****

**CONSOLIDTAED MATRIX: SUBMISSIONS MADE ON THE NATIONAL HEALTH INSURANCE BILL [B11-2019]**

| BILL [B11-209] Chapter/Clause | **STAKEHOLDER COMMENTS** | **STAKEHOLDER RECOMMENDATIONS** | **PROPOSED AMENDMENTS** |
| --- | --- | --- | --- |
| Preamble | The Preamble provides a vague description of how the NHI will be funded and much of the detail pertaining to the sustainability of the funding mechanisms related to the NHI is either lacking or unclear. | Suggestion: Add a clause addressing the social and economic determinants of disease, which will include cooperation with and action by other sectors. This is paramount to reducing the burden of disease, and the overall burden on the health system. A coordinated, whole of government approach which links with the NHI objectives is required.  “quality personal health care services” should be emphasised as a separate point. Financial protection should be defined and should be checked against the Competition Act. | AND IN ORDER TO –   * achieve the progressive realisation of the right of access to quality personal health care services, within a strengthened public and private health system; |
| **Clause 1: Definitions** | “Primary health care”   * definition fails to capture the spirit of the Primary Health Care Approach, as defined in the Alma Ata Declaration of 1978. * definition needs to define allied health professionals more clearly. It is unclear whether the NHI Bill is specifically referring to practitioners who are registered with the Health Professions Council of South Africa (HPCSA) and who are not allied health professionals by that definition. In addition, the definition needs to stipulate which practitioners are envisaged as allied health professionals and as such primary health care practitioners. * should clearly mention Environmental Health/ Municipal Health Services. * definition should include palliative services.   “emergency medical treatment”   * should be defined so that there is a common understanding.   “healthcare professional”   * should be defined to mean any persons registered with the health statutory councils in South Africa. * the Bill excludes, pharmacists, pharmacies and pharmacy support personnel. It would not be possible to achieve the goals of the NHI without pharmacists.   “health care service”   * definition is vague and does not cover all health services, as clearly defined in the National Health Act (NHA). * Provincial, district and municipal health care services are not clearly defined * should make reference to a legislation where Municipal Health Services has been defined. * should include the provision of services using digital channels. * should include environmental health.   “primary health care nurse”   * should be defined as per the South African Nursing Council (SANC). * Primary care nursing professional is a category not recognized by SANC and must be removed.   “ambulance services”   * in terms of the Constitution, this falls within the exclusive jurisdiction of the provinces. The NHI Bill however defines “emergency medical services” as inclusive of ambulance services and only provides for one payment mechanism for such services.   “health goods and health-related product”   * The use of terminology is confusing as a different, undefined term of “*health products”* is then used in clause 38. * definitions do not allow for the services rendered by orthotic and prosthetic health care providers. * the definition of “health-related products” should be removed from the NHI Bill, and the correct term should be “health goods” or “health products”, with the preference for health products as this is the internationally accepted term as used and defined by the World Health Organization (WHO). In addition, health products should include medicines, vaccines, diagnostics and medical equipment. As such, the definition would be aligned to the vision of universal health coverage (UHC).   “complementary cover”   * as read with the provisions of clauses 6(o), 8(2) and 33 creates uncertainty and threatens access of patients to existing health cover and their right to obtain their own social security cover. * definition is problematic if read with other sections of the NHI Bill related to services “not reimbursable” by the NHI Fund. It is suggested to include a section dealing with complementary cover, cover of medical schemes, etc.   “comprehensive health care services”   * makes no direct provision for the progressive realisation of health care by means of benefits, especially in providing orthotics and prosthetics. Orthotics and prosthetics are essential due to the direct impact on the outcome of the medical intervention.   “health care service provider”   * the concern is that the definition of health care service provider appears only in clause 1; whereas, in the NHI Bill references are made to health care providers. In addition, the definition of a “health care service provider” differs from the same definition in the National Health Act (NHA), where it is defined as a person registered at a professional council. * Clarity is required regarding health service providers such as community health workers, mid-level workers and traditional healers. * The definition of the “National Health Act” is too broad for the purposes of this legislation.   “referral”   * definition excludes private health establishments, which is against the spirit and intention of the NHI Bill. It is proposed that “in terms of section 44(2) of the National Health Act”be removed from the definitions.   “strategic purchasing”   * should include health goods. In addition, clarity is needed on what is meant by active purchasing. * definition is inconsistent with the text of the NHI Bill and should be reconsidered. | “complementary medicine” should be included under Definitions.  “basic health services” must be clearly defined to be in line with the Constitution as well as accepted international standards.  “comprehensive health care services”, the definition is vague and needs to specifically include Environmental and Municipal Health Services.  Consistency in the use and definition of terms for “medical devices” and “in vitro diagnostics (IVDs)”. These are currently used in the Medicines and Related Substances Act.  All references to “quality” should be replaced with “good quality”.  The words “reasonable quality” should be replaced by phrases that quantify the quality instead of leaving it to be subjective.  Replace the term “beneficiary” with the term “user”. All beneficiaries will be “users” as defined in the NHA, but not all “users” will be beneficiaries of the NHI Fund.  The definition for “central hospital” should refer to public and privatehospitals.  A “health establishment” also refers to health care practice. It is proposed that health care practice should be excluded from the definition of “health establishment” as it is included under “health care service provider”.  Need to define what municipal health care services are.    “Contracting Units for Primary Health Care” and “District Health Management Office” need to be defined clearly.  The definition for “Formulary” referred to in clause 38(4), should be defined.  Reasonable time period” – To ensure stakeholder compliance with the provisions of clause 6(1)(f), these terms should be defined and the parameter be determined for when a delay in access to health care services is unreasonable.  A definition for “reasonable time period” should include “to access healthcare services within published time periods aligned with globally accepted standards”.  “Timely” – This term should be defined in terms of specific time periods.  “Reasonable quality” – the term “reasonable quality” as set out in clause 11(1)(g) requires definition.    The NHI Bill is silent on how “reasonable quality” will be determined, which raises concern about whether medicines will need to be registered with the South African Health Products Regulatory Authority (SAHPRA).  “Best practices” – the term “best practices” set out in clause 11(1)(i) is undefined in the NHI Bill in terms of how the Fund will give effect to developing “best practices” and to what extent stakeholder participation will be encouraged when the Fund develops these practices.  “health worker” needs to be defined.  “medical equipment” and “health technology” should be defined in the NHI Bill.  Definitions for “conflict of interest”, “related party” and “confidential information” should be provided in the NHI Bill. Furthermore, the definition for “confidential information” should include the term “financial interest”. | Proposed definition for “primary health care”: ‘‘primary health care’’ means addressing the main health problems in the community through providing promotive, preventive, curative*, palliative* and rehabilitative services.  “personal health care service benefits” under “complementary cover” must be defined.  The proposed definition is “*personal health care service benefits”,* these are health care services, which are taken within a patient’s private capacity as opposed to that which takes place under the instruction of a health care practitioner or within the setting of a health care organisation.  PHC definition: The word “care” has been omitted from “primary allied health care professionals”.  To correct the “health goods and health related products” definitions, the insertion of a new definition should be considered as follows: *“health product”* means a product regulated in terms of the Medicines and Related Substances Act (Act 101 of 1965), the Hazardous Substances Act (Act 15 of 1973), the Foodstuffs, Cosmetics and Disinfectants Act (Act 54 of 1972) and/or any other product regulated by a law governing its quality, efficacy or performance and supply of products used within the provision of health care service.  The definition for “provider payment” should exclude the phrase *“in a way that creates appropriate incentives*”, as this might be interpreted as perverse.  The definition for “provider payment” should exclude the word *“uniform*” to allow for flexibility in the development of different reimbursement models.  “supplier” must be defined. The proposed definition is:  *“supplier” means a natural or juristic person in the public or private sector providing goods and services other than personal health services. This includes companies that manufacture, wholesale, retail, distribute or import health products.* |
