. While it is assumed that counties should naturally take them up on employment, that does not happen because counties are citing budgetary constraints.

Perhaps the frustration stems from the obfuscation of the law in terms of the institution or level of government that has the power to engage the health human resource. While it may be deduced that the human resource function in the health sector is a devolved function, practice

\(^{58}\) S 17 Health Act
Draft-subject to review

does not reveal it to be an easily resolvable question, which is an issue that stood out during the negotiations following the doctors’ strike. The Council sets norms and standards and leaves it at that. The Authority on the other hand focusses on professionalism of practitioners. Nowhere is it mentioned in the Act that Counties specifically should be the ones to deal with the health human resource. Even though on a strict interpretation, functions not assigned to any of the levels of government are by implication reserved for the national government, it may also be argued that since the national government sets policy in health, county governments should take the cue and busy themselves with implementation. It is also possible that this function can only be effectively carried out jointly particularly at this nascent stage of devolution where counties largely rely on resources and support from the national government. However, if counties are to develop best practices on health human resources, then certainty in the law becomes mandatory and it may well be that the Act is up for amendment with this issue in mind. It must be specified that while the national government will train, county governments will employ and, the arrangement may well be one where counties take up health human resource deployed to them from a central point depending, of course, on a calculation as to what their needs are; the truth being that as population rises, the need for doctors, nurses, clinical officers, surgeons and what-have-you will never be satisfied.

7.1.2 Devolved conflicts
S 19(1) purports to establish a county executive department for health with respect to every county. Moreover, in subs (2), the section sets up the office of the County Director for health as a technical advisor on all matters relating to health in the county, an advisor to the County Health Executive Committee member and the Governor as well. This office appears to be the link between the two levels of government. However, both the department, and the office are embedded within the County structures and most certainly within the executive. The question is whether there is a constitutional fit for the department and the office within the county executive system. It must be recalled that even though both levels of government are interdependent and are required to carry out their business in cooperation with one another, and even through the national government may make certain supervening decisions in relation to counties, county governments are not thereby rendered beholden to the powers of the national government and in fact do enjoy some level of autonomy. One of this is in the area of creation of departments and offices in their public service structures as contemplated under art 235 of the Constitution. For all intents, it would seem that in terms of creation of dockets, county governments have the say. This is likely to impugn the constitutionality of the county executive department for health created under the Act. On methodology, the department and directorate also seem to be a hard fit. All counties have an executive committee member in charge of health, complete with directors and officers, all answerable as a unit to the Governor and to the County Assembly. To whom is the department and directorate established under s 19 answerable to for accountability purposes? What is the hierarchical relationship between the department and the directorate on the one hand, and the county executive committee member for health on the other? What different things would the s 19 outfit do from what the CEC for health does? Is it possible that this is merely another layer of bureaucracy, likely to multiply inefficiencies rather than smoothen operations? What kind of practical relationship should the executive department and county director have with the county executive member in charge of health? The ambiguity
of the place of the s 19 department within then county health administrative structure is likely to brew unnecessary conflict.

7.2 Professional (over)regulation

The Act defines a health professional as any person who has obtained health professional qualification and is licensed by the relevant regulatory body as a health professional. Doctors, nurses, dentists, health extension workers, clinical officers, psychiatrists, etc. are all healthcare professionals. These officials must be regulated if high professional standards are to be maintained. Such regulation is expressed to be undertaken by national government institutions, more particularly, the Kenya Health Professions Oversight Authority, which is required to work with other regulatory bodies established under different laws. The Authority has an overarching role cutting all the regulatory bodies. It has power to monitor how these other bodies execute their mandate and intervene in disputes arising amongst them. In a rather confusing manner, the Authority has been granted the power to “receive and facilitate resolution of complaints from patients, aggrieved parties and regulatory bodies.” The question that arises is whether the Authority has superior complaint handling powers beyond those held by say the Nursing Council, the Medical Practitioners and Dentists Board, the Pharmacy and Poisons Board among others. This is all more complicated by the provision of section 60 (1) of the Act which states that: “The obligation to inspect, monitor and evaluate the standard of performance in all the services regulated and professionals engaged in the health sector both public and private shall be undertaken by the respective regulatory bodies provided they are not in conflict with the functions of the Authority as stipulated in this Act under any other written law.” Thus, the power of existing regulatory bodies is not readily discernible from a reading of their parent legislation. Some elimination exercise must be done to determine where conflicts exist and what residual functions are left for the old bodies.

