MATRIX ON THE HEALTH BILL 2015, RECOMMENDATIONS BY CIVIL SOCIETY ORGANISATIONS WORKING ON VARIOUS ASPECTS OF THE RIGHT TO HEALTH

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Clause	**Marginal Note**	**Rationale for amendment**	**Proposed amendment**
	Preamble	We recommend this preamble as it is more concise	An act of parliament to give effect to the right to health as provided for in the Constitution and provide for the regulations of the health sector and for connected purposes
PART 1: PRELIMINARY PROVISIONS			
2	Interpretation section	We recommend that internationally accepted definitions be utilized in the drafting of the bill. These include definitions on emergency medical treatment and informed consent.	emergency treatment" means medical treatment other immediate intervention requiring immediate care and treatment before any other definitive medical and surgical management can be procured

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			Informed Consent 'means voluntary consent obtained freely, without threats or improper inducement, after appropriate disclosure to the patient of adequate and understandable information in a form and language understood by the patient' "Abortion is the premature expulsion of the products of conception from the uterus before the foetus is viable. Abortion can be spontaneous or induced".
3 (b)	Objects of the Act	Include **palliative care** as part of the protections that the state must fulfil progressively.	protect, respect, promote and fulfil 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, **Palliative care,** and the right to emergency medical treatment
4 (c)	Protection of vulnerable groups in the health sector.	We recommend that clause 4(c) include the protection of the rights for people with rare diseases, orphan diseases, and neglected diseases. We also recommend that the clause include Key and affected populations as part of the interest groups. This section is critical to capture these groups that would ordinarily be left behind in provision of health services.	(1) The national and County governments shall put in place laws, policies and programmes, including special programmes, to ensure equal access to health services by vulnerable and marginalized populations including women, children, adolescents, youth, persons living with disability, mental health patients, Key and Affected populations and the elderly among others. (2) The measures referred to under subsection (1) shall include- (a) the protection of rights of such individuals including the rights to participate in decisions affecting them, the right to confidentiality, subject to applicable laws and the right to access to information among others; (b) the right to access information in formats that take into account the different kinds of disability; (c) the right to medical treatment or therapy.
New Clause		In June 2013, the president issued a Directive regarding free maternity services to all women. This Directive has been poorly implemented with many cases of maternity detention happening as	The national and county governments shall ensure free – (a) access to vaccination for all children ; (b) **maternity care for all pregnant women;** and

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		evidenced in the judgment in Petition 562 of 2012. There is need to enshrine the Directive into a legislative statute.	(c) treatment to all children under five years. (d) Treatment for the elderly(aged 70 and above)
PART II: HEALTH RIGHTS AND DUTIES			
6	Reproductive health	Clause 6 (1) (c) and (2) seem to focus purely on abortion regulation yet the marginal note is titled 'reproductive health'. Reproductive health encompasses much more than abortion regulation and extends to contraceptives, emergency obstetric care, and maternity services among others. We therefore propose that the whole clause is deleted and replaced with the recommended clause.	Every person has a right to reproductive health care which includes a) right to access reproductive health services b) the right to maternal, new born and child health services including pre and post natal treatment and emergency obstetric care. c) the right to services for the prevention and treatment of STIs d) the right to be informed of the full range of modern family planning methods and their effects on the body. e) The right to make an informed choice regarding the reproductive health services to be provided
6	Reproductive Health	In the alternative to the above proposal, Clause 6(1) (b) Right to appropriate health care services that will enable **parents to go through pregnancy safely**. This should be replaced with 'women' as they are the ones who go through pregnancy. An inclusion of parents suggests both spouses and excludes single mothers who rightfully also go through pregnancy. Clause 6(1)(c) delete the phrase 'All such cases shall be regarded as comprising notifiable conditions' The inclusion of pregnancy related conditions as notifiable conditions like would be with Cholera or Ebola, when the pregnancy complications defined in this section are neither transmissible nor communicable would stigmatize reproductive health related medical services and thus could deter patients from seeking services and providers from providing them. We further recommend **deletion of the requirement that medical providers must have a valid licence to perform safe abortion**. This section erroneously implies that health care providers need to	Clause 6(1)(b) replace the word 'parents' with 'women' Clause 6(1)(c) delete the phrase 'All **such cases shall be regarded as comprising notifiable conditions'**

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		receive special licensing to provide abortion care. Abortion care is a medical procedure and providers can be trained as part of their overall training. To require a special license for this service is discriminatory as it is not required of other medical procedures.	
7	Emergency treatment	We recommend that the bill include a provision for enabling legislation on emergency medical care.	The Cabinet Secretary, in consultation with county governments and relevant stakeholders, shall make regulations on emergency medical treatment.
New Clause		If the version of Section 7 proposed above is not adopted, this an alternative clause that would allow the Cabinet Secretary to make all rules and regulations.	The Cabinet Secretary, in consultation with county governments and relevant stakeholders, shall, from time to time, make rules and regulations on health related matters.
8	Health information	We recommend that the Bill adopts wording that addresses the kind of health information that must be publicised and made available to the public by both national and county facilities. This is missing in the draft. The clause will help in actualizing Article 35 of the Constitution which is critical in provision of Health services.	The information to be publicised and made accessible to the public shall include- (a) the types, availability and cost of any health service; (b) the structure for the delivery of health services; (c) normal working schedules and timetables of visits of patients; (d) procedures for access and use to the health services; (e) procedures for providing feedback on quality of services; (f) the rights and duties of users and health care providers; (g) the management of environmental risk factors to safeguard public health; (h) health profiles by diseases per county; (i) disease outbreak (j) the cost of drugs and commodities by the health providers; (k) national and county health sector plans and budgets; (l) information on sources of funding of the health sector; and