| CHAPTER 1: PURPOSE AND APPLICATION OF ACT | | | |
| **Clause 2: Purpose of Act** | The proposed system in the NHI Bill will not increase access to health care on a progressive basis. Rather it will deprive many of the access that they currently enjoy. The NHI Bill currently contradicts a number of UHC principles as outlined in the 2017 White Paper. While the NHI Bill successfully addresses fragmentation in financing, it risks further fragmentation across a number of other health system dimensions.  Clarity is required regarding which institutional arrangements are to be put in place, and how these will be implemented to support the implementation of NHI, as significant restructuring and strengthening of the system are required. |  | Clause 2(a) “serving as the ~~single~~ national purchaser and ~~single~~ national payer of health care services in order to ensure the equitable and fair distribution and use of quality health care services;”  Clause 2(c) “providing for equity and efficiency in funding of health care services by the pooling of funds and the ~~strategic~~ centralised purchasing of health care services, medicines, health goods and health-related products from ~~accredited and~~ contracted health care service providers.” |
| Clause 3: Application of Act | Clarification is needed as to why the NHI Bill does not apply to members of the State Security Agency (clause 3(2)(b)). While it is understood that the National Defence Force has its own medical service, the rationale for excluding the State Security Agency is not clear.  Clause 3(3): Laws such as the Protection of Information Act, 2013 and the Consumer Protection Act, 2008 are constitutional laws and derive their authority from the Constitution. Therefore, the NHI Bill cannot override them. These laws are excluded from the NHI Bill in clause 3(3).  Clause 3(5): The NHI Bill excludes the Competition Act. The exclusion of oversight by the Competition Commission could allow for potential abuse of dominance or horizontal collusion.   * The NHI Bill provides a possible violation of section 217 of the Constitution by excluding the Competition Act. This could be problematic and would detract from a price negotiation system that would provide flexibility in pricing and adaptability to the needs of specific populations and areas. * It is unclear from the NHI Bill what the effect of the exclusion of competition principles from the conclusion of transactions under the Act will be and how this will play out in practice. | Since the Fund is not subject to the provisions of the Competition Act, it is crucial to ensure that the implementation of the referral pathways, including the criteria regulating same, are objectively justifiable, based on best medical evidence and do not give rise to unintended consequences of preferring certain health care service providers or health establishment over others. It would be prudent for the Fund to annually review and update the criteria that govern referral pathways. | Clause 3(5) should be deleted:  ***Only the NHI Fund should be exempt from the Competition Act. Heath care providers and suppliers should be subject to the Competition Act because they should not be allowed to engage in anti-competitive practices in relation to the Fund. The proposed amendment in the schedule of the Bill to the Competition Act achieves this.*** |
| **CHAPTER 2: ACCESS TO HEALTH CARE SERVICES** | | | |
| Clause 4: Population coverage | Clause 4(1)(e): The conditions for the users must be clear and adhered to. Clarification is needed as to the specific categories of foreign nationals. Will these include people without documentation, illegal foreigners, etc.? What steps will be taken or followed when these conditions are not met?  Clause 4(2)(a): Clarity is needed on what constitutes emergency care for asylum seekers and refugees. Furthermore, what will happen if a refugee or asylum seeker requires an assistive device, such as a wheelchair, brace, splint or communication device to enable functioning, from such emergency incidents?   * concerns that taxpayers will be expected to pay, among others, for the health care services of illegal immigrants and other foreigners and visitors to South Africa. This is not supported as taxpayers are already overburdened. * the provisions relating to asylum seekers and illegal immigrants will be impossible for doctors to implement. * To deny refugees access to only a few health care services will not be constitutional and they should be provided with access to healthcare in the same way and manner as the rest of the population of South Africa. It is submitted that they should have access to mental health care, in particular, to assist them with the list of difficulties they may be facing. * concern around the lack of full population coverage and the restricted access to health care services for asylum seekers and illegal foreigners. There are human rights considerations as well as the potential impact of communicable diseases that are not notifiable, including HIV, on overall population health. * the Bill’s provision for asylum seekers and undocumented immigrants amount to an unjustified limitation on access to health care services. * eligibility of foreigners could potentially cause an influx of foreign nationals into the country. This may place a greater burden on the already under-resourced health care system.   Clause 4(3): The rights of children to care under the NHI Fund must therefore exceed what is set out in the definitions of the NHI Bill under “health care service”.   * Clarity is needed on how the children of asylum seekers and illegal immigrants will gain access to health care. The State should extend antenatal and obstetric services to asylum seekers and illegal foreigners. It is unclear whether the NHI Fund will cover a range of additional essential services for children of asylum seekers and illegal immigrants. | Clause 4(1) should be amended to include the purchasing of health care services on behalf of a temporary resident and/or visa/permit holder.  It would be important at a population health level, for asylum seekers and illegal foreigners currently in the country, to be afforded the same rights as refugees, to access health care services.  Asylum seekers, undocumented migrants, students (including foreign nationals on study visas) and all children should be included as beneficiaries to clause 4(1).  Government needs to address urgently misinformation regarding the eligibility of foreign nationals as it relates to NHI benefits.  The NHI should include NGO's and NPO's in assisting the health care system with concerns related to asylum seekers or illegal foreigners.  Private medical insurance should be compulsory for any foreigner residing within South Africa.  The NHI Bill should include descriptive information on how emergencies should be handled, specifically as it relates to specialist interventions.  The Council for Medical Schemes should be required to include in its list of acceptable medical schemes, international medical schemes that can be used by foreign nationals travelling to South Africa. | Clause 4(1): The use of the term “illegal foreigner” should be reconsidered.  Clause 4(1)(b) “health care services for notifiable conditions of public health concern.    Clause 4(4) the phrase “user” should be replaced with “beneficiary” |
