



**COUNCIL OF COUNTY GOVERNORS RECOMMENDATIONS ON THE HEALTH BILL 2015 FOR
ORAL SUBMISSION TO THE HEALTH COMMITTEE OF THE NATIONAL ASSEMBLY ON 25TH
AUGUST 2015**

PREPARED BY PETER WANYAMA, LEGAL COMPLIANCE SPECIALIST

PREAMBLE REMARKS

- (a) The Council of Governors recognises the efforts that were expended in the coming of the Draft Health Bill 2015. However, we note with great concern that the spirit of consultation with the County Governments was not extensively exhausted during the development of the Bill. It is obvious that the Draft Health Bill fails to embrace the tenets of devolution as anchored in the Constitution. In its current form, the Bill seeks to seize county healthcare services and cede the same to the National Government contrary to Articles 6(2), 186, 189 and the Fourth Schedule of the Constitution. County Governments wish to appeal to this committee to carefully re-examine this Bill to avert future acrimonies between the two levels of government and arrest any future litigation that may be instituted on the same.
- ii. The Council believes that if we nurture the spirit of consultation, give and take within the parameters of the Constitution all problematic issues will be addressed. The Council believes that the strategy to be adopted in policy and

legislative development should be consultative and Counties should not be viewed as mere stakeholders but ought to be respected as legitimate actors in the statutory development process. It will help in seamless implementation if they are involved right from the inception stages. In sum, Counties and the Ministry of Health are like the co-joined twins, joined at the hip in so far as health service delivery is concerned. We are all keen and desirous to deliver better health care services to Kenyans but this must be within the constitutional functional assignment provisions and structures that clearly identify our respective roles.

- (b)** The Bill has provisions that seek to usurp the supremacy of the Constitution, and further seeks to recentralize the health function back to the National Government. Where this is the case the Council has pointed out these problematic clauses and has proposed suitable legislative amendments.
- (c)** We also wish to note that the transfer of any function must be governed by Article 187 of the Constitution. We are aware that constitutionally Level 5 Hospitals have already been transferred to the Counties pursuant to a constitutional transition process. To take them over compulsorily through a statutory classification is a direct attack on devolution.
- (d)** The Draft Bill adopts a legislative philosophy and design that appears to undermine the functional, procurement and financial autonomy of counties in the health sector. The role of the Ministry is to manage national referral facilities (as they existed before the promulgation of the Constitution), and to set policies and standards for the county healthcare systems. Certainly, not to take over county functions ostensibly to improve health care at the county level. In our proposals we have identified areas where this is the case and preferred proposals that meet the constitutional threshold.
- (e)** The flow of the Bill is not systematic, it does not correctly reflect the institutions and functions of devolved units, and fails to harmonize the relationship between the National Government and the County Governments.

- (f) The language of the Bill fails to respect statutory clarity and in this regard it needs to embrace the principles of statutory interpretation. We have offered proposals on aspects of the bill where the language is capable of different interpretations.
- (g) Overall, the Council of Governors urges this Committee to reconsider more legitimate stakeholder consultation and incorporate all proposed amendments to this Bill. It is imperative that unconstitutional provisions be reviewed and redrafted in acceptable perspectives, and where necessary deleted. Counties are a critical player in the health sector.

The table below outlines the problematic clauses in the Bill, identifies the Council's recommendations and outlines a justification for each recommendation.

DRAFT BILL BEFORE THE NATIONAL ASSEMBLY	COG'S PROPOSED AMENDMENT	JUSTIFICATION/EXPLANATION
Objective clause :- AN ACT of Parliament to establish a unified health system, to coordinate the inter-relationship between the national government and county government health systems, to provide for regulation of health care service and health care service providers, health products and health technologies and for connected purposes.	Objective clause :- We propose the House amends the objective clause by deleting the words '<i>unified</i>' that immediately appears after the words '<i>establish a</i>' and insert the following words '<i>to provide for national and county governments' functions in relation to health</i>' immediately before the words '<i>to coordinate</i>' The new clause should read as follows AN ACT of Parliament to establish a health system, to provide for national and county government functions in relation to health, to coordinate the inter-relationship between the national government and county government health systems, to provide for regulation of health care service and health care service providers, health products and health technologies and for connected purposes.	(a) The use of word unified health system is capable of other interpretations. It actually connotes a centralised health system. This is not the case in our constitutional dispensation. (b) Apart from providing the framework for inter-governmental relations in the health sector, the objective clause should also capture the essence of the bill, which is to provide for functions of both levels of government in the health sector pursuant to the Fourth Schedule of the Constitution of the Republic of Kenya.
2. In this Act unless the context otherwise requires -	We propose the House amends Clause 2 o the Bill by inserting the a new definition of health system immediately after the definition of 'health facility' to provide a follows:- "A health system" means the organization of people, institutions, and resources that deliver health care services to meet the health needs of target populations.	This term "health system" has not been defined within the preliminary section. It is important to define what a health system means. This helps in interpreting the bill.