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			(m) procedures for lodging complaints.
9	Consent	We recommend that emphasis is placed on having clearer clauses on consent by children and mature minors. Reference can be made to Section 14 of the HIV & AIDS Prevention and Control Act 2006 that allows minors/ children to consent in special circumstances. The HIV Prevention and Control Act gives circumstances when children can consent to HIV testing by indicating that 'Provided that any child who is pregnant, married, a parent or is engaged in behaviour which puts him or her at risk of contracting HIV may, in writing, directly consent to an HIV test.	Insert a clause that recognises the evolving capacity of mature minors to consent to their own treatment. 'The state shall take into consideration the legal ability of minors to consent to a range of health care services including reproductive health care based on the evolving capacity of the minor'. 'Medical care necessary and likely to prevent imminent and significant harm to a child patient with an emergency medical condition shall not be withheld or delayed because of problems obtaining consent from the Guardian/Parent'
10	Information Dissemination	We recommend that the bill adopt this wording for the information dissemination section as it places focus on the needs of the individual receiving the information.	(1) Every person has a right to public health information. (2) Subject to Article 35 (1) (b) of the Constitution, the national government, county governments and every organ within the state health System shall facilitate access to information by the public on the health functions for which they are responsible. (3) The information to be publicised and made accessible under subsection (2) shall include- (a) the types, availability and cost of any health service; (b) the structure for the delivery of health services; (c) normal working schedules and timetables of visits of patients;

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			(d) procedures for access and use to the health services; (e) procedures for providing feedback on quality of services; (f) the rights and duties of users and health care providers; (g) the management of environmental risk factors to safeguard public health; (h) health profiles by diseases per county; (i) disease outbreak (j) the cost of drugs and commodities by the health providers; (k) national and county health sector plans and budgets; (l) information on sources of funding of the health sector; and (m) procedures for lodging complaints. (4) In disseminating information under section 10, every organ of the national and county government shall a) take into consideration (i)the age, literacy of the person (ii) the need to reach persons with disability (iii) the cost incurred in disseminating the information (iv) the local languages (v) the most effective method of communication in the local area (b) ensure that the information is easily accessible and available free of charge or at a reasonable cost taking into consideration the medium used for availing information (c) the information shall be made available (i)for inspection by a person free of charge (ii)by supplying a copy to any person

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			upon his or her request and upon payment of a reasonable fee (iii)on the internet, provided that the information is held by the institution in electronic form (5) A health care provider shall provide information to users taking into account the age, literacy, disability, culture and the language of the user. (6) Where the user of the information is a minor or incapacitated for any reason, the information shall be given to the parent, guardian or next of kin. (7) The information provided to a user shall include - (a) the health status of the user 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 explanation on the implications, risks, and legal consequences of such refusal.
11	Confidentiality	We recommend that our recommendation is adopted as it extensively addresses the issues of right to privacy in line with Article 31 of the Constitution. This will actualise the right to privacy as it relates to health sector.	(1) A healthcare provider shall not disclose any information concerning a user, without their prior written consent. (2) Notwithstanding subsection (1) confidential information may be disclosed in the following circumstances - (a) with the written consent of that person; (b) if that person has died, with the written consent of that person's, parent, spouse, adult offspring personal representative, administrator or executor or partner;

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			(c) if that person is a child with the written consent of a parent or legal guardian of that child; (d) if that person is unable to give written consent, with the oral consent of that person or with the written consent of the person with power of attorney for that person; (e) if, in the opinion of the medical practitioner, that person has a disability by reason of which the person appears incapable of giving consent, with the written consent, in priority order, of— (i) a parent of that person (ii) adult offspring of that person (iii) spouse of that person (iv) guardian of that person; (v) a partner of that person; or (f) to a person, who is directly involved in the treatment of that person; (g) if non-disclosure of the information represents a serious threat to public health; (h) where the disclosure is required for the professional management of the condition involved; (i) to a court where the information contained in medical records is directly relevant to the proceedings before the court or tribunal; (j) if the person to whom the information relates dies, to the Registrar of Births and Deaths pursuant to section 18 of the Births and Deaths Registration Act; or (k) if authorized or required to do so under this Act or any other written law. (3) Subsection (1) shall not apply to the following: a) A disclosure of statistical or other information which is not reasonably expected to lead to the identification of the person to whom it relates. b) Sharing information for the purposes of improved

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			patient outcomes, teaching, professional development. (4) The Cabinet Secretary shall make regulations relating to disclosure of information.
12	Health Care Providers	We recommend the adoption of this wording /clause as it notes the rights of health care workers and makes provisions to ensure protection of health care workers in the course of duty. This is in line with Article 41 of the Constitution.	.(1) The Rights and duties of healthcare providers shall include - (a) not to be discriminated on account of their social status, gender, ethnicity, health status or any of the enumerated grounds under Article 27 of the Constitution; (b) right to fair renumiration (c) the right to a safe working environment that minimizes the risk of disease transmission and injury or damage to the healthcare personnel or to their clients, families or property or to abuse from any person. (d) Provide protection and treatment to health care providers who may get infected or contract any illness in the cause of their duties (2) Notwithstanding the provisions of paragraph (1) (a), the head of any health facility may impose such conditions on the service that may be provided by a healthcare provider taking into account their health status and only to the extent that the conditions imposed are lawful and necessary in the circumstances. (3) All healthcare providers, whether in the public or private sector, shall have the duty to provide health care, in accordance with the applicable professional standards.
13	Duties of users	We recommend that this section be deleted as the information would be covered by section 10 of our recommendations.	
14	Complaints	We recommend that this section is deleted and instead placed in a new part that establishes a Health Tribunal to deal with all forms of medical complaints. The aspects on right to information in the current draft at this section are equally well covered in our proposed comprehensive section on right to information.	
15	Duties of national government	We recommend that the committee adopts this version as it clearly captures the duties of the National Government and is more concise than the version in the current draft. This will help	The national government ministry responsible for health shall - (a) develop health policies, laws and administrative