| Clause 5: Registration of users | Clause 5: The NHI Bill makes no provision for the registration of aged persons and mentally challenged adults.  Clause 5(1): The NHI Bill stipulates that users of NHI services must register with an accredited provider. If registration is limited to a particular accredited provider, what are the implications for people who move or become ill on holiday or business?   * The NHI Bill does not contain a provision expressly stating that membership to the NHI Fund is mandatory. It is not clear how employees who have not registered with the NHI will be managed. * There is no need to register with the NHI if a user is already registered on the Department of Home Affairs (DHA) identification system as the NHI system is linked to the DHA system. Any person contemplated in clause 4(1) – (3) should be able to walk into a primary health care service provider or establishment and upon identification via DHA’s identification system receive health care. Health care is sought when needed and a user/patient may not have the necessary documents. Registration is merely an administrative obstacle for the public as well as the NHI personnel. * What will the implications be for a person who travels to another province and health care services are needed?   Clause 5(2)(a): The registration of undocumented children whose births are not registered could result in barriers to access health care.  Clause 5(5): The requirement to provide proof of residence will exclude vulnerable persons and deny them access to health care services.  Clause 5(5)(b): What will be the implications for a person who cannot provide an original birth certificate? Will this affect the person’s NHI benefits? Does this imply that a user may only visit a specific hospital or clinic? | Clause 5 must be expanded to allow for the registration of the user who is on vacation or not within the geographical area in which they have registered. Add a clause on how this will be managed.  Consideration is required on how injured employees, who are not registered under the NHI Fund, requiring medical treatment or medical assessment to be eligible for compensation will be dealt with. Their inability to get medical access may compromise their ability to access compensation benefits under the Compensation Fund.  Clause 5(4)(b) should be reconsidered and provide that an appropriate person with sufficient expertise and skill is required to perform the registration, and that must be designated by the provider or health establishment to assist the child to register, rather than “any employee”.  Clause 5(5): Regarding ‘proof of habitual place of residence’. Not all residences have proof of habitual residence. It is not clear how this will impact the registration of the user. The implications of not having any documents as stipulated in this clause should be discussed in the Bill.  It is recommended that explicit provisions in the NHI Bill, for how users without documentation will be registered in the system and retain their right to access health care services despite not having documentation. | Add a clause to include other recognised means of identification such as “passport and drivers licence”  Clause 5(7) ~~Unaccredited health establishments whose particulars are published by the Minister in the Gazette.~~ The fund must~~, on behalf of the fund~~, register beneficiaries and maintain a register of all ~~users~~ these beneficiaries containing such details as may be prescribed.  A potential typing error where clause 5(7) states that “Unaccredited health establishments must maintain a register of all users”. Should clause 5(7) not start with the word “An accredited”? |
| **Clause 6: Rights of users** | Clause 6: In relation to user access to accredited facilities, there is a risk for limited coverage of services and/or increased costs for users who have to travel to other facilities should the facility they are meant to access not be/no longer be accredited.  Clause 6: There is a lack of transparency as to what is available and; hence, nothing to prevent the State from withholding a reasonable standard of care under the “available and appropriate” clause. This is a concern, given the State’s failure to procure and provide appropriate medication and food in a number of its hospitals.  Clause 6(d): The term "unreasonable grounds" is not defined in the NHI Bill and it is, therefore, unclear under what circumstances the refusal of health services will be reasonable or unreasonable and whom at a health establishment will be charged with deciding when to refuse access to health service benefits. Should an injured employee be refused treatment, this could exacerbate their injury and increase the related compensation costs that are borne by the Compensation Fund. This increased cost may have to be passed on to employers which may not be sustainable.  Clause 6(f): Clarity is required as to who will determine the standards and what recourse will be available when "reasonable time periods” are exceeded. The NHI Bill similarly does not specify whether a user who is already consulting with a particular specialist for a pre-existing condition will be permitted to continue consulting with the aforementioned specialist unless a referral is first obtained in terms of clause 7(2)(d)(ii).  Clause 6 (o):   * creates duplicative coverage by medical schemes and undermines the single-payer model of NHI. * This clause has implications for the package of health care services that will, or should be, offered by accredited health care providers, and for health care service providers whose scope might fall outside the NHI funded benefits package. Additionally, there might be the case where unaccredited providers may decide to offer services not provided for in the Formulary, which could affect the performance of the accreditation system, the organisation of health services in a region, and the quality of care provided. * There are also views that clause 6(o) prohibits patients from obtaining out of Formulary treatments in the NHI. This is problematic, as these patients would often be vulnerable and may not be able to fund such care out of pocket or afford medical scheme cover. * Further on clause 6(o), users of the NHI Fund retain the right to seek additional medical funding support from private medical aid schemes, not all citizens can afford to contribute to two medical insurance funds. A concern is that the extent of conditions and treatment that will be covered under the NHI may not be exhaustive and may leave other conditions uncovered, such as rare diseases. | The implications for rural areas is that there may be insufficient service providers or that users have to incur costs to travel to the accredited facilities that may be out of their geographical areas.  The NHI Bill must clearly express that a healthcare practitioner will not lose his/her accreditation if he/she prescribes medicines not set out in the Formulary in circumstances where the costs of the medicines would not have otherwise been covered by the Fund or based on clinical criteria such as treatment failure. | A clause should be added that addresses management of the user should they present with a medical emergency.  Clause 6(o) “to ~~purchase~~ pay out of pocket means, health care services that are not covered by the Fund through a complementary voluntary medical insurance scheme registered in terms of the Medical Schemes Act, any other private health insurance scheme or out of  pocket payments, as the case may be. |
| Clause 7: Health care services coverage | Clause 7(1): It is argued that this clause contains no criteria to guide the Benefits Advisory Committee (BAC) in making its determination, meaning that the BAC can determine a package of benefits arbitrarily with no reference to the reality of the healthcare needs of society, or what good clinical practice and appropriate treatment would mean.  Clause 7(2)(d)(ii): With the imposition of referral pathways, injured employees run the risk of not being referred to a specialist at all in the event that the primary health care provider is of the opinion that the referral is not necessary. In certain remote areas, the choice of accredited healthcare service providers may be limited or non-existent.   * Who will develop and ensure that the referral pathways are efficient and effective? * Will referral pathways be specific to geographical areas, or will there be generic referral pathways related to levels of care in the healthcare system?   Clause 7(2)(d)(iii) states that a user is not entitled to healthcare services purchased by the Fund if he or she fails to adhere to the prescribed referral pathways.   * What mechanisms will be put in place to safeguard patients who are transferred outside the pathways for specific reasons? * What degree of choice will be available to patients in consultation with the referring doctor?   Clause 7(2)(f) centralises the provision of health care by placing the management of all central hospitals under the NDoH. Provinces are at the coalface of the delivery of health services and must be given more funds to improve public health care, not less.   * Designating a central or tertiary hospital to national administration will negatively affect the district health system, separating central hospitals from the burden of disease within the community. * Clarity is needed on how the national government will take control of the decision-making that will be allocated to the hospitals on assets that are owned by the provinces.   Clarity is needed in clause 7(2)(f)(iv) on what is meant by “cost centres”.  Clarity is needed in clause 7(3) on how the portability of users will be initiated and who needs to initiate the action of porting a user to a different primary health care provider.  Clause 7(4): It is imperative that the element of reasonableness is included in the circumstances where funding of treatment may be refused. This would ensure that the funding for treatment is not refused on unreasonable grounds.  Clause 7(4)(c): The Formulary and Essential Medicines List (EML) must be set on the basis of evidence-based medicine. Drug procurement cannot be based exclusively on the Formulary. | It is proposed that the framework for referral pathways be reconsidered to allow freedom of choice.  Clause 7(4)(a): Medical "necessity” must be objectively determinable.  The criteria in terms of which the health service benefits package must be set must be spelt out in the NHI Bill itself.  The State should ensure that patients that are unresponsive to treatment, or experience other forms of treatment failure also have access to medicines to address their needs.  The Formulary should include innovative medicines and a sustainable choice of generics. The Essential Medicines List (EML) must ensure that existing access to medicines and molecules by patients in terms of the existing EML prior to implementation of the NHI Bill, is not reduced or limited post the implementation of the NHI.  Medicines on the EML must be exclusively locally manufactured. Hence, a “Restricted List” of products, which cannot be imported into the country, should form part of the NHI Bill.  The state procurement of medicines, medical devices and equipment, distribution of medicines to health care centres and all other services should be set aside for majority black-owned companies. | Under clause 7(1): it is argued that there is no reason why the Minister should be consulted by the Fund for the purchase of healthcare services. Hence in consultation with the Minister should be deleted. |