3. The object of this Act is to— (a) establish a national health system which encompasses public and private institutions and providers of health services at the national and county levels and facilitate in a progressive and equitable manner, the highest attainable standard of health services; (b) protect, respect, promote and fulfill the health rights of all persons in Kenya to the progressive realization of their right to the highest attainable standard of health, including reproductive health care and the right to emergency medical treatment; (c) protect, respect, promote and fulfill the rights of children to basic nutrition and health care services contemplated in Articles 43(1) (c) and 53(1) (c) of the Constitution; (d) protect, respect, promote and fulfill the rights of vulnerable groups as defined in Article 21 of the Constitution in all matters regarding health; and (e) recognize the role of health regulatory bodies established under any written law and to distinguish their regulatory role from the policy making function of the national government.	We propose the House amends Clause 3 of the Bill by inserting the a new paragraph <i>(f) give effect to the provisions of the Constitution on devolution of health services;</i> after paragraph (e). The amended clause should read as follows :- 3. The object of this Act is to— (a) establish a national health system which encompasses public and private institutions and providers of health services at the national and county levels and facilitate in a progressive and equitable manner, the highest attainable standard of health services; (b) protect, respect, promote and fulfill the health rights of all persons in Kenya to the progressive realization of their right to the highest attainable standard of health, including reproductive health care and the right to emergency medical treatment; (c) protect, respect, promote and fulfill the rights of children to basic nutrition and health care services contemplated in Articles 43(1) (c) and 53(1) (c) of the Constitution; (d) protect, respect, promote and fulfill the rights of vulnerable groups as defined in Article 21 of the Constitution in all matters regarding health; (e) recognize the role of health regulatory bodies established under any written law and to distinguish their regulatory role from the policy making function of the national	Devolution is a peremptory national value and principle of governance. It can't be ignored in policy and legislative development initiatives like the present one. Since the bill seeks to provide for devolved functions and aspects of intergovernmental relations in the health sector, the Council proposes that it becomes a key policy objective of the bill. These objectives are important for the following reasons:- (a) they help in setting the tone of the bill. In essence they help to improve the content of the bill; and (b) even though they ought not to set a hierarchy of norms, they help in a great deal in interpreting the text of the Bill. The interpretation of the bill can be done by the policy implementers at both levels of government or at a court of law when there is a dispute.
---	--	--

	government; and (f) give effect to the provisions of the Constitution on devolution of health services.	
8. (1) Every health care provider shall inform a user or, where the user of the information is a minor or incapacitated, inform the guardian of the— (a) user’s health status except in circumstances where there is substantial evidence that the disclosure of the user’s health status would be contrary to the best interests of the user; (b) range of promotive, preventive and diagnostic procedures and treatment options generally available to the user; (c) benefits, risks, costs and consequences generally associated with each option; and (d) user’s right to refuse recommended medical options and explain the implications, risks, and legal consequences of such refusal. (2) The health care provider concerned must, where possible, inform the user as contemplated in subsection (1) in a language that the user understands and in a manner which takes into account the user’s level of literacy. (3) Where the user exercises the right to refuse a treatment option, the health provider may at its discretion require the user to confirm such refusal in a formal manner. (4) In this section, the word “user” refers to any person who seeks or intends to seek medical care from a health care provider and the expression	We propose the House amends the Bill by deleting the entire clause 8 and substituting thereof with the following new clause:- 8. (1) Every person has a right to public health information. (2) Subject to Article 35(1) (b) of the Constitution, the national government, county government 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; d) Procedures for access and use to the health services e) Procedures for providing feedback on quality 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 profile by diseases per country;	As it is Clause 8 of the Bill seeks to limit the provisions of Article 35 of the Constitution with respect to the right to information without providing qualifications/ statutory safeguards.

“health care provider” includes any health facility.	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.	
15. (1) The national government ministry responsible for health shall — (a) ensure the development and regular updating of a national health policy and government legal framework following the letter and spirit of the Constitution, issue guidelines for its application and promote its implementation at all levels; (b) develop and maintain an organizational structure of the Ministry at the national level comprising of technical directorates; (c) ensure the implementation of rights to health specified in the Bill of Rights, and more particularly the progressive realization of the right of all to the highest attainable standard of health including reproductive health care and the right to emergency treatment; (d) ensure, in consultation and collaboration with other arms of government and other stakeholders, that there is stewardship in setting policy guidelines and standards	We propose the House amends the Bill by deleting the entire clause 15 and substituting thereof with the following three new clauses- Duties Of The National Government 15. Subject to the Constitution, the national government ministry responsible for health shall- (a) Develop health policies, laws and administrative 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 county governments, develop, adapt and customize regional and	(a) Clause 15 (1) (c), (q), (u), and (w) and are all functions that can be undertaken by both levels of government in the performance of their constitutional functions. The bill attempts to vest them exclusively to the national government. (b) Clause 15 (1), (d), Whilst clause 15(1) (d) of the Bill is important, it does not recognise the other level of government as required by Article 6(2) and 189 of the Constitution. County governments are not just stakeholders in the health sector. They are a level of government and thus a critical player in the health sector. (c) Clause 15 (1) (f), (h), and (o) of the bill all provide for devolved functions. With these clauses national government will have taken over devolved functions. This is unconstitutional. The Constitution has clearly delineated the responsibilities of the two levels of government. (d) Clause 15 (1) (j) provides that national government shall set guidelines for the