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		minimize the ambiguity about what the National Government should do in the health sector.	procedures and programmes in consultation with county governments and health sector stakeholders and the public for the progressive realisation of the highest attainable standards of health (b) develop standards for health service delivery in accordance with section 45 and 46; (c) set standards and guidelines for the health care service delivery in accordance with the Fourth Schedule of the constitution (d) in consultation with the health authority, develop, adapt and customize regional and international health standards to regulate the health sector (e) set standards and formulate policies to guide the practice of traditional and alternative medicine as well as Palliative Care. (f) develop and regulate research for health standards (g) put in place intervention measures to reduce the burden of communicable and non-communicable diseases, emerging and re-emerging diseases, neglected diseases, especially among marginalised and vulnerable population (h) develop standards for the protection of the health and safety of consumers in all other sectors and promote, encourage collaboration and consultation with these sectors for the effective implementation of the standards; (i) put in place mechanisms for enforcement of the health standards including, where necessary prosecution of offenders; (j) provide capacity building and technical assistance to county governments as may be required; (k) coordinate the development of criteria for

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			determining the equitable sharing of funds allocated to the health sector under articles 202(2), 204 and any other funding derived from external loans and grants; (l) determine the key national health indicators in consultation with the County governments; (m) coordinate national disasters and emergencies; (n) develop a national health information management system which information system includes the indicators that take into account the needs of vulnerable and marginalized groups and Key and affected populations and information (o) facilitate all forms of research that can guide the development of appropriate health policies; (p) develop and manage the national health referral facilities and ensure progressive access to healthcare in these facilities by all; (q) determine the human resources skills and capacity required for health service delivery for the national government
	New Section: Duties of the County Governments	We recommend the bill adopt this section as it captures the duties of County Governments. As this is a contentious issue, it is important for the Health Bill to be explicit on this point.	The county governments shall be responsible for – (a) the development of county policies, laws, administrative procedures and programmes for the progressive realisation of the highest attainable standards of health based on county health indices and which meet the national policies, laws and standards (b) developing county health laws, policies and administrative procedures provided that where there is a conflict between the national or county laws and this Act this Act shall take precedence over other laws; (c) ensuring health service delivery in line with the national standards; (d) put in place measures to promote health and mitigate for adverse effect on the health of the people including-

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			(i)promotion of nutritional foods and ensure food hygiene in consultation with other sectors and regulatory bodies (ii)ensure and promote provision of quarantine services especially in ports, borders and frontiers health services (e) ensure availability of safe water and sanitation services (f) provision of minimum package standards of immunization (g) promotion of environmental hygiene and safeguard occupational health standards promotion of healthy lifestyles including physical activity, reduction of excessive use of alcoholic products and other addictive substances and to counter exposure to tobacco smoke (h) coordinating and implementing county health sector activities, including development of county health strategies, partner coordination, data management and research and training; (i) facilitating registration, license and accreditation of county health facilities in accordance with national standards developing guidelines to facilitate equitable access to county health services by vulnerable and marginalized groups and persons with disability; (j) collaborating with other sectors to ensure effective implementation of national health standards for the protection of health and safety of the consumers; (k) overseeing the enforcement of health standards in other sectors in respect of delegated functions from the national government (l) coordinate county disasters and

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			emergencies (m) report on timely basis disasters, existing epidemics surveillance (n) collaborating with and providing access and practical support for monitoring standards compliance undertaken within the county by the national government department responsible for health, the Authority and professional regulatory bodies established under any written law; (o) providing access, collaboration and practical support for operations of the national government at the county level; (p) establishing administrative and operational frameworks to entrench the values and principles of the Constitution in all health sector departments and institutions; (q) developing and promoting public participation in the planning of county health activities and management of county health facilities; (r) carrying out skills competence assessment, train and capacity building, notwithstanding continuous professional development of healthcare professionals. (s) Supervise internship programmes in line with the national standards (t) develop and manage the county health referral facilities and ensure progressive access to healthcare in these facilities by all; (u) determine the human resources skills and capacity required for health service delivery for the county government. (v) Timely notification to the national government and other counties on notifiable diseases
	New Section:	We recommend the bill this section as it captures the duties for	(1) National and county governments may, through the

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	Intergovernmental collaboration for health service delivery.	intergovernmental collaboration.	health sector inter-governmental consultative fora and in line with the Constitution the Inter-Governmental Relations Act and any other law, collaborate, cooperate and coordinate in the delivery of health services. (2) Activities of the Inter-governmental forum shall include - (a) developing of criteria for determining matters requiring intergovernmental consultation; (b) developing of inter-governmental agreements for joint implementation of any activities for health service delivery; (c) consultation on transfer of functions from the national government to any of the counties subject to the Constitution and any other written law; and (d) developing of criteria for equitable access to health services and resources, the management of health resources and development of systems to facilitate the flow of funds for delivery of health services under articles 202(2) and 204 and any funding derived from external loans and grants. (3) Two or more County governments may form joint committees to facilitate collaboration, cooperation and coordination of health sector activities to enhance health service delivery. (4) A joint committee formed under subsection (3) may undertake, among others, the following activities - (a) Determination of health issues of common concern to the counties; (b) the development of inter-county agreements for joint implementation of, or collaboration on any of the activities for health care delivery in the counties concerned; (c) development, management and financing of shared health facilities and programmes; and (d) arrangement for procurement, warehousing and

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			the distribution, for the public health services, of health products and technologies.
	New Section: Partnerships with other actors.	We recommend the bill this section as it captures the duties of non-state actors who play a critical role in health service delivery.	**.** (1) The National and County governments may partner with the private sector and Non state actors in the delivery of health services. (2) Partnerships entered into under subsection (1) may be for the purposes of, among others - (a) mobilization of resources; (b) joint capacity building programs; (c) procurement of medical supplies and technologies; (d) development and management of health infrastructure; (e) coordination of response during emergencies and disasters; and (f) exchange of expertise and personnel. (g) Strengthening of health systems
19	County Health Systems	We recommend that this section is deleted as it will be covered in the new section Duties of the County Governments and the County Government Act.	
20	Duties of county executive department for health	We recommend that this section is deleted as it will be covered in the new section, Duties of the County Governments, and the County Government Act. It is also important to emphasize as health interrelates with all the other departments, therefore its role is not only for the Executive Department of Health.	
21	Coordination	We recommend that this section is deleted as it will be covered in the new section, Partnerships with other actors, and the County Government Act.	
22	Public Health Facilities	We recommend that this section is deleted as it has already been captured in section 2 of this bill that defines what a public health facility is.	
23	Public Private Partnership	We recommend that this section is deleted as it will be extensively covered in the new section, Partnerships with other actors, and the County Government Act.	
24	Retention of Service Provision	We recommend that this section is deleted as it will be covered in Section 15 and the new Section on Duties of the County Governments.	
25	Classification levels of	We recommend that this section should be deleted and a provision	The Cabinet Secretary, in consultation with county