| Clause 8: Cost coverage | Clause 8 creates duplicative coverage by medical schemes and undermines the single-payer model of NHI.  Concern was expressed on the possible violation of the Constitution with the usage of the word “must” in clause 8(2) instead of the word “may”.  Clause 8(2): It is not clear how this clause will be implemented. What control does the NDoH have over the cost of services provided by private medical schemes for services not covered by the Fund? Will the fund be managed from national with representatives from province and the districts? How is the gap between these levels going to be managed? There needs to be a clear pathway of communication established between these levels that are part of the NHI Bill.  Clause 8(2)(b): This clause will encourage non-adherence to the referral pathway and will create a parallel system by undermining referral pathways.  There are views that the BAC will not have the operational presence or reach to implement clause 8(2)(c) of the NHI Bill.  The current regulatory framework governing medical schemes leaves them vulnerable to anti-selection and will decrease the affordability of medical scheme cover for members (due to higher monthly contributions required). Clause 8(2) is likely to exacerbate anti-selection, and as a result, increase the cost associated with medical scheme membership.  It was argued that people must be free to pay for health care services in whatever manner they choose. A restriction on a person’s freedom to pay for health care services amounts to a restriction on access to health care services. In addition, there is a constitutional right to freedom of association. People should not be forced to join a medical scheme or take out private insurance in order to pay for health care services not covered by the Fund if they do not wish to do so. |  | Clause 8(2) is unnecessarily restrictive and should rather read […] “through a voluntary medical insurance scheme or *any other means*” […]  An amendment is proposed in the wording of clause 8(2)(c) to refer to the *“health care service provider”* rather than the Benefits Advisory Committee.  On the role of medical schemes, a part of clause 8(2), refers to a voluntary medical insurance scheme, should be removed since it contradicts clause 33 on what is to be covered by private medical schemes. |
| CHAPTER 3: NATIONAL HEALTH INSURANCE FUND | | | |
| Clause 9: Establishment of the Fund | There are views that while the NHI Fund is planned to be fully functional during the last phase of the implementation process, it is clear from its required capacity and resources that, unless the NDoH proactively plans and begin the process of implementation appropriately, even more, serious delays would be encountered, which would undermine the credibility of the NHI.  The centralisation of the function of the Provinces in delivering healthcare, which is the second-largest function of all the Provinces, at a national level infringes on their Constitutional mandate.  Clarity on the role of the Minister of Finance is sought in this regard.  The importance of entrenching accountability and exactly how the Fund will be managed better than any other statutory body is imperative. | The establishment of the Fund with its specialised technical skills, would require adequate time for its capacity to be built and be fully functional. |  |
| Clause 10: Functions of Fund | The NHI Fund is empowered to issue directives (clauses 10(1)(f) and 56). In terms of administrative law principles, a regulatory body normally issues directives and the NHI Fund is not a regulatory body.  There is a view that clause 10(1)(g) results in direct market manipulation by Government in setting prices. It is proposed that a separate, independent regulatory body be set up to determine prices in the medical industry.  Clause 10(1)(l): clarity on what type of accreditation will be required of suppliers is needed. In addition, if accreditation is required, who will do that accreditation? Existing accreditation bodies such as SAHPRA for health goods must be recognised.  Most international well-run health systems centralise pooling and decentralise planning, organising, purchasing and running health services. However, the NHI Bill proposes the opposite and requires careful evidence-based motivation. | For the Fund to execute its functions and powers, strong, efficient and quality operations must be in place, and service provision must be high-quality, acceptable, appropriate and timely.  The ambit of the NHI Fund’s powers to issue directives must be set out clearly in the NHI Bill.  Oversight of the Fund must be centralised in a body independent of the Fund.  Compliance with and the prevention of duplication with already existing accreditation/certification legislation should be ensured.  It is proposed that the NHI Fund accounts to the Board instead of the Minister.  Clause 10(1)(o) should provide for remedial action based on the findings. | Under clause 10(1)(d) it is suggested that the word “certified” be inserted before “accredited” to align with subsection (b).  Insert new clause 10(1)(v): *“Establish mechanisms to co-operate and collaborate with non-health sectors to ensure the prevention of ill health and disease”.*  Clause 10(3) should be amended as follows: “The Fund performs its functions in accordance with health policies approved *in accordance with the National Health Act.*” |
| **Clause 11: Powers of Fund** | The price-setting mechanism contemplated in clause 11(2)(e) is incompatible with many requirements of the PFMA and PPPFA and undermines section 217 of the Constitution.  Clause 11(1)(h) suggests that the Fund will investigate complaints against itself. No justification is given for this. A body that is independent of the Fund, such as the Health Ombud, should investigate complaints against the Fund.   * the Fund must not be seen to be the player and the referee. This does not provide for the requisite checks and balances, and users, providers, health establishments or suppliers would not regard this as credible.   The Performance Monitoring Unit of the NHI Fund that is mentioned in the White Paper is no longer mentioned in the NHI Bill. This seems to be a very important unit, and it is not clear why it was removed. | It is recommended that the NHI Bill explicitly state how clause 11(1)(d) will work.  Clause 11(1)(l) should include that the sharing of information should be subject to laws applicable to such information, for example, the POPI Act.  The NHI Bill should adequately delineate the relationship between the Single Exit Price (SEP) system created by the Medicines and Related Substances Act 101 of 1965 and the procurement of medicines at the “lowest possible price” as contemplated in clause 11(2)(e) of the NHI Bill.  Complaints against the Fund, healthcare providers, health establishments and suppliers should be investigated, in collaboration with law enforcement agencies, statutory councils and regulatory authorities.  It is proposed that the procurement process must be clear and efficient; reimbursement must be transparent and timeous; and that the Central Supplier Database (CSD), managed by National Treasury, be maintained in the NHI Fund. | Clause 11(1)(h) should be amended to provide for the establishment of an independent Ombud, or independent investigation function outside of the Fund.  Clause 11(i)(vi) should be amended as follows: *“fraud prevention, waste and abuse within the Fund and the national health system”.*  Clause 11(1)(m) should be amended to include: *“conclude an agreement with any person for the performance of any particular act or particular work, or supply of health goods, or the rendering of healthcare services in terms of this Act, and terminate such agreement, in accordance with the prescribed legal terms and conditions and the provisions of the Constitution;”*  Clause 11(2)(e) should be amended to read: *“negotiate the most cost-effective price for goods and healthcare services without compromising the quality of its services, the interests of users or violating the provisions of this Act or any other applicable law”.* |