for human food consumption, dietetic services; (e) offer technical support at all levels with emphasis on health system strengthening; (f) develop and implement measures to promote equitable access to health services to the entire population, with special emphasis on eliminating the disparity in realization of the objects of this Act for marginalized areas and disadvantaged populations; (g) develop and promote application of norms and standards for the development of human resources for health including affirmative action measures for health workers working in marginalized areas; (h) provide for medical audit of deaths with a special emphasis on maternal and neonatal deaths as a tool for the further development of obstetric and neonatal care; (i) develop, through regulatory bodies, standards of training and institutions providing education to meet the needs of service delivery; (j) set guidelines for the designation of national and county referral health facilities; (k) through respective regulatory bodies to develop and ensure compliance on professional standards on registration and	international health standards to regulate the health sector. (e) Set standards and formulate policies to guide the practice of traditional and alternative medicine. (f) Develop and regulate research for health standards. (g) In consultation with county governments, 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 standards; (i) Put in place mechanisms for enforcement of the health standards including , where necessary prosecution of offenders; (j) Provide capacity building and technical	designation of national and county referral health facilities. Conceivably, these guidelines can't be used to take over devolved functions. The guidelines must conform to the letter and spirit of the constitution. Facilities that are already transferred to counties can't be reclassified back to the centre using this clause. This will be unconstitutional. There is need to subject this power to the Constitution and also create a framework where they are devolved with full consultation of the other level of government (e) .Clause 15 (1) (n) states that the national government will provide for accreditation of health services. It is not clear what this means. It can be used as a conduit to undermine the devolved government. It is important for the bill to simply state that national government will policies, norms and standards in the health sector. Issues that are problematic in the sector are better addressed through a forum of inter-governmental relations for the sector that is supposed to be convened by the Cabinet Secretary responsible for health in accordance with the Intergovernmental Relations Act 2012. (f) Clause 15 (2) of the bill provides that the Cabinet Secretary responsible for Health shall make regulations on any matter where it is necessary or expedient in order to implement any provision of this Act and to implement
--	--	--

licensing of individuals in the health sector; (l) coordinate development of standards for quality health service delivery; <u>(m) provide for accreditation of health services;</u> <u>(n) provide for accreditation of health services;</u> (o) coordinate all health aspects of disaster and emergencies; (p) ensure through intergovernmental mechanisms that financial resources are mobilized to ensure uninterrupted access to quality health services country wide; (q) promote the development of public and private health institutions to ensure their efficient and harmonious development and in the common interest work towards progressive achievement of the right to health; (r) provide for the development and expansion of a countrywide national health information management system; (s) facilitate all forms of research that can advance the interests of public health; (t) develop and manage the national health referral facilities; (u) promote the use of appropriate health technologies for improving the quality of health care; (v) collaborate in the common interest with	assistance to county governments as may be required; (k) Coordinate the development of criteria for 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 information from the counties in accordance with section 42 (o) Facilitate all forms of research that guide the development of appropriate health policies; (p) Determine the human resources skills and capacity required for health service delivery for the national government. Duties Of The County Governments	within Kenya measures agreed upon within the framework of any treaty, international convention or regional intergovernmental agreement to which Kenya is a party. Whilst this section is important, the constitutional obligation to consult the other level of government as provided for in Article 6 (2) and 189 of the Constitution can't be wished away. Therefore it is important to require consultation with the other level of government. This won't in any way compromise or take away the powers of the Cabinet Secretary. Actually, it will help in seamless implementation of government policies whether defined by local circumstances or informed by multilateral or treaty obligations. In view of the foregoing, the Council proposes that the present clause 15 of the bill be broken down into three distinct clauses in the manner proposed. The first clause to provide for the functions of the national government while the second clause to state the functions of the county governments while third clause to capture the aspects of inter-governmental relations. We have proposed how these clauses should be stated.
---	---	--

the health authorities of other countries and with regional and international bodies in the field of health; (w) establish an emergency medical treatment fund for emergencies to provide for unforeseen situations calling for supplementary finance; and (x) provide policy guidelines in public-private partnerships for health to enhance private sector investment.	16. Subject to the Constitution, the county government shall be responsible for- (a) The development of county policies, laws, administrative procedures and procedures and programmes for 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 is 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- (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; (h) 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; (i) Coordinating and implementing county health sector activities , including development of county health strategies, partner coordination, data management and research and training; (j) 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;	
--	---	--