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	health care	is inserted in the Health Bill that mandates the Cabinet secretary to make regulations for the classification and roles of the institutions. This should of course be done in a consultative manner	governments and relevant stakeholders, shall make regulations on the classification and roles of the institutions.
New Clause	**Intergovernmental collaboration for health service delivery.**	In line with Act No. 2 of 2012 there is need for the Health Bill to recognise potential; Intergovernmental collaboration for health services delivery between national and county governments through the health sector inter-governmental consultative fora. This aspect has not been well captured in the current draft and is critical for the delivery of health services between the two levels of government.	National and county governments may, through the health sector inter-governmental consultative fora and in line with the Constitution, the Inter-governmental Relations Act and any other law, collaborate, cooperate and coordinate in the delivery of health services.
New Part: **HEALTH PROFESSIONS TRIBUNAL**			
New Clause	Complaints.	We recommend that a different part be added for the complaints, along with establishing a Health tribunal to deal with all forms of medical complaints. We recommend this be added because it will make the complaint procedure more accessible to patients. We recommend that the Health Bill establish a health tribunal for any person to file a complaint about the manner in which he or she was treated at a healthcare facility and have the complaint investigated appropriately. The Tribunal shall have jurisdiction to hear and determine complaints arising out of the conduct of any health care providers; to hear and determine any matter or appeal arising from the administrative processes made within the Bill.	(1) Any person has a right to file a complaint about the manner in which he or she was treated at a healthcare facility and have the complaint investigated appropriately. (2) The national government and the county governments shall establish and publish the procedure for the lodging complaints within public and private health care facilities in the areas of the health system for which they are responsible.
New Clause	Health Tribunal		(1) There is established a tribunal known as the Health Professions Tribunal consisting of: (a) a chairman who shall be an advocate of the High Court of Kenya of not less than ten years standing appointed by the Judicial Service Commission Five (5) members of not less than Seven(7) years professional standing elected from health professional bodies and holding a current practicing certificate; (b) Three (3) persons representing service users nominated by the Consumer Federation of Kenya, National Council of Persons with Disabilities and Consumer Federation of

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			Kenya (COFEK) (c) The secretary of the Tribunal who shall be the administrative officer. (d) In the constitution of the membership of the tribunal, the principle of equality including regional balance and application of the not more than Two thirds gender rule shall be applied. (2) The names of the persons appointed as members of the tribunal shall be published in the Gazette, and they shall before be assuming office, take an oath or solemn affirmation before a judge of the High Court (3) The members of the tribunal shall hold office for a period of three years and shall be eligible for re appointment subject to a maximum of two terms (4) There shall be paid to the members of the Tribunal such remuneration and allowances as the Cabinet Secretary may, in consultation with the Salaries and Remuneration Commission, determine. (3) The Office of a member of the Tribunal shall become vacant— (a) at the expiration of three years from the date of appointment; (b) if the member ceases, for any reason, to be such advocate or medical practitioner as referred to in subsection (1); (c) if the member dies (d) if the member resigns by notice in writing addressed to the Cabinet Secretary (e) If a member is convicted of a criminal offence and sentenced to imprisonment for a term exceeding six months without an option of a fine (f) A member is removed from office on the following grounds- (i) violation of the constitution or any other written law, including contravention of Chapter Six of the

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			Constitution (ii) gross misconduct (iii) physical or mental incapacity that leads to inability to perform the function office (iv) incompetence or neglect of duty (v) bankruptcy
New Clause	Jurisdiction of the Tribunal.		**32.**(1) The Tribunal shall have jurisdiction— (a) to hear and determine complaints arising out of the conduct of any health care providers; (b) to hear and determine any matter or appeal arising from the administrative process pursuant to the provisions of section 28(2) as may be made to it pursuant to the provisions of this Act. (2) All matters before the Tribunal shall be decided by the votes of a majority of the members present and voting. (3) The jurisdiction conferred upon the Tribunal under subsection (1) excludes criminal jurisdiction. (4) The Tribunal shall have all the powers of a subordinate court of the first class to summon witnesses, to take evidence upon oath or affirmation and to call for the production of books and other documents. (5)In its determination of any matter the Tribunal may take into consideration any evidence which it considers relevant to the subject of the matter before it, notwithstanding that the evidence would not otherwise be admissible under the Evidence Act. (6) A person aggrieved by the decision of the Tribunal under this section may appeal to the High Court in such manner and time as may be prescribed by the rules. (7)The Chief Justice may in consultation with the chairperson of the Tribunal, and by Notice in the *Gazette* make rules governing the practice and procedure of the Tribunal.
Part VI: Health Professionals Oversight Authority			

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46	Board of the authority	We recommend that the number of members should be reduced and the law should give authority to non-state actors to nominate members	
48	Functions of the Authority.	We recommend this version is adopted as it extensively spells out the function of the authority.	1) The functions of the Authority shall relate to all health professions and professionals including medical practitioners and dentists, clinical officers, nurses, laboratory technicians and technologists, nutritionists and dieticians, counsellors and psychologists, physical, occupational, speech therapists and any other health professional and shall be to — (a) Facilitate the development of professional standards including research into new fields of medicine for delivery of quality health services. (b) Promote and set standards for provision of quality health care by all health professionals in the public and private sectors. (c) Regulate the practice of recognized professions in the health sector and exercise general supervision over the practice of such professions; (d) superintend over the general practice by emerging health professions; (e) setting standards for promotion and regulation of inter-professional liaisons between and among the health professions in the interest of the public; (f) Advice on the policy in respect of health standards. Undertake the registration and licencing of individuals in the health sector (g) Determine the fees payable in respect of licencing of professionals for practice (h) Maintain a master register of all health professionals (i) Prescribe the conditions under which people