| CHAPTER 4: BOARD OF FUND | | | |
| **Clause 12: Establishment of Board** | There is a view that clause 12 is inconsistent with the PFMA and that there is a clear contradiction between clause 12 that states the NHI Board is accountable to the Minister and paragraph 6.12 (pg. 52) of the Memorandum that states that the Board is accountable to Parliament.  The accountability of the Board to the Minister is of concern. It is essential that the Board of the NHI Fund should be, and should be seen to be independent.  No provision is made for the Compensation Commissioner or representatives of the Compensation Fund to be part of the NHI Board. | Given the significant resources the Fund will manage; it is proposed that the accountability to establish the Board should sit with Parliament or an Independent Judicial Panel rather than an individual (Minister) over whom there is too little oversight.  The Board should be accountable to the users of the Fund. It is vital that the appointment of the Board, CEO, procurement officer, chief financial officer, etc. are done at arm’s length to the State. The NHI cannot emulate other SOEs and needs transparent appointment processes.  All amendments and decisions taken by the Board should be publicly announced.  Consideration should be given to the costs of setting up and running Boards and Committees, which could be substantial. The Fund could be run as a government component/agency and therefore reduce the expenditure on setting up a Board. |  |
| **Clause 13: Constitution and composition of Board** | The Minister holds extraordinary powers in the constitution of the Board.  Clause 13(3): The process to appoint the advisory panel must be clarified in the NHI Bill. It is not clear what the shortlisting procedure will be.  Clause 13(5)(e) should be broadened to include personal or professional interests in the Fund or the health sector by immediate family members which may also lead to a conflict of interest.  Clarity is also needed as to who will be shortlisting candidates for appointment to the Board. Furthermore, names of shortlisted candidates should be published for public comment.  As the NHI Fund is deemed to become a public enterprise of utmost importance for the country, it may contribute to increasing public trust in the NHI, if the Board is appointed by Parliament and is accountable to Parliament as well as to the Minister.  Clause 13(7): It is suggested that such resignation also should be in accordance with recognised labour standards that would include required periods of notice.  Clarity is needed on potential contradiction, clause 13(8)states that the Minister may remove a Board member who is disqualified in terms of any law or who is unable to continue to perform their functions of office for any other reason. And clause 13(9), states that the Minister may dissolve the Board on good cause.  Dissolving the Board “on good cause” is entirely at the discretion of the Minister and can thus be susceptible to political whims. This undermines the independence of the Board. The threat of removal without any oversight, on any ground, and without due inquiry, would render board members unlikely to express views that may not align with that of the government or the majority of Board members. | Clear, explicit, recruitment and appointment for all Board members and executives are required to retain the independence of the Board, guard against interference in governance matters and best serve the stated objectives of the Fund.  The Minister should not have a representative on the Board. This is to prevent undue political interference.  Accountability should be set for the Board and the public should be allowed to participate in its appointment.  The dissolution of the Board or the removal or resignation of members should proceed through Parliament.    There needs to be active participation of strategic members of EXCO on the Board. There were views are that the CEO should be given voting powers.  Clause13(5) should specify that the Board members should not have criminal records or convicted for fraud and corruption, and must be persons of high integrity, requisite expertise and experience. In addition, disqualification of Board members should be similar to that of directors under the Companies Act.  Further, Board Members should have no previous history of working in industries that are associated with imposing a health burden: alcohol, tobacco, pharmaceuticals, etc.  Whenever a position on the Board becomes vacant before the expiry of the term of office referred to in clause 13(5), the Minister may appoint any other competent person, who meets the criteria listed in clause 13(5) of the Bill, to serve for the remainder of the term of office of the previous member, irrespective of when the vacancy occurs.  It is advisable that a provision be included to the effect that the removal of a Board member in terms of clause 13(8) should be done only after due inquiry and upon recommendation by the Board.  The areas of expertise for Board members should include: large scale fund management and administration, public procurement and the PFMA, strategic purchasing and pricing, international, public or private sector best practice, human resources, legal and governance.  To ensure transparent governance, a clause allowing for transparency regarding the dissolution of the board should be included. The same applies to the appointment of acting Board members.  Clause 13(9): The dissolution of the Board should require an inquiry and must be based on specified, objective grounds. Objective grounds for the dissolution of the Board may include poor or non-performance of functions and abuse of power. Under such circumstances, the Minister should be obligated to refer the matter to Parliament for consideration and where Parliament recommends that the Board be dissolved, the Minister has no discretion and must dissolve the Board. As such, Parliament must play an oversight role in the appointment of the Acting Board.  How does the Office of Health Standards Compliance fit into the Board of the Fund? Specific provision is required for close coordination between the Fund and the OHSC.  A new solution to the election of board members specifically for NHI is required. This NHI Board will control one of the biggest budget items in South Africa and would require the most dedicated, experienced and qualified board members to exercise proper control. Consideration of fit and proper status (including solvency, criminal history, previous conduct on other boards and/or removal from positions of trust, conflicts of interest, etc.) should be part of the selection process. | Clause 13(5)(b):have appropriate technical expertise, skills and knowledge or experience in health care service financing, health economics, public health planning, monitoring and evaluation, law, actuarial sciences, information technology and communication, public service administration, business management;  Clause 13(8)(c): The phrase “any other reason” is subjective and it is recommended that it be removed. |
| **Clause 14: Chairperson and Deputy Chairperson** | There are views that this clause is against the principles of democracy, enshrined in the Constitution.  It is put forward that clause 14(1) should prevent the Minister from appointing the member of the Board who represents him or her from acting as Chairperson. | The Board, and not the Minister, should in line with good corporate governance rules, appoint the Board chairperson and vice-chairperson.  The Bill should clearly state the powers and functions of the Chairperson, Deputy Chairperson as well as powers and functions of individual members to clarify potential conflict and ensure an efficient Board.  The Chairperson should be elected at the first siting of the Board and such result should be made formal by a Ministerial letter of appointment.  A definitive fixed term of appointment of the Board should be specified. |  |
| **Clause 15: Functions and powers of Board** | The inherent requirements for Board members are too vague.  Clause 15(3)(c) states that the Board must advise on comprehensive health care services to be funded by the Fund through the Benefits Advisory Committee. Sufficient expertise should be on the Board to ensure that this is possible. This requirement must be stated in clause 13(5)(b).  The powers of the Board are not comprehensive enough. The Board must be in control of the Fund and be responsible for steering the Fund. It must play a leadership and strategic role. The Board must also have the power to delegate functions without abdicating its responsibility.  It is submitted that there is an overlap between the functions of the Board in clause 15(3)(b) and the functions of the NHC in terms of the NHA, causing confusion.  There should be a separation between political and operational spheres as this may weaken the role of the Board. | The Board or its representatives should meet every six months to share information.  The NHI Bill should specifically set out how the Board will function in terms of the quorum required to make binding decisions, and whether the Chairperson will be the deciding vote in situations where deadlocks arise.  The functions and duties contemplated in the King Code of Corporate Governance should be included in the outline of the Board’s functions and powers.  It is recommended that each board member should serve a minimum term of three years to promote the independence of the Board and ensure continuity.  The remuneration and conditions of service of Board members should be clearly stipulated.  On clause 15(3)(d): The Board members should be selected so that they are able to fulfil these functions. Furthermore, it is not clear whether the Board can co-opt or contract advisors to assist with this activity. This should be added to the clause.  Clarity should be provided as to the meaning of “collective bargaining” as referred to in clause 15(3)(f). | Clause 15(3)(b) should state that the NHI Fund Board would have to, over time, develop a package of comprehensive health care services. |