Section 60 (2) then goes ahead to list the specific bodies alluded to in section 60 (1). It means that the regulatory functions of these bodies whether aimed at institutions or individual professionals have been saved and exist side-by-side with similar powers exercisable by the Authority. Indeed when it comes to dealing with complaints from patients, the Cabinet Secretary is expected to develop rules of procedure that will enable the Authority receive and facilitate the resolution of complaints from patients, aggrieved parties and regulatory bodies. So, does the Authority have concurrent jurisdiction with those other regulatory bodies, or are its powers superior? A reading of the Act in tandem with the laws establishing the various health regulatory bodies does not give a clear picture and would seem to show some degree of contradiction. It must be remembered also that s 14 of the Act obligates the national and county governments to establish the “procedure for laying of complaints within public and private health care facilities...” While it seems that these procedures are internal to each institution, and while the Authority has overriding power in terms of how the complaint is handled, it is not apparent whether there is a link between this mechanism, and the one to be undertaken by the Authority under s 48(d), and also the processes tenable within the relevant regulatory bodies, such as MPDB, the Nursing Council, the Pharmacy and Poisons Board, etc. This abiding ambiguity can also be seen in section 61 which states that: “Any health professionals seeking to form a professional regulatory must

59 S 2 Health Act
adhere to the criteria prescribed by the Cabinet Secretary in consultation with the Authority.” This seems to suggest that the Cabinet Secretary has the power to approve the formation of a professional regulatory body in the same league as MPDB, or PPB merely through regulatory fiat. This flies in the face of the hitherto existing practice where all such bodies have been established by an Act of Parliament.

Further regulatory obfuscation is likely result from the combined effect of s 17(i) which shoulders the Director General for health with the responsibility to “provide guidelines for registration, licensing, certification and gazettement of all health facilities”, and s 19(5)(e) which gives power to the County Director of Health to “supervise all health facilities within the County.” Added to this is the elaboration in s 20(d) that one of the purposes of a county government is to “facilitate” registration, licensing and accreditation of providers and health facilities. The arrangement here seems to be that once the Director General sets the standards, then it is the counties that should enforce them. The vertical synergies must be very strong for this formula to work. Significantly though, it must be recalled that there are existing professional regulatory bodies whose mandate has not been vitiated by the Act. How should they fit into this scheme? Worse, how should providers and professionals organize themselves in this context? Would a doctor for example be subject to the jurisdiction of the County Director, or should he/she submit to the MPDB in matters of registration, and even regulation? That doctor’s lot is not made any better when he/she considers that, one of the functions of the Council under s 31(f), is maintain a master register for “all health practitioners in the counties”, and that the Authority has a similar function of maintaining “a duplicate register of all health professionals working within the national and county health system.”

The Act requires that a single regulatory body be set up via legislation to regulate health products and health technologies. While the term “health product” has not been defined, “health technology” is said to refer to “the application of organized knowledge and skills in the form of devices, medicine, vaccine, procedures and systems developed to solve a health problem and improve the quality of life.” The regime of law set to be created under part IV of the Act is in certain respects parallel with that under the Pharmacy and Poisons Act. For example, the products and technologies that should be licensed and regulated in terms of that part of the Act appear like the products and technologies that would fall under the jurisdiction of the regulatory body in the Pharmacy and Poisons Act, the Pharmacy and Poisons Board. This can be discerned from the subject matter definitions under the Pharmacy and Poisons Act. For example, “drug” is defined to include any medicine, medicinal preparation or therapeutic substance.” The term

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60 S 48(a)
61 S 2
“manufacture” is defined to mean “any process carried out in the course of making a product or medicinal substance and includes, packaging, branding, mixing, assembling, distillation, processing, changing of form or application of any chemical or physical process in the preparation of a medicinal substance or product but does not include dissolving or dispensing the product by diluting or mixing it with some other substances used as a vehicle for administration.” “Medicinal substance” is defined to mean any medicine, product article, or substance which is claimed to be useful for any of the following purposes:

(a) Treating, preventing or alleviating disease or symptoms of disease
(b) Diagnosing disease or ascertaining the existence degree or extent of a physiological condition or
(c) Preventing or interfering with normal operation of a physiological function whether permanently or temporarily and whether by way of terminating, reducing, postponing or increasing or accelerating the operation of the function in human beings or animals.” Further the term medicine is defined to mean “any medicament or curative or preventive substance, whether proprietary or in the form of a preparation.”

These definitions clearly encapsulate the kind of matters that the Health Act that will fall under the single regulatory body potentially rendering naught the functions of the Pharmacy and Poisons Board under s 3 of the Pharmacy and Poisons Act. The logic seems to be that an all-encompassing body will be created to not only license health products and technologies, but to also conduct laboratory tests, control clinical trials, conduct advertising and promotion and regulate contractors for medical devices. Again, this is potentially broad and the anticipated legislation must clarify whether the existing mechanisms will continue to function or will be repealed or modified to fit into this new regime.