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			who are not citizens may practice in Kenya; (j) Liaise with similar authorities in other countries to determine regional standards for the practice of health professionals across the borders. (k) set the code of conduct of professionals in consultation with professional bodies (l) monitor and coordinate inspections of all public and private health care facilities or premises and practices; (m) in collaboration with other public and private sector agencies, facilitate, conduct, promote and coordinate research and dissemination of findings on data relating to the health professions and serve as repository for such data (n) enhance co-operation and coordination between the national and county governments and other stakeholders involved in the implementation of the standards set under this Act; (o) Undertake investigations of any complaints concerning registered persons and health care providers under this Act and ensure that timely and appropriate processing of such complaints in a just and fair manner is undertaken and decisions made in the best interest of the public; (p) develop and maintain co-operation with other regional and international institutions in areas relevant to achieving the Authority's objectives; (q) Establish mechanisms for the enforcement of health standards at all levels in the country including the inspection, monitoring and evaluation of the by all public and private actors.

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			(r) Determine the minimum standards for the training and accreditation of courses in public and private health training institutions (s) Perform such other functions as may be conferred on it by this Act or any other written law. (2) In undertaking its functions at (1) above, the authority shall work with professional bodies and take into account the ethical standards set by the health professions; (3) The authority may create such directorates that shall be necessary for the efficient and effective carrying out of its functions.
	Powers of the Authority	We recommend this version is adopted as it extensively spells out what the Authority has the power to do.	(1) The Authority shall have power of entry to conduct announced or unannounced inspection of health facilities from time to time as they deem fit. (2) The Authority shall have power to order the total or partial closure of any health facility that is non-complaint with the set standards or is running a health facility without a certificate. (3) An order issued under section 2 shall be in writing and shall be issued to the person in charge of the health facility. (4) The order shall state the following; (a) The nature of the non-compliance (b) The extent of the non-compliance (c) The period in which the non-compliance is to be rectified by the health facility (5) For purposes of section (2), where an order has been issued, the County Executive Committee members for health shall ensure that reasonable alternative and accessible health services are provided for the community affected by the closure of the health facility. (6) The non-compliance order shall remain in force until the Authority is satisfied that there is compliance.
	Repeal of certain Acts and regulatory bodies.	We recommend that this section be added so that the some of the functions of other regulatory bodies shall transfer to the authority.	The functions carried out under the following regulatory bodies shall be transferred to the authority; consequently

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	CAP 260 CAP 257 Cap 253A Cap 253 Cap 243 Cap 244 Cap 253B No. 12 of 2013		the Acts establishing the following regulatory bodies are repealed - (a) the Clinical Officers Council established under the Clinical Officers (Training, Registration and Licensing) Act; (b) the Nursing Council of Kenya established under the Nurses Act; (c) the Kenya Medical Laboratory Technicians and Technologists Board established under the Medical Laboratory Technicians and Technologists Act; (d) the Medical Practitioners and Dentists Board established under the Medical Practitioners and Dentists Act; (e) the Radiation Protection Board established under the Radiation Protection Act; (f) the Council of the Institute of Nutritionists and Dieticians established under the Nutritionists and Dieticians Act; (g) the Public Health Officers and Technicians Council established under the Public Health Officers (Training, Registration and Licensing) Act, 2013 and (h) Counsellors and Psychologists Board established under the Counsellors and Psychologists Act 2014
55	Funds of the Authority	We recommend this version is adopted as it extensively spells out the sources of funds of the authority.	(1) The Funds of the Authority shall consist of— (a) moneys allocated by Parliament for the purposes of the Service; (b) any grants, gifts, donations, loans or other endowments given to the Service; (c) such funds as may vest in or accrue to the Service in the course of the exercise of its powers or the performance of it functions under this Act; (d) moneys from any other lawful source accruing to the Fund. (2) The Authority shall open and maintain such bank accounts as are necessary into which shall be paid

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			moneys payable to the Fund.
57	Annual Estimates	We recommend that this version be adopted as it makes explicit the process for arriving at annual estimates.	1) At least three months before the commencement of each financial year, the Authority shall cause to be prepared estimates of the revenue and expenditure of the Authority for that year. (2) The annual estimates shall make provision for all the estimated expenditure of the Authority for the financial year concerned and in particular, shall provide for the— (a) payment of remuneration in respect of the members and staff of the Authority; (b) payment of pensions, gratuities and other charges in respect of benefits which are payable out of the funds of the Authority; (c) maintenance of the buildings and grounds of the Commission; (d) funding of training, research and development of activities of the Authority; and (e) creation of such funds to meet future or contingent liabilities in respect of benefits, insurance or replacement of buildings or installations, equipment and in respect of such other matters as the Authority may think fit. (3) The annual estimates shall be approved by the Cabinet Secretary before the commencement of the financial year to which they relate and shall be submitted to the Cabinet Secretary for tabling in Parliament.
60	Relationship with other regulatory bodies	We recommend that this sections is deleted because it is addressed in the Section on Functions of the Authority	
PART VII—REGULATION OF HEALTH PRODUCTS AND HEALTH TECHNOLOGIES			
62	Establishment of the Health Products and Technologies Agency	We recommend that this entire chapter is adopted because it places further emphasis on the issue of procurement.	(1) There shall be established, a single regulatory body for regulation of health products and health technologies to be known as the Health Products and Technologies Agency (2) The Agency shall be a body corporate with perpetual succession and a common seal, capable of performing all acts that bodies corporate may by law perform including the following— (a) suing and being sued;

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			(b) taking, purchasing or otherwise acquiring, holding, charging or disposing of movable and immovable property; (c)borrowing money or making investments; and (d) doing all such things or acts for the proper discharge of its functions under this Act, which may be lawfully performed by a body corporate (3)The agency may form committees for the better carrying out of its mandate under this Act or any other written law.
63	Functions of the Agency		(1) The Health Products and Technology Agency shall – (a) Promote availability of quality health products and health technologies (b) Set standards for regulation of health products and technologies in line with the relevant international standards including the World Health Organization (WHO) guidelines and other international standards ratified by Kenya. (c) carry out assessments for guiding the licensing of commercial and industrial activities relating to health products to enforce compliance with the national policies and standards. (d) License manufacturers and distributors of health products, technologies, veterinary products, poisons and mining chemicals; (e) maintain a register of the health products and technologies, including veterinary products and technologies, poisons and poisonous products, mining chemicals, traditional and complementary medicines and nutritional formulations and therapeutic feeds; (f) Set standards on the safety and efficacy