| **Clause 16: Conduct and disclosure of interests** | There is a lack of good and ethical governance relating to the Board and CEO. Clause 16 does not actually make provision for or compel, Board members to disclose any interests that may conflict with the proper performance of his or her functions.  Clause 16(1)is framed too narrowly to protect the Fund sufficiently. Similarly, clause 16(3) only provides for the prevention of direct material interests of a monetary nature.    Clause 16(3): There are views that this should include indirect material interest to avoid clever restructuring of financial interests to circumvent this section of the NHI Bill. | Clauses 16(1) and (3) should be carefully constructed to guard against conflict, corruption and capture.  Clause 16(1) should be redrafted to include any direct or indirect conflict of interest, including paid employment, that may be in conflict with the proper performance of his or her functions.  Clause 16(3) should be amended to include indirect interests, and it should not be confined to monetary interests alone. |  |
| **Clause 17: Procedures** | A unique and unconventional corporate governance feature is that the Board *“*mustdetermine its own procedures” in consultation with the Minister. All these ministerial interactions and consultative requirements cannot be overlooked in terms of governance and accountability of all parties concerned. |  | The phrase “in consultation with the Minister” should be substituted with “*after consultation with the Minister*”. |
| **Clause 18: Remuneration and reimbursement** | The remuneration and conditions of service of Board members should be clearly stipulated. | It is recommended that the Independent Commission for the Remuneration of Public Office-Bearers determine the remuneration of the Board members. |  |
| **CHAPTER 5: CHIEF EXECUTIVE OFFICER** | | | |
| **Clause 19: Appointment** | Clause 19(1) indicates that a transparent and competitive process will be undertaken to appoint the CEO. However, subsection 3 then goes on to indicate the decision will be made by the Minister who must approve the recommendation of the Board. This presents a potential conflict of interest, with the Ministers having excessive influence, and could undermine the autonomy of the CEO. It is suggested that this appointment be confirmed at a higher level, either by Parliament or by the Presidency.  Clause 19(2) indicates that the Board, which was appointed by the Minister, will conduct interviews and that the Minister will approve the recommendation of the Board. This presents a potential conflict of interest, with the Minister having excessive influence, and could undermine the autonomy of the CEO.  It is unclear who is empowered to remove the CEO.  The powers of the CEO to deal with the financial affairs of the Fund are akin to the kinds of powers the PFMA envisages be entrusted to the accounting authority of a public entity (its Board). | The Board must appoint the CEO and other executive officers after a thorough and fair process that places qualifications and experience above all other considerations.  The eligibility criteria, or the lack thereof, should also extend to the appointment of the CEO.  The CEO must conclude a performance agreement with the Board.  The Bill must expressly state that the CEO, in carrying out his / her duties, should be subject to fiduciary duties akin to those provided for in section 50 of the PFMA. |  |
| **Clause 20: Responsibilities** | Clause 20(2)(e): While it is laudable that the NHI Bill makes provision for investigative powers in cases of corruption and maladministration within the NHI Fund, it is concerning that this does not occur through any independent body.  Other stakeholders do not support the creation of an investigative unit as contemplated in clause 20(2)(e), stating that it is likely to confer powers to the CEO, which would be open to abuse. | The NHI Bill does not provide for the establishment, constitution and composition of the investigative unit. As the impartiality of this Unit is crucial to the correct functioning thereof, the NHI Bill should in fact, at the very least, provide for the constitution and composition thereof.  Clause 20(2)(e) should be aligned with subsection (3)(i) to ensure that there are no different units with similar functions. The unit should also be independent to enhance accountability and trust.  It is essential that the investigative unit to be established functions completely independently from the Fund, the Department, the Minister and any other related persons and entities.  Clause 20(3)(g) appears to overlap with the Office of Health Products Procurement contemplated in clause 38. Hence, the governance structure should be aligned.  There is a need for a clear role definition between the different committees and some units to be established by the CEO in terms of clause 20(3). Specifically, this refers to the BAC and Benefits Design Unit (clause 20(3)(b)); Health Care Benefits Pricing Committee and Provider Payment Mechanisms and Rates (clause 20(3)(c)) Unit as well as the Provider Payment Unit (clause 20(3)(f)). | Clause 20(1)(c) should be removed since there are no decisions specified in subsection (6).  Clause 20(2)(e)(ii) “liaising with the Province and District Health Management Office concerning any matter contemplated in subparagraph (i).”  Clause 20(3)(f) appears to be a duplication of the duties under subsection (3)(c) and; therefore, should be removed.  Clause 20(5)(c) should ensure consistent use of applicable terminology and; hence, should read as follows: “*the number of accredited and approved, contracted healthcare service providers, health establishments and suppliers*.”  Clause 20(5)(d) should be amended to read: “*the health status of the population in accordance with the metrics as may be prescribed*.” |
| **Clause 21: Relationship of CEO with Minister, DG and OHSC** | The reporting lines in clause 21 of the NHI Bill between the Executive Authorities and the Administration needs to be expressed more clearly.  It is argued that the notion expressed in clause 21(2) is highly unlikely when there is a clause in the NHI Bill that states that “the Board will forward their recommendations to the Minister for approval by Cabinet”. |  |  |
| **Clause 22: Staff at executive management level** | No input |  |  |
| CHAPTER 6: COMMITTEES ESTABLISHED BY THE BOARD | | | |
| **Clause 23: Committees of Board** | In terms of Committees, and given the extensive jurisprudence and recommendations by, for example, the King Reports, it would have been expected of the NHI Bill to propose an Audit Committee, a Remuneration Committee and perhaps a specific Patient Interest or similar committee, with powers to co-opt independent members of such Committees.  Due to governance concerns, Board members should not serve on Committees. Furthermore, members of committees should not be employed by the State.  Clarity should be provided as to the membership of these committees. | The Board, and not the Minister, should establish all Committees in this section.  The governance framework must comply with the King Code of Corporate Governance (King IV).  The committees should appoint a chairperson from among its members, not the Minister.  The size of these committees must be specified in the NHI Bill.  Requirements for all these committees should be aligned and included in the NHI Bill. These should include disclosure of interests, procedures and remuneration. The procedures should also include disqualification criteria, conflict of interest and the filling of vacancies. These should all be the responsibility of the Board. | Clause 23(2) should be removed due to governance concerns. |