7.4 Public health system

The Act requires that the national health system shall devise and implement measures to promote and to counter influences having an adverse effect on the health of the people. Many of the interventions listed are public health matters, perhaps within the proper preview of the Public Health Act, which, curiously, is neither repealed nor amended by the Health Act. It must be that the latter seeks to clarify and consolidate the law on public health. However, the public health functions suggested under the Health Act are currently mostly undertaken by the county governments. Indeed a number of county assemblies have passed or are considering passing public health and sanitation bills, the provisions of which reflect what is in the Health Act. The inclusion of reproductive health under the broad concept of advancing public and environmental health is curious, and perhaps incongruous. Matters to do with family planning, unsafe sexual practices, maternal health, genital mutilation and so on, admittedly evoke serious public health concerns. However, they involve individual rights as well and a national health system dealing with them should also take a distinctly human rights based approach. Moreover, the national health system in dealing with reproductive health rights must take into account already existing or contemplated instruments and policies on the issue. The attempt being made is to provide a statutory basis for some of the policy frameworks on reproductive health rights. It seems therefore that a lot of work will need to be done to provide coherence in the context of the Health Act and perhaps further clarification in terms of the duties of the national and county governments.

62 See Part III Health Act 2017
7.5 Mental health

The Act calls for legislation to among other things protect the rights of individuals suffering from mental disorders. This is a marked departure from what is manifested in the existing legal regime, which ignores human rights dimensions of mental health. Perhaps this is an opportunity to steer the proposed legal development in tandem with current norms and standards in the area of mental health. The legal approach to mental health is now focused on enhancing individual capacities of persons deemed to have mental health issues rather a patronizing model that sees such people as objects to be managed and incapable of making their decisions. This in agreement with many human rights treaties that deal with mental health issues, including the UN Convention on the Rights of Persons with Disabilities (CRPD). The legislation anticipated under this provision must also take account of international best practices and current norms and standards in the area of mental health.

7.6 Traditional and alternative medicine

Regulation here is proposed to be by way of policies formulated by the national government but implemented by counties. Moreover, an Act of Parliament is to be passed to establish a regulatory body to regulate the practice of traditional and alternative medicine. Currently no law determines issues of regulation or registration and officially, traditional medicine and alternative treatment do not form part of the health system of Kenya. Many Kenyans resort to them as an alternative or even in addition to conventional medicine. In some regions where health services are non-existent, traditional forms of medicine may be the only available source of treatment. The trouble is fake medicine men that misrepresent the skills they have or who engage in mystic and magical practices. A recent study has established that over 70% of all traditional herbal preparations is contaminated. This makes it urgent that the contemplated statute, together with regulations and standards be promulgated as soon as possible.

7.7 Organ, blood and gamete donation and transfusion

This area of law is governed with other previously existing laws, which have not been repealed. Section 80 sets rules for harvesting of organs or gametes. It also calls upon the Cabinet Secretary to prescribe regulations establishing criteria for approval of organs transplant facilities and a procedure to be applied for such approval. It further creates offences section 81 sets criteria for donation of organs through wills. Section 82 regulates donations for pathology purposes. Finally, the Act requires that an Act of Parliament be passed establishing an entity known as the Kenya National Blood Transfusion Service to provide for the institutional organizational of blood transfusion service in the country. The Human Tissue Act, a 1977 legislation that governs the same matters as Part XI of the Health Act is not explicitly repealed, perhaps the assumption being that a court faced with an issue relating to both would exploit rules of interpretation to determine

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63 The Convention on the Rights of Persons with Disabilities and its Optional Protocol (A/RES/61/106) was adopted on 13 December 2006 at the United Nations Headquarters in New York, and was opened for signature on 30 March 2007

64 Health Act, Part X

65 Arthur Okwemba, “Kenyan herbal drugs 'highly' contaminated”, Daily Nation, 7th February 2010

the applicable statute. For an administrator, or a practitioner, that may not be an easy distinction to make.

7.8 Private sector participation
The Act seeks to encourage active participation by the private sector by creating what would be an environment conducive for private capital investment in healthcare.\(^{66}\) Private providers are supposed to complement the government in view of serious resource constraints in the public health system.\(^{67}\) The Act employs a carrot and stick approach to dealing with private providers. Whereas the government commits itself to facilitating private providers through licensing procedures, it also expects licensed entities to perform certain duties. Section 91(1)(b) binds private institutions to provide emergency services in their area of expertise “required or requested either by individuals, population groups or institutions without regard for the prospect or otherwise of direct financial reimbursement.” This is a hard sell on private practitioners who, generally, set up with a view to making profits, or at any rate, not to make losses. It amounts to calling on private providers to use their own resources to perform what essentially is a public duty. Without an appropriate mechanism for reimbursement, it is tantamount to an illegal exercise of “taking” powers of the government without provision for proper compensation. Indeed the Act in certain places supposes that some form of compensation will be made available to such institutions. Section 91(2) says that private institutions and healthcare workers would be entitled to compensation “under similar terms as contemplated under this Act.” It is not clear what compensation this subsection is in reference to. However, out of the obligations of the county government under the Act, there is the responsibility to make “due provision and develop criteria to compensate healthcare facilities for debts arising through failure to secure payment of treatment by indigent users.”\(^{68}\) Thus it may be that county governments have the duty to establish compensation mechanisms under the Act. This must be read together with the national governments duty to “establish an emergency medical treatment fund for emergencies to provide for unforeseen situations calling for supplementary finance.” This can be read to mean that the national government working in tandems with the counties must develop mechanisms that cushion private institutions and healthcare workers against losses they may incur while meeting the rather onerous duty of providing emergency treatment to persons unable to pay.