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			of health products and technologies; (g) undertake inspection of all facilities for the manufacture, storage and distribution of health products and technologies; (h) In consultation with the health committee of the council on Science and Technology, monitor clinical trials and use of new health products for purposes of determining eligibility prior to their registration; (i) develop and periodically review the regulations and procedure for registration of health products and technologies; (j) develop the regulatory framework to guide packaging, advertising and promotion of health products and technologies; (k) conduct relevant research including prioritized post market surveillance of health products and technologies for safety and quality; and (l) regulate disposal of health product and technologies. (m) Set standards for warehousing of health products and technologies (n) Set standards for the licensing and sale of health products and technologies (2) The Agency shall manage the National Quality Control Laboratory for the purposes of testing, analysing and regulating medical products and technologies including veterinary products, mining chemicals and poisons.
64	Licences		**.**(1) The agency shall develop guidelines for the licensing of dealings relating to and the sale of health products and technologies (2) No person, firm or institution may engage in one or

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			more of the activities specified in section 34(1) whether by way of trade or otherwise, unless one has a valid licence granted by the Agency established under this Part. (3) Any person, firm or institution possession of a licence issued under this section shall display the same at a conspicuous place and shall produce the licence for inspection when required to do so by any officer from the Agency established under this Act. (4) All health products and technologies, including traditional and complimentary medicines and food products claimed to be medicines, vaccine or any therapeutic claim intended for use by members of the public, whether free or on cost shall be eligible for registration only if- (a) after due assessment, it is found to achieve the therapeutic or the intended effect it claims to possess or which may reasonably be attributed to it; (b) it is sufficiently safe under the normal conditions of use; (c) it is made and packaged according to satisfactory standards. (5) Any person who engages in the dealing or sell of health products and technologies contrary to this section and without the approval of the agency commits an offence.
65	Procurement and supply of health products and technologist.		**.**(1)The procurement of health products and technologies shall be undertaken in line with the relevant procurement and disposal laws. (2) Procurement, warehousing and distribution of health products and technologies shall respect the principles of protection of health and safety of consumers, sustained supply, economies of scale, cost effectiveness and quality standardization. (3) The national and county governments shall put in place strategic reserves for health products and technologies to safeguard outages and emergencies.

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66	Register of traditional and alternative medicines.		The Agency shall maintain a register of traditional and alternative medicines, mechanisms and take necessary measures to determine the interactions between those traditional medicines and conventional medicines and treatment
67	Repeal of the Pharmacy and Poisons Act		1) The functions carried out under the Pharmacy and Poisons Board established under the Pharmacy and Poisons Act shall be transferred to the agency (2) The Pharmacy and Poisons Act is hereby repealed. (3) The National Quality Control Laboratory established under Section 35C of the Pharmacy and Poisons Act shall continue to exist as an agency of the Medical Products and Technologies Agency.
68 (1) (e)		Consider unsafe abortion in clause 68 (1) (e) as it is one of the leading causes of death for women in Kenya.	The National health system shall devise and implement measures to promote health and to counter influences having an adverse effect on the health of the people including—a comprehensive programme to advance reproductive health including (i) effective family planning services; (ii) implementation of means to reduce unsafe sexual practices; (iii) **unsafe abortions** (iv) adolescence and youth sexual and reproductive health; (v) maternal and neo- natal and child health; (vi) elimination of female genital mutilation; and (vii) maternal nutrition and micro nutrient supplementation.
PART VIII: PROMOTION AND ADVANCEMENT OF PUBLIC AND ENVIRONMENTAL HEALTH - We recommend that this Part is deleted because these issues have already been captured in other parts of the bill.			
PART X—TRADITIONAL AND ALTERNATIVE MEDICINE - We recommend that a specific Act of Parliament is developed to adequately address the issue of Traditional & Alternative Medicine. We also note that there are on-going consultation on the Traditional Health Practitioners Bill 2014			
PART IX: HUMAN ORGANS, HUMAN BLOOD, BLOOD PRODUCTS, OTHER TISSUES AND GAMETES.			
New Clause	Establishment of the Kenya Blood Services	We recommend that the proposed clause in this Matrix is adopted as it more adequately addresses the issues relating to human organs, human blood, blood products and other tissues and gametes. We further note that the issue of Making wills is not suitable for the health bill and should be left to other laws like the Succession Act.	(1).There is established a service, to be known as the Kenya Blood Service (2) The Service shall be the successor to the Blood Transfusion Service existing immediately before the coming into force of this Act. (3) The Service shall be a body corporate with perpetual succession and a common seal, capable of performing all acts that bodies corporate may by law perform including

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			the following— (a) suing and being sued; (b) taking, purchasing or otherwise acquiring, holding, charging or disposing of movable and immovable property;; (c)borrowing money or making investments; and (d) doing all such things or acts for the proper discharge of its functions under this Act, which may be lawfully performed by a body corporate. (4) The Headquarters of the Service shall be in the capital city however the Service may establish offices in other parts of the country.
New Clause	Functions of the Service		The functions of the service shall include a) To develop a comprehensive and coordinated blood service based on voluntary non-remunerated blood donations so as to guarantee availability of adequate and safe blood in Kenya. b) To set standards on the safety of tissues, gametes, blood and blood products and services. c) To build capacities of health professionals on safety, removal, usage, storage and disposal of tissues, blood and blood products or gametes d) To monitor and enforce the implementation of standards set under this Section. e) To establish blood transfusions services throughout the country in collaboration with national and county governments f) Establish a strategic national blood reserve for effective address of emergencies and disasters. g) Develop mechanisms for regulating the provision of blood services in all Counties in the Republic of Kenya as required by this Act or any other written law h) advice the Cabinet Secretary on matters relating to tissues, gametes, blood and blood products i) undertake and promote relevant research on tissues, gametes, blood and blood products
New Clause	Director		.(1) There shall be a Director of the service who shall be recruited competitively by the public service commission