| **Clause 24: Technical Committees** | It is unclear what “Technical Committees” mean and what functions such committees would fulfil without violating corporate governance principles and interfering in the day-to-day management of the Fund.  There are concerns that the NHI Bill does not explicitly allow for expertise from the private health sector in the composition of the structures of the Fund, including the Board, the BAC, Health Benefits Pricing Committee, Stakeholder Advisory Committee and the interim committees established or to be established during the implementation of the NHI.  The inherent requirements for the Technical Committee’s members are too vague.  It is not clear if the Technical Committees are comprised of members of the Board. It is assumed that these are not, given that the following is included in clause 24(3) [the person much be “fit and proper”, “have appropriate expertise or experience”, etc.].  It should be stated whether additional expertise can be brought in, or an expert can be co-opted into the Committee. | There is insufficient provision for the relative sizes, appointment processes and mandates of the various Committees in the NHI Bill. Committee members must have expertise across all aspects of health care service benefits, including medical technology, and pricing.  The NHI Bill should explicitly allow for private sector expertise in the composition of the Committees and other structures of the Fund.  There are views that there is an overlap between the tasks of the committees described in the NHI Bill and the action plans arising from the Presidential Health Compact. It is proposed that there be a process to identify these areas of overlap and coordinate actions accordingly to ensure optimal use of resources.  Academia should be included in the Technical Committees.  The eligibility criteria of persons to serve as members of these committees should also be strengthened.  Furthermore, the NHI Bill should set out a clearer framework for the establishment and composition of each of these committees, and that at minimum, the following issues should be addressed in respect of each committee:   * + Term of appointment;   + Procedure for appointing members;   + Minimum number of annual meetings;   + Fitness of persons that may be appointed;   + Compliance to employment equity policies;   + Procedure to fill vacancies on the committee;   + Number of persons to comprise the committee;   + Procedure for removal of members of the committee; and   + How remuneration of members will be determined. | Clause 24 should be combined with clause 23 since technical committees remain committees appointed by the Board. |
| CHAPTER 7: ADVISORY COMMITTES ESTALISHED BY MINISTER | | | |
| **Clause 25: Benefits Advisory Committee** | The NHI Bill does not adequately set out the appointment process, term, powers and functions of the advisory committees that will be supporting the Fund.  From a governance standpoint, the Minister should not be allowed to establish committees with independent powers that are imposed on the Board of the Fund. Hence, the title should be “Advisory Committees established by the Board”.  Clause 25(5) does not include private health establishments. How will the BAC determine the baskets of services that may be reimbursed at private health establishments?  No provision is made here for the representation of professional bodies or statutory bodies such as the HPCSA. | Clause 25(2): Membership of the BAC should include technical expertise in nursing and pharmacy as these professions are at the frontline of NHI implementation in the context of PHC Re-engineering.  The benefits package should not diminish the range of medicine molecules currently available and allow for a wide choice of medicines.  There must be a clear correlation between the recommendations of the BAC, affordability and the budget. A disjuncture will be disastrous and will need to be carefully managed and coordinated.  The minimum requirements should address the number of persons comprising the committee; appointment procedure; term of appointment; fitness of persons that may be appointed; minimum qualifications and experience; compliance to employment equity policies; procedure for removal of members; procedure to fill vacancies; remuneration or how remuneration will be determined; and the minimum number of annual meetings.  It is recommended that the Board be responsible for appointing members of the BAC. A transparent process for the appointment of these members must be set out in the NHI Bill.  The inherent requirements for the members must fit the responsibilities of these committees.  It should be stated whether additional expertise can be brought in, or an expert can be co-opted into the Committee.  If outside members are to be appointed then the appointment criteria should be similar to those of the Board members, including having proven expertise in the area, and not having a criminal record, etc.  It is recommended that the Benefits Advisory Committee and the Health Care Benefits Pricing Committee include at least two representatives from organized labour and civil society.  Members of the BAC should be selected from professional associations and be guided by the principles of evidence-based medicine and international treatment guidelines to ensure that proper systems are in place for determining an appropriate benefits package.  Clause 25(5)(b): The treatment guidelines and protocols must be evidence-based, approved by the Board and published in the Government Gazette.  Clause 25(5)(c): The Committee should only recommend to the Board.  It is proposed that the BAC be independent of the NHI and that it should operate under the auspices of the independent Supply Side Regulator as recommended by the Health Market Inquiry. | Clause 25(2) - Suggested deletion:  “The membership of the Benefits Advisory Committee, appointed by the Minister,  must consist of persons with technical expertise in medicine, public health, health economics, epidemiology, and the rights of patients, ~~and one member must represent the "Minister~~.”  Clause 25(2): Suggested addition: include individuals with biomedical engineering expertise and experience with medical devices and IVDs, as well as individuals with actuarial, financial, legal, business and IT expertise. |
| **Clause 26: Health Care Benefits Advisory Committee** | It is not clear how this Committee will function and how services and goods will be priced with relation to a service like occupational therapy if a representative from the professional grouping of occupational therapy is not included in this Committee.  Given the economic considerationsof supply and demand, as well as those pertaining to trade and industry, the appointment of this Committee should not be confined to those exclusively charged with improved health outcomes.  International best practice provides that such a committee be clearly defined in terms of their function to set prices objectively and independentlyfrom the functions of the Board, who are charged with the overall management of the Fund.  Clause 26(2) omits some key areas of expertise required for the discharge of such functions. | The Minister, in consultation with the Minister of Trade Industry and Competition, should appoint this Committee.  It is recommended that the required areas of expertise be expanded to also provide for those with expertise in coding and costing of health care; the pricing of private sector provision hospitals and medical professionals in particular; the cost of research and development and new health care technologies; the cost of medical infrastructure, goods and services; and those with competition law and local health care supply chain expertise. | Clause 26(2): Suggested edit: “expertise in actuarial science, medicines, epidemiology, health management, health economics, health financing, labour and rights of patients, and public health medicine, and one member must represent the Minister.”  Clause 26(2): Suggested addition: include individuals with experience in medical devices and IVDs. |
| **Clause 27: Stakeholder Advisory Committee** | The clause lists all stakeholders, other than business, while business is a key stakeholder that should form part of the stakeholder grouping.    The functions of the Stakeholder Advisory Committee are not clear, particularly how they can impact processes or decision-making.  It is not clear to whom the Stakeholder Advisory Committee will be accountable. | This clause must be amended to include business as a stakeholder to the Committee.  It is recommended that brokers or financial product advisory structures form part of the listed stakeholder groups represented on the Stakeholder Advisory Committee.  Include supply chain management experts within the Stakeholder Advisory Committee to provide critical guidance – particularly during the Fund’s inception stages.  The role of the Stakeholder Advisory Committee needs to be clarified and the priority-setting process should be within the remit of this Committee. | Suggested edit: “associations of health professionals, providers, patient advocacy groups and public health medicine in such a manner” |
| **Clause 28: Disclosure of interests** | It is proposed that all committees must function under the auspices of the Board. |  |  |
| **Clause 29: Procedures and remuneration** | It is proposed that the Board must determine these by notice in the Gazette. |  |  |
| **Clause 30: Vacation of office** | The Bill should include a clause that reflects the disqualification criteria, as well as a provision for conflict of interest.  Provision needs to be made for deceased members. |  |  |
| CHAPTER 8: GENERAL PROVISIONS APPLICABLE TO OPERATION OF FUND | | | |