- | | | |
|--|--|--|
| | <p>(k) Collaborating with other sectors to ensure effective implementation of national health standards for the protection of health and safety of the consumers;</p> <p>(l) Overseeing the enforcement of health standards in other sectors in respect of delegated functions from the national government ;</p> <p>(m) Coordinate county disasters and emergencies;</p> <p>(n) Report on timely basis disasters, existing epidemics surveillance;</p> <p>(o) Collaborating with and providing access and practical support for monitoring standards compliance undertaken within the county by the national government ministry responsible for health , national government regulatory bodies, and professional regulatory bodies established under any written law;</p> <p>(p) Providing access , collaboration and practical support for operations of the national government at the county level;</p> <p>(q) Establishing administrative and operational frameworks to entrench the values and</p> | |
|--|--|--|

	principles of the Constitution in all health sector departments and institutions; (r) Developing and promoting public participation in the planning of county health activities and management of county health facilities; (s) Carrying out skills competence assessment, train and capacity building, notwithstanding continuous professional development of healthcare professionals; (t) Supervise internship programmes in line with the national standards; (u) Develop and manage the county health referral facilities and ensure progressive access to healthcare in these facilities by all; (v) Determine the human resources skills and capacity required for health service delivery for the county government; and (w) Timely notification to the national government and other counties on notifiable diseases. Intergovernmental Collaboration For Health Service Delivery 17. (1) National and County governments may,	
--	---	--

through the health sector inter-governmental consultative for 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 inter-governmental 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 any other written law; and
- (d) Developing a 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 the distribution, for the public health services, of health products and technologies.	
16. (1) There shall hereby be established the office of the Director-General for health. (2) The Director-General for health shall be recruited through a competitive process and appointed by the Cabinet Secretary.	We propose the House amends the Bill in clause 16(2) by deleting the words '<i>Cabinet Secretary</i>' immediately appearing after the words '<i>appointed by the</i>' and substituting therefor with the words '<i>Public Service Commission</i>' The new clause 16 (2) should provide as follows:-	The Cabinet Secretary can only appoint an officer in the public service on delegation by the Public Service Commission. Article 234 (2) vests the powers to the Commission.

	(2) The Director-General for health shall be recruited through a competitive process and appointed by the Public Service Commission .	
17. The Director-General shall— (e) promote the public health and the prevention, limitation or suppression of infectious, communicable or preventable diseases within Kenya; (f) advice the two levels of Government on matters of national security on public health; (h) prepare and publish reports and statistical or other information relative to the public health; (j) register, license and gazette all health facilities;	We propose the House amends the Bill in clause 17 as follows:- (a) in paragraph (e) by inserting the words ‘<i>in consultation with county governments</i>’ immediately after the words ‘<i>promote the public health and the prevention.</i>’ (b) In paragraph (f) by inserting the words ‘<i>through forums of inter-governmental relations convened by the Cabinet Secretary</i>’ immediately after the words ‘<i>national security on public health</i>’ (c) In paragraph (h) by inserting the words ‘<i>in consultation with county governments</i>’ immediately before the words ‘<i>prepare and publish reports</i>’ (d) By deleting the paragraph (j) The amended paragraph should read as follows:- 17. The Director-General shall— (e) in consultation with county governments, promote the public health and the prevention, limitation or suppression of infectious, communicable or preventable diseases within Kenya; (f) advice the two levels of Government on matters of national security on public health through forums of inter-governmental relations convened by the Cabinet Secretary; (h) in consultation with county governments	These functions of the Director General are too wide. They encroach on the functional autonomy of county governments. Issues of national importance that counties ought to be aware of are coordinated through a forum of intergovernmental relations that is convened by the Cabinet Secretary. It is also not clear how the DG will register, license and gazette all health facilities. Of what purpose? This is extremely unconstitutional. We have redrafted these clauses to offer some clarity.