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			and appointed by the Cabinet Secretary. (2) A person shall be qualified for appointment as a Director under this section if such person— (a) is a citizen of Kenya; (b) has experience of not less than seven years; (c) has at least five years of proven experience in management; and (d) meets the requirements of Chapter Six of the Constitution. (3) The Director shall be the Chief Executive Officer of the Service and shall— (a)be responsible for the carrying out of the functions of the service; (b)be responsible for the day-to-day administration and management and the control of the other staff of the service; (c)manage and disburse funds from the service for the purposes of this Act; and (d) perform such other functions as may be assigned to it by the Board. (4)The Director shall hold office for a term of five years but shall be eligible for re-appointment for one further term of five years. (5) The Director may be removed only for— (a) inability to perform the functions of the office of director arising out of physical or mental incapacity; or (b) gross misconduct or misbehaviour; or (c) incompetence or neglect of duty; or (d) violation of the constitution; or (e) any other ground that would justify removal from office under the terms and conditions of service.
New Clause	Appointment of Staff		(1) The Cabinet Secretary may appoint such officers and staff of the Service as maybe necessary for the proper performance of its functions under the Act (2) The staff appointed under subsection (1) shall serve on such terms and conditions as the Service, in consultation with the Public Service Commission, may

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			determine. (3) The Public Service Commission may, upon request by the Cabinet Secretary second to the Service such number of public officers as may be necessary for the proper performance of the functions of the Service. (4) A public officer seconded to the Service shall, during the period of secondment, be deemed to be an officer of the Service and shall be subject only to the direction and control of the Service
New Clause	Terms and Condition of service		The salaries and allowances payable to, and other terms and conditions of service of the staff of the Service shall be determined by the Cabinet Secretary on the advice of the Salaries and Remuneration Commission.
New Clause	Removal of tissue, blood, blood products or gametes from living persons		(1) A person may not remove tissue, blood or a blood product or gamete from the body of a living person or carry out the transplantation of such tissue except - (a) with the written consent of the person from whom the tissue, blood, blood product or gametes are being removed in the prescribed manner; (2) The Cabinet Secretary shall prescribe through regulations- (a) the criteria for the approval of organ transplant facilities; and (b) the procedural measures to be applied for such approval.
New Clause	Use of tissue, blood, etc. removed from living person. Cap. 248		(1) A person may use tissue or gametes removed or blood or a blood product withdrawn from a living person only for such medical or dental purposes as may be prescribed. (2) The following tissue, blood, blood products or gametes may not be removed or withdrawn from a living person for any purposes contemplated in subsection (1) - (a) tissue, blood, a blood product or a gamete from a person who is mentally ill within the meaning of the Mental Health Act; (b) tissue which is not replaceable by natural process from a minor;

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			(c) a gamete from a minor; (d) placenta, embryonic or foetal tissue, stem cells and umbilical cord, excluding umbilical cord progenitor cells.
New Clause	Offence		(1)Any person who – (a) contravenes the provision of the above sections; (b) fails to comply with the provision of the sections; or (c) charges a fee for a human organ; commits an offence and is liable on conviction to a fine of not less than ten million shillings or to imprisonment for a period of ten years or both the fine and imprisonment (2) Any medical practitioner or professional who contravenes the provisions of this section commits an offence and is liable on conviction to a fine of not less than ten million shillings or to imprisonment for a period of ten years or both the fine and imprisonment (3) A medical professional found guilty shall be suspended from practice for a period of five years
New Clause	Prohibition of reproductive cloning of human beings.		(1) A person shall not, for purposes of the reproductive cloning of a human being - (a) manipulate any genetic material, including genetic material of human gametes, zygotes or embryos; or (b) engage in any activity, including nuclear transfer or embryo splitting. (2) For purposes of this section - (a) reproductive cloning of a human being means the manipulation of genetic material in order to achieve the reproduction of a human being and includes nuclear transfer or embryo splitting for such purpose; and (b) therapeutic cloning means the manipulation of genetic material from either adult, zygotic or embryonic cells in order to alter, for therapeutic purposes, the function of cells or tissues.

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			(3) The cabinet secretary shall develop regulations to provide for- (a) circumstances to allow for therapeutic cloning utilising adult or umbilical cord stem cells (b) the importation or exportation of human zygotes or embryos (4) The Cabinet secretary shall prescribe conditions to permit therapeutic cloning utilising adult or umbilical cord stem cells (5) A person who contravenes the provision of this section commits an offence and is liable, on conviction, to a fine not exceeding five million shillings or imprisonment for a period not exceeding eight years or to both.
New Clause	Purposes of donation.		(1) A donation under section 35(2) may only be made for purposes of- (a) training of students in health sciences; (b) health research; (c) advancement of health sciences; (d) therapeutic purposes, including the use of tissue in any living person; or (e) the production of a therapeutic, diagnostic or prophylactic substances. (2) This Part does not apply to the– (a) preparation of the body of a deceased person for the purposes of embalming; (b) making of incisions in the body for the infusion thereof by a preservative; or (c) restoration of any disfigurement or mutilation of the body before its burial.
New Clause	Revocation of donation.		A donor may, prior to the harvesting of the relevant organ, revoke a donation in the same way in which it was made or, in the case of a donation by way of a will or other document, or by the intentional destruction of that will or document**.**
New Clause	Post mortem examination of bodies.		**.** (1) Subject to subsection (2), a post mortem examination of the body of a deceased person may be conducted if-