While there is ground for expecting the health system to protect the interests of private providers, the law is not very clear in terms of the exact obligations mounted on both levels of government. Unlike other jurisdictions such as the United States, the legal regime on health fails the robustness test on the issue of compensating private providers who are called upon to administer emergency services. The United States’ *Emergency Treatment and Labor Act* has created an elaborate system that while obligating private providers to respond to emergencies, allows them to claim compensation on account of resources spent. EMTALA was Congress’s response to the increased cases of uninsured patients being turned away from mostly private hospitals, which considered them to be a financial risk in view of the high cost of medical services in the United States. While requiring the relevant hospitals to render necessary help, EMTALA

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\(^{66}\) *Health Act* Part XIII

\(^{67}\) Ibid s 88(2)

\(^{68}\) See *Health Act*, s 20(l)
created a system of compensation to cushion businesses against the risk of financial losses likely to be incurred. Such hospitals have been allowed to claim against the funds established under the Act. In Kenya, the law creates an obligation but does not establish a financial cushion to private healthcare providers and institutions. Obviously, this will discourage any institutions from going out of their way to provide emergency treatment, notwithstanding the risk of criminal prosecution under the Health Act. Rules need to be developed under the Act to establish a fund from which providers can claim compensation when they render emergency care that ends up not being paid for.

7.9 Health research
The Cabinet Secretary is required to establish a National Health Research Committee as a technical committee in charge of making recommendations “on the national research for health policy and on various priorities to be accorded in the area of research for health.” The Committee has a fairly wide mandate under the law, perhaps overlapping with that of already existing research bodies. For harmonization purposes, well established institutions such as KEMRI established under the Science Technology and Innovation Act (referred to in the Health Act as the Science and Technology Act) would have to “review its programmes to optimally attune to the health interests of the population and the overall programme of health research.” It seems therefore that the Committee will be a body above KEMRI; an institution with established structures, systems and programmes which has been in the forefront of medical research in Kenya for decades. It is not entirely clear why the Health Act could not simply create a synergy with KEMRI rather than setting a completely new body that will have to be equipped to perform its roles properly. The risk here is that the new body may want to take up the roles of KEMRI with attendant tensions and fallouts that arise whenever two or more entities exercise concurrent jurisdiction. Perhaps there is an opportunity to clear this up by the legislation that the Act requires Parliament to pass to give full effect to the provisions therein.

8. Conclusion
The Health Act is a “mother legislation” that seeks to implement the health rights guaranteed by the Constitution. It also seeks to clarify the devolution matrix in the context of health. These are objectives that must be achieved if the right is to make any sense. The problem is that many of the counties were not prepared to take up health as one of their functions at the time that it was handed over to them. The devolution should have both been programmatic and programmatic. Counties were given more than they could handle and hence the mess that continues to dog health. The Health should have been the legislation to clarify all these issues. The approach it has taken is to give prominence to the national government, perhaps in a belated acknowledgment that perhaps devolution of health was done in a haphazard manner and the authorities should have been deliberate and circumspect in handing health over to the counties. What the Health Act does is that while it pays homage to the devolution structure under the Constitution, in the end, this appears tokenistic because it has consolidated significant powers and functions in the national government even though these have been stated to be in the realm of policy. The risk is that confusion is likely to result in terms of who takes certain decisions remembering that counties have been clothed with a certain level of autonomy. These differences must be resolved if the Act is to make sense at all. The regulation of professionals is
also not as clear-cut as it should and it is quite possible that multifarious regulatory regimes will bear upon healthcare providers at the same time. Different national institutions may claim similar jurisdiction, in the same way that there may be contested vertical and horizontal jurisdiction, creating an atmosphere of uncertainty. Finally, the Health Act is a skeletal piece of legislation that needs host of rules, regulations, norms, standards and additional legislation to flesh out. Serious work on these, and any necessary amendments and clarifications must be start now if the goal of attaining the right to the highest attainable standard of health is to be a reality soon.