	prepare and publish reports and statistical or other information relative to the public health;	
19. (1) There shall be established with respect to every county, a county executive department responsible for health, which shall be in line with the health policy guidelines for setting up county health system and shall in all matters be answerable to the Governor and the County Assembly subject to the provisions of the Constitution and of any applicable written law. (2) There shall be established the office of the County Director of health who shall be a technical advisor on all matters of health in the County.	We propose the House amends the Bill in clause 19 as follows:- (a) By deleting clause 19(1) and (2) and substituting therefor with the following new clauses:- 19. (1) There shall be established for each county government a department responsible for health. (2) The department shall comprise – (a) The County Executive Committee member responsible for health; (b) The chief officer; and (c) The County Director of health (b) In clause 19(4) by deleting paragraph (a) and substituting thereof with the following new clause ;- (a) be a qualified health professional duly registered by a recognised statutory body. (c) In clause 19 (5) by deleting paragraph (f).	a) The Constitution vests the executive authority at the County level to the County Executive Committee. This clause, while well intentioned, makes a mockery of this. It is constitutionally untidy. Besides, the mandate of establishing and abolishing county offices is the prerogative function of the county government as provided for in the County Government Act. The proposed forum by Director general provide avenue to control counties that is unacceptable. Cooperation across the two levels of government is provided under Inter-Governmental Relation Act 2012. b) The proposal that the county director of health will be answerable to Director General at the National Level is unconstitutional. The relationship between the two levels of government is one of consultation and co-operation. c) The Cabinet Secretary health is under a duty to convene a forum of inter-governmental relations to address pertinent issues relating to ppublic health occurrences including disease outbreaks, disasters and any other health matters. d) It is also important to open up the qualifications of County Director of Health in the manner proposed.

20. The county executive department responsible for health shall, in furtherance of the functions assigned to it under Fourth Schedule of the Constitution be responsible for—	We propose the House amends the Bill in clause 20 by deleting the words ‘<i>The county executive department</i>’ immediately appearing before the words ‘<i>responsible for health</i>’ and substituting thereof with the words ‘<i>The county department</i>’ The amended clause should provide as follows - 20. The county department responsible for health shall, in furtherance of the functions assigned to it under Fourth Schedule of the Constitution be responsible for—	The reference to ‘county executive department’ in the bill is constitutionally untidy. We have provided the correct reference.
24. Subject to section 15 of the Sixth Schedule to the Constitution, the management, operation and further development of public health facilities institutions shall be devolved progressively to the county government, and in assessing suitability of devolution to a given county the following considerations shall apply— (a) the eligibility and capacity of a given county to assume the responsibility involved; and (b) maintenance of access to any such devolved institution by authorized bodies	We propose the House amends the Bill by deleting the entire clause 24.	Clause 24 is irrelevant as the Fourth Schedule of the Constitution has already devolved health care. As per the Fourth Schedule of the Constitution, health services excluding management of national referral health facilities and health policy have been devolved to the County Governments. Progressive devolution is an alien concept. Moreover, national government is constitutionally obligated to undertake capacity building and render technical assistance to counties. In this regards, national government is required to develop short-term, medium-term and long-term administrative measures to ensure that county governments undertake devolved health functions in accordance with national policy, norms and standards.
25 .Without prejudice to the distribution of health functions and services between the national and county levels of government as set out in Fourth Schedule of the Constitution, the national Government shall manage and be responsible	We propose the House amends the Bill in clause 25 as follows:- (a) In clause 25 (a) by inserting the words ‘ and not transferred to the counties at the commencement of this Act’ immediately after	(a) This clause should be rephrased in the manner proposed. If Clause 25(a) is allowed, the National Government will simply classify some devolved facilities as national facilities thereby taking them away from the

for— (a) any public health institution classified as a national referral facility under this Act; (c) any institution or service dependent for its function on expertise that is a shared resource as classified from time to time in regulations under this Act (f) facilitation through inter-governmental institutions, procurement and supply chain management of public health goods including vaccines, pharmaceutical and non-pharmaceuticals for the purpose of ensuring control of highly infectious and communicable health conditions, putting measures for quality assurance and standards as well as measures for guarding against resistance strains in the interest of public health; and	the words ‘national referral facility’ The amended clause should provide as follows:- 25 .Without prejudice to the distribution of health functions and services between the national and county levels of government as set out in Fourth Schedule of the Constitution, the national Government shall manage and be responsible for— (a) any public health institution classified as a national referral facility and not transferred to the counties at the commencement of this Act ; (b) by deleting clause 25 (b); (c) by deleting clause 25 (c); (d) by deleting clause 25 (d) and substituting thereof with the following new clause:- (d)..laboratories and other institutions that were designated as national at the time of the commencement of this Act or laboratories established by an Act of Parliament. (e) by deleting clause 25 (f); (f) by deleting clause 25 (g);	management of counties. In case of any reclassification of facilities, the process and criteria would have to be agreed upon by both National and Counties. The use of the phrase ‘without prejudice’ does not really cure the legislative mischief in this clause. (b) Under Clause 25 (c) the responsibility over a shared resources that is devolved falls squarely on the concerned county government. It can’t be taken over simply because it is a share resource. We have proposed that this clause be deleted from the bill. (c) Clause 25 (f) undermines the constitutional authority of Counties to undertake own procurement by purporting to give the National Government the power to manage procurement and supply chain management of public health goods. Procurement is a vital component of the devolved health function and counties cannot be denied the same. We have proposed that this clause be deleted from the bill. (d) Clause 25 (g) is already provided for in Article 186 of the Constitution. There is no need to replicate it here.
26. The technical classification of levels of health care shall be as set out in the First Schedule. <i>(In the First Schedule it provides as follows;-</i> 1. The In-charge is a registered medical practitioner with a Masters degree in a health related field and with training and experience of	<i>In the First Schedule there is a classification that is proposed. We propose amendment as follows:-</i> a) In note that appears under classification of Level 1 at page 267 of the bill, the House deletes the words ‘<i>The in charge is the community health extension worker</i>’ and	(a) Persons who are in charge of level 1, 2 and should be qualified in the manner stated. (b) The technical classification under clause 26 takes away level 5 hospitals from the management of the counties. This claws back