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			(a) the person when alive gave consent thereto; (b) the next of kin, namely; spouse, , adult offspring, parent, guardian, adult brother or adult sister of the deceased, in the specific order mentioned, gave consent thereto; or (c) such an examination is necessary for determining the cause of death. (2) A post mortem examination may not take place unless authorized in writing and in a manner prescribed by this Act or any other written law by- (a) the medical practitioner in charge of clinical services in the hospital or authorized institution or of the mortuary in question, or any other medical practitioner authorized by such practitioner; or (b) in the case where there is no medical practitioner in charge of clinical services, a medical practitioner authorized by the person in charge of such hospital or authorized institution. (c) next of kin, namely; spouse, partner, adult offspring, parent, guardian, adult brother or adult sister of the deceased, in the specific order mentioned, gave consent thereto.
New Clause	Disposal of dead bodies		The cabinet secretary may make regulations in consultation with the county governments, imposing any conditions and restrictions with respect to the means of disposal of dead bodies otherwise than by burial or cremation, a) as to the period of time a body may be retained after death on any premises b) with respect to embalming or preservation c) the use of unclaimed bodies by medical schools and scientific institutions for studies and research
PART X HEALTH FINANCING We recommend that the provisions in this Part emphasize that both National and County Governments are supposed to fundraise for resources for health locally, regionally and internationally.			
PART XIII—THE PRIVATE SECTOR PARTICIPATION -- We recommend that this section is deleted because it is catered for in the sections on partnerships			

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with non-state actors and between counties and the national government**.**			
PART XIV—PROMOTION AND CONDUCT OF RESEARCH FOR HEALTH			
New Clause	State Research for Health Committee.	We recommend that this entire chapter is adopted as it more adequately addresses the issues relating to research.	1) the Cabinet Secretary through the national research for heath committee established under the Science and Technology Act , identify priority areas for health research (2) The Cabinet Secretary shall promote and facilitate adequate coordination and effective carrying out of research within the health sector. (3). The county governments may in consultation and collaboration with the Biological and Health Sciences Committee, promote and facilitate research on health on identified priority areas. (4) Research for health in any identified priority areas may be carried out by any public or private entity in line with the relevant applicable standards.
New Clause	Composition of the Committee.		**.** (1)The Committee established under section 56 shall consist of - (a) a chairperson, who shall be a distinguished health researcher and renowned in a health discipline; (b) one representative from Kenya Medical Research Institute; (c) one representative from the National Commission for Science, Technology and Innovation; (d) the Head of the directorate of the Ministry of health responsible for research and development; (e) one representative from the National Health Authority; (f) two representatives from public universities; (g) one representative from private universities (h) one representative from Health Products and Technologies Commission; (i) one research expert with orientation to traditional and alternative medicine;

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			(j) One research expert with orientation in clinical trials; and (k) one distinguished bio-medical science researcher. (2) The membership of the Committee shall, as much as possible, reflect ethnic, gender and regional balance. (3) The Head of the Directorate responsible for health research shall be the Secretary to the Committee. (4) The Business and Affairs of the Committee will be undertaken in accordance with Schedule Two with the necessary modifications. Except as may be provided in the Schedule, the Committee may regulate its own procedure.
New Clause	Term of office.		**.** (1) The term of office of the Chairperson shall be three years, renewable for one further term of three years. (2) The chairperson may resign through a letter addressed to the Cabinet Secretary. (3) A member of the Committee shall hold office for a term of three years and shall be eligible for re-appointment for one further term of three years. (4) A member of the Committee may resign through a letter addressed to the Cabinet Secretary.
New Clause	Functions of the committee.		**.** (1) The Committee shall undertake the following functions - (a) advice the Cabinet Secretary on a National Policy on health Research; (b) recommend research priority areas for health (c) recommend resource needs for research (d) recommend strategies for mobilization of funds for research promote collaboration between research institutions, non-governmental organizations, universities and health institutions in the funding, promotion and conduct of health research; (e) recommend strategies for capacity strengthening for health research; (f) develop a research data base;

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			(2) In identifying priorities for health research the Committee shall give due regard to— (a) the disease burden; (b) intervention strategies; (c) the cost-effectiveness of interventions aimed at reducing the burden of disease; (d) the availability of human and institutional resources for the implementation of an intervention at the level closest to the affected communities; (e) the health needs of vulnerable groups such as women, older persons, children and people with disabilities; (f) the health needs of communities; (g) National security; and (h) emerging and re-emerging health issues.
New Clause	Consent to research.		(1) Notwithstanding anything to the contrary in any other law, research on experimentation on a living person may only be conducted: (a) with the written informed consent of that person; (b) if the person is a child or a person with mental disability, with the written consent of a parent or legal guardian of that person; or (c) with the approval from relevant Ethics Committees. (2) The person whose consent is sought to be obtained under subsection (1) shall be adequately informed of the aims, methods and anticipated benefits and the potential hazards and discomforts of the research.
New Clause	Research on minors.		(1) Where research or experimentation is to be conducted on a minor for a therapeutic purpose, the research or experimentation may only be conducted- (a) if it is in the best interest of the minor; (b) in such manner and on such conditions as

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			may pose the least risk to the minor; and (c) with the informed written consent of the parent or guardian of the minor. (2) Where research or experimentation is to be conducted on a minor for a non-therapeutic purpose, the research or experimentation may only be conducted – (a) in such manner and on such conditions as may be prescribed by the Committee; and (b) with the informed written consent of the parent or guardian of the minor.
New Clause	Funding for research.		Having regard to the necessity of both scientific and policy research in the field of health in Kenya, and the cross cutting nature of health, a reasonable portion of the national Research Fund as established in the Science, Technology and Innovation Act, 2013, shall be allocated for health research.
New Clause	Contravention of the Part.		A person who contravenes any provision of this Part commits an offence and is liable on conviction to a fine not exceeding one million shillings or a fine of two years or both.
PART XV—E—HEALTH – We are of the opinion that the issues of health information systems can be better articulated in policies and regulations as opposed to statutes. We therefore recommend that this chapter is deleted.			
PART XVI—INTER-DEPARTMENTAL COLLABORATION -- We recommend that this entire chapter is deleted as it has been addressed in Sections 15, 16, and 17 of the draft Bill.			
ENABLING LEGISLATION AND REGULATIONS – TIME FRAMES We recommend that for all clauses within the Bill that are geared towards establishment of enabling legislation and regulations, must give timelines within which the enabling legislation and or regulations are to be made.			