over ten (10) years in senior management. 2. Level 5 and 6 shall be National Referral Hospitals. 3. Facilities from levels 2-5 can be upgraded by the Director-General based on a set criteria. .	substituting thereof with the words ‘ <i>The in charge is a qualified health professional duly registered by the relevant statutory body</i>’ b) In note that appears under classification of Level 2 at page 267 of the bill, the House deletes the words ‘<i>The in charge is a nurse or clinical officer</i>’ and substituting thereof with the words ‘ <i>The in charge is a qualified health professional duly registered by the relevant statutory body</i>’ c) In note that appears under classification of Level 3 at page 267 of the bill, the House deletes the words ‘<i>The in charge is a clinical officer</i>’ and substituting thereof with the words ‘ <i>The in charge is a qualified health professional duly registered by the relevant statutory body</i>’ d) In note that appears under classification of Level 6 at page 269 of the bill at Number 2, the House deletes the words ‘<i>Level 5</i>’ immediately appearing before the words ‘ <i>and 6 shall be.</i>’ e) In note that appears under classification of Level 6 at page 269 of the bill at Number 3, the House deletes the entire note 3 and substituting thereof with the following new paragraph:- 3. Subject to the Constitution, facilities from levels 1-5 can be upgraded by the Director-General based on a set criteria developed in consultation and concurrence of county	devolution of healthcare. It is unconstitutional. The National Government cannot unilaterally reclassify health facilities. Counties must be consulted and give consent to any reclassification of a health facility within their control. Under the first schedule on Level 6 Tertiary Hospitals, there is an indication that level 5 and 6 hospitals shall be National referral Hospitals. (c) This Bill cannot by itself upgrade county facilities already transferred to counties into national referral hospitals. (d) Part 3 of the same section indicates that facilities from levels 2-5 can be upgraded by the Director-general based on set criteria. This is unacceptable and should not be allowed to take place. These are county government functions and allowing a National government institution to have an overbearing mandate as this will not only usurp county governments functions but is also a strategy to recentralize county functions back to national government.
---	---	--

	governments. Provided that the upgrade shall not lead to the transfer of a facility from one level of government to the other level of government.	
27. (1) There is hereby established the Kenya Health Professions Oversight Authority charged with the responsibility of providing an oversight role to the regulatory function of the national health system and ensuring the adequate co-ordination of joint activities of regulatory bodies within the health sector.	We propose the House amends the Bill in clause 27 by deleting the words '<i>charged with the responsibility of providing an oversight role to the regulatory function of the national health system and ensuring the adequate co-ordination of joint activities of regulatory bodies within the health sector</i>' immediately appearing after the words '<i>Kenya Health Professions Oversight Authority</i>' The amended clause should provide as follows:- 27. (1) There is hereby established the Kenya Health Professions Oversight Authority. f	(a) There is no need for clause 27 (1) to establish and provide the functions of the Authority when the functions are already outlined in clause 30 of the bill. . (b) However, the Health Professional Oversight Authority would fit in so long as its role is limited to amalgamating all the health regulatory bodies and associations and developing standards for the professionals' bodies and has no role in management or appointment of human resource. (c) Management of human resource for health is under the county governments. However in case of need for posting or distribution of human resource can be undertaken under an inter- governmental mechanism like the committee that has just distributed the newly posted medical doctors to ensure principle of equitable distribution of human resource across counties

28. (1) The Authority shall comprise— (a) a chairperson who shall be appointed by the Cabinet Secretary and shall be a health professional who meets the requirements of Chapter six of the Constitution of Kenya; (b) the Principal Secretary of the Ministry of health or his representative; (c) the Director-General for health or his representative; (d) the Attorney General or his representative; (e) one member nominated by each of the health regulatory bodies established under an Act of Parliament; (f) three representatives nominated by the health professional associations registered by the Registrar of Societies who are not regulated or registered by any regulatory body; (g) one representative from the private sector appointed by the Cabinet Secretary; (h) one representative from consumer rights bodies appointed by the Cabinet Secretary; and (i) the Chief Executive Officer, appointed by the Authority, through a competitive process and who shall be the secretary to the Authority. (2) The Authority shall be supported by a Secretariat which shall be headed by the Chief Executive Officer. (3)The powers of the Authority shall be vested in the advisory Board. (4)The business and affairs of the Authority shall be conducted in accordance with the Second	We propose the House amends the Bill by deleting clause 28 and substituting thereof with the following new clause:- 22. (1) The Authority shall comprise- (a) A chairperson, who shall be appointed by the Cabinet Secretary and shall be a health professional who meets the requirements of Chapter six of the Constitution of Kenya; (b) The Director-General for health or his or her representative; (c) The Attorney General or his or her representative; (d) Three member nominated by each of the recognized health professions; (e) Three representatives nominated by the Council of County Governors; (f) One representative from consumer rights bodies appointed by the Cabinet Secretary; and (g) One person nominated by each of the following bodies- 1. Civil Society Organizations in the	The Composition of the Board of the Authority should include representatives from both levels government as well as the private sector.
--	---	--

Schedule.	health sector; ii. Kenya Private Sector Alliance representing the health care providers in Kenya; and iii. The registrar of the Authority who shall be an ex officio member without voting rights. (2) The Authority shall be supported by a Secretariat which shall be headed by the Registrar. (3)The business and affairs of the Authority shall be conducted in accordance with the Second Schedule.	
30. The Authority shall– (a) maintain a master register of all health professionals working within the National Health System;	We propose the House amends the Bill in Clause 30 by deleting clause paragraph 30 (a)	It is our view that the respective regulatory bodies will keep the concerned register. The role of the Authority is to oversight these does.
PART V OF THE BILL:-PROVISIONS ON HEALTH PRODUCTS AND HEALTH TECHNOLOGIES	We propose the House amends the Bill by deleting the entire Part V and substituting thereof with the following new Part V:- 42. (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	(a) Clause 32 of the Bill ought to establish the proposed agency. It is unconventional for an Act of Parliament to list the functions of an agency in its content and then go ahead to propose that the agency will be established by another Act of Parliament (b) Clause 37 of the Bill is unconstitutional. County Government enjoy financial and procurement autonomy. Procurement through KEMSA is a matter that is better

	by law perform including 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 (3) The agency may form committees for the better carrying out of its mandate under this Act and any other written law. 43. (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 Organisation (WHO) guidelines and other international standards ratified by Kenya.	handled through inter-governmental agreements not stated in this manner.
--	---	---

- | | | |
|--|--|--|
| | <ul style="list-style-type: none"> 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 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 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 products 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, analyzing and regulating medical products and technologies including veterinary products, mining chemicals and poisons.	
--	--	--

44.(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 more of the activities specified in section 34(1) whether by way of trade or otherwise, unless one has a valid license granted by the Agency established under this part.

(3) Any person, firm or institution possession of a license issued under this section shall display the same at a conspicuous place and shall produce the license 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;

1) It is sufficiently safe under the

	normal conditions of use; b) 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 approval of the agency commits an offence. 45.(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 an 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. 46. 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. 47 (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.	
38. (1) The National health system shall devise andimplement measures to promote health and to counter influences having an adverse effect on the health of the people including— (a) interventions to reduce the burden imposed by communicable and non-communicable diseases and neglected diseases, especially among marginalized and indigent population; (b) interventions to promote healthy lifestyle including physical activity, counter the excessive use of alcoholic products and the adulteration of such products, reduce the use of tobacco and other addictive substances and to counter exposure of children and others to tobacco smoke; (c) the promotion of supply of safe foodstuffs of sufficient quality in adequate quantities and the promotion of nutritional knowledge at all population levels; (d) general health education of the public;	We propose the House amends the Bill in clause 38 by deleting the word '<i>national</i>' appearing immediately before the words '<i>health system</i>' The amended clause should provide as follows:- 38. (1) The health system shall devise andimplement measures to promote health and to counter influences having an adverse effect on the health of the people including— (a) interventions to reduce the burden imposed by communicable and non-communicable diseases and neglected diseases, especially among marginalized and indigent population; (b) interventions to promote healthy lifestyle including physical activity, counter the excessive use of alcoholic products and the adulteration of such products, reduce the use of tobacco and other addictive substances and to counter exposure of	We have proposed that the word 'national' be deleted from the clause so as to make this an obligation of both levels of government.

(e) a comprehensive programme to advance reproductive health including— (i) effective family planning services; (ii) implementation of means to reduce unsafe sexual practices; (iii) adolescence and youth sexual and reproductive health; (iv) maternal and neo- natal and child health; (v) elimination of female genital mutilation; and (vi) maternal nutrition and micro nutrient supplementation.	children and others to tobacco smoke; (c) the promotion of supply of safe foodstuffs of sufficient quality in adequate quantities and the promotion of nutritional knowledge at all population levels; (d) general health education of the public; (e) a comprehensive programme to advance reproductive health including— (i) effective family planning services; (ii) implementation of means to reduce unsafe sexual practices; (iii) adolescence and youth sexual and reproductive health; (iv) maternal and neo- natal and child health; (v) elimination of female genital mutilation; and (vi) maternal nutrition and micro nutrient supplementation.	
PART VIII:-TRADITIONAL AND ALTERNATIVE MEDICINE	We propose the House amends the Bill by deleting the entire Part VIII	The Council is aware that there is a Traditional Health Practitioners Bill, 2014 and therefore this part should be covered in that particular Bill.
48 (3) 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.	We propose the House amends the Bill in clause 48 (3) by inserting the words '<i>in consultation and concurrence of the Chairperson of the Council of County Governors</i>' immediately appearing before the words '<i>Cabinet Secretary shall</i>' The amended clause should provide as follows. 48 (3) The Cabinet Secretary shall in consultation and concurrence of the Chairperson of the Council	Blood transfusion will dominantly be undertaken in the counties. The obligation to consult and get concurrence of counties is constitutionally enshrined (Article 6 (2) and 189 of the Constitution)

	of County Governors prescribe through regulations- (a) the criteria for the approval of organ transplant facilities; and (b) the procedural measures to be applied for such approval.	
54. (1) The Ministry of health shall ensure progressive financial access to universal health coverage by taking measures that include—	We propose the House amends the Bill in clause 54 (1) by inserting the words ‘<i>in consultation with county governments and collaboration</i>’ immediately after the words ‘<i>health shall</i>’ The amended clause should provide as follows:- 54. (1) The Ministry of health shall in consultation and collaboration with county governments ensure progressive financial access to universal health coverage by taking measures that include—	The obligation created by this section is a shared one
55. The National Treasury shall facilitate the opening and maintenance of a bank account for purposes of operationalizing conditional grants, donations and any other monies for every health facility both at national and county levels in line with public financial management Regulations.	We propose the House amends the Bill by deleting clause 55.	This clause should be deleted. Conditional grants are funds that are given to the counties from the national governments own share of revenue and ought to be disbursed through the County Revenue Fund to aid in accountability purposes. Any funding mechanism that contravenes the Public Finance Management Act 2012 and the Constitution won’t be allowed. Operating bank accounts outside the provisions of the PFM will greatly undermine financial management at the national and county level.
56. (1) The Cabinet Secretary shall pursue strategies conducive to the development of private health services and their attunement to the needs of the population.	We propose the House amends the Bill in clause 56 by inserting the words ‘<i>and County Governors</i>’ immediately after the word ‘<i>Cabinet Secretary</i>’	Health is a shared function.

	The amended clause should provide as follows:- (1) The Cabinet Secretary and County Governors shall pursue strategies conducive to the development of private health services and their attunement to the needs of the population.	
72. The Cabinet Secretary shall, in consultation with the Director-General for health ensure the enactment of legislation that provides for among other things	We propose the House amends the Bill in clause 72 by deleting the words ‘<i>with the Director-General for health</i>’ and substituting thereof with the words‘ <i>with the Chairperson of the Council of County Governors</i>’ The amended Clause shall provide as follows:- The Cabinet Secretary shall, in consultation with the with the Chairperson of the Council of County Governors’ ensure the enactment of legislation that provides for among other things	The obligation to consult and get concurrence of counties is constitutionally enshrined (Article 6 (2) and 189 of the Constitution)
75 (3) All specialists shall be treated as a national asset in order to sustain internship training and specialist services to ensure standards and equity.	We propose the House amends the Bill by deleting clause 75(3)	Counties can sponsor the training of specialist who should be compelled to work for the counties that supported them
Clause 78 of the Bill contains provisions on public service in the health profession.	We propose the House amends the Bill by deleting clause 78	Matters relating to public service of all workers including health professionals are already covered in the County Government Act 2012. There is no need to replicate them here.
79. The Cabinet Secretary shall make regulations generally for the better carrying out of the provisions of this Act and without limiting the generality of the foregoing, theCabinet Secretary may make regulations for—	We propose the House amends the Bill in clause 79 by inserting the words ‘<i>in consultation and concurrence of the Chairperson of the Council of County Governors</i>’ immediately appearing before the words ‘ <i>Cabinet Secretary</i>’ The amended clause should provide as follows:- The Cabinet Secretary in consultation and	The obligation to consult and get concurrence of counties is constitutionally enshrined (Article 6 (2) and 189 of the Constitution)

	concurrence of the Chairperson of the Council of County Governors shall make regulations generally for the better carrying out of the provisions of this Act and without limiting the generality of the foregoing, the Cabinet Secretary may make regulations for—	
--	---	--