| **Clause 31: Role of Minister** | The role of the Minister is excessive and undesirable. This clause is potentially open to legal and constitutional challenges.  Clause 31(1): The granting of extensive powers to the Minister has the effect of making key decisions subject to arbitrary political decision-making. The legal requirements and clinical elements of the system must be rational, objective, transparent, and not left to political intervention.  Clause 31(1)(b): The Fund is a Schedule 3A entity and the responsibility for governance and stewardship should lie with the Board.  The proposed governance structure of the NHI raises concerns. It does not meet the standards of good corporate governance as recommended in the King IV Report on Corporate Governance and it will entrench significant political power, which is to be avoided in the context of the current economic challenges created by political interference at SOEs.  There is a need for streamlining the NHI Management to mitigate overlapping roles. This will ensure management and successful implementation of the NHI Bill and assist in issues of accountability and transparency on the performance of the NHI.  Bureaucratic control will stifle innovation and promote corruption, adding to overall costs.  Two powers of the Fund and the Minister is concerning from a constitutional and rule legislative perspective, namely:   * That certain regulations could be published and finalized without public comment (clause 55(3)); and * That binding “directives” can be issued by the Fund (clause 56).   Autonomy of the Fund: The NHI Bill establishes the Fund as a Schedule 3A autonomous public entity, yet the powers of the Minister are heavily concentrated throughout the structure of the Fund thereby undermining its autonomy. Greater clarity is needed regarding the administrative structures that support the Fund and the CEO.  Appointees to the Board: Clause 13(1), (3), (8), and (9) grant too much power and authority to the Minister of Health. There are no mechanisms in place to ensure that the Minister (a political appointee) would not appoint his or her own party’s preferences onto the Board. This would allow for political appointees rather than technical experts who would be capable of independent oversight of the NHI.  The autonomous powers conferred on the Minister of Health to appoint and remove the eleven members of the NHI Board and to appoint the Chairperson of the Board is a concern.  The Minister, just like in other SOEs, is the sole appointer of this Board and certainly leaves him/her vulnerable to cadre deployment. There is a need to employ better checks and balances than what is stipulated in chapter 4 of the Bill.  There is concern with both the appointment process of the Board and its reporting lines. The proposed governance structure concentrates power on the Minister and does not adequately ensure the independence of the Board, which is essential given its extensive powers, including strategic purchasing and buying and selling of property. It locates excessive indirect authority with the Minister.  There are no mechanisms in place to ensure that a Minister is not vulnerable to potential political influences that might lead to politically motivated appointments, rather than purely technical experts, who would be in a better position to provide unbiased and independent oversight. The importance of the clear separation of political and administrative powers across every level of the public health system must find expression in the NHI Bill.  Submissions do not support the extensive role of the Minister of Health as set out in the NHI Bill. The NHI Bill gives the Minister the power to potentially veto every significant decision that the Board can make. This means that the Board cannot be held accountable for its decisions. This is contrary to well-established principles of corporate governance. The Board must not be able to escape accountability because of a decision by the Minister. The Board must be accountable for all of its decisions.  The Board must be free to appoint or terminate the services of the CEO of the Fund without the approval of the Minister. It is accountable to the Minister in terms of the PFMA but this does not mean it should have to obtain the Minister’s input on every decision it makes.  At the facility level where central hospitals will become “semi-autonomous” entities, it is critical that appropriate governance structures are designed to optimise service delivery and accountability especially as the Bill does not align the DHMOs with the District Health Councils established in section 31 of the NHA.  It is necessary to develop a new mechanism for the appointment of Board members for the NHI Fund. The budget envisaged for the NHI Fund will form one of the largest budget items, and a qualified, experienced and capable board, held to the highest standards of fiduciary duties, will be imperative to the Fund executing its mandate adequately.  The Minister has been afforded wide powers to regulate on issues significant to the operation of the Fund, and implementation of the NHI Bill, without sufficient guidance from the legislature as to how these wide powers should be exercised. Notwithstanding this, many of the issues on which the Minister can regulate are essential to the framework of the NHI scheme and, as such, are better placed in the NHI Bill (and having been considered by the legislature).  Adequate governance frameworks aimed at strengthening accountability mechanisms across the different stakeholders are required. The NHI Bill does not guarantee the independence of the Board and CEO. The Minister has extensive unfettered powers under the NHI Bill, though in certain instances, the Minister’s powers are exercised in consultation with other bodies or functions of the NHI. The governance processes in respect of the selection and functioning of the committees are also not adequately defined. Adequate representation of suppliers of medical technology products is encouraged. | The Fund and its Board members should be ultimately accountable to Parliament, and the powers of the Minister should be reduced to minimise the risk of political co-option.  The governance of the Fund must be decentralised and be inclusive to ensure transparency and accountability. Currently, the governance of the Fund falls largely on the Minister of Health. The Board of the Fund must be accountable to Parliament, rather than the Minister.  It is recommended that further roles be expressed in the NHI Bill for other stakeholders, in addition to the Minister, in the appointment process. Along with members of Parliament and the Minister, the structure responsible for the NHI Board appointment should include other health sector stakeholders with expertise. Mechanisms should be put in place to avoid potential conflict of interest that would hinder Board members’ ability to carry out their duties and to limit political interference in its processes.  For the appointment of Board members, a more decentralized approach, with more stakeholders involved and stronger mechanisms for transparency and public involvement is recommended. Furthermore, the appointment process should be located in Parliament.  Power must be diffused from the Minister to include a greater role for other stakeholders to create checks and balances against undue political influence.  The proposed Ministerial Advisory Committees must be converted into a Board.  The accountability mechanism of the NHI must be clearly defined in the NHI Bill to ensure that Government is accountable to the people and to deal with corruption. Although the NHI Bill addresses the penalties for corruption and fraud, it still does not explain how it will curb corruption and fraud.  Parliament (an ad-hoc or Portfolio Committee on Health, or a hybrid thereof) should conduct interviews and recommend names of board members. This is also in line with clause 49 of the NHI Bill, which states that NHI Fund will be appropriated annually by Parliament. Instead of the Minister, it is recommended that the President appoint members of the Board. The removal of board members should follow established principles and protocols regarding nomination by Parliament and appointment by the President. The Board should have the powers to appoint its Chairperson and Vice-Chairperson. The Board must appoint the CEO (and other executive officers) after a thorough and fair process that places qualifications and experience above all other considerations.  The NHI Bill should include further mechanisms for accountability and oversight, which are legislated. The process of appointing and removing members of the Board should be akin to the process of appointing and removal of members of Chapter 9 institutions whereby the NA is involved in the process. The Minister, in consultation with Parliament, should appoint committees.  There need to be clear definitions of powers, roles and capacities of all committees in relation to the Board and the Minister.  The Minister’s oversight powers should be reduced or counter-balanced by another authority, such as Parliament. Mechanisms should be specified beyond the public interview process, defined in clause 13(3), to ensure that appointments are not politically motivated, and there should be an open process of appointment, such as that used for appointing the SARS Commissioner.  The Fund should be accountable to Parliament, and the powers of the Minister should be reduced to minimise the risk of political co-option. International evidence has shown the importance of having a long-term vision that is not undermined by the five-year political life cycle of a Minister and leadership that is vulnerable to political motivation.  The Board must be able to determine benefits to be covered by the Fund without the prior approval of the Minister. The Board should be appointed by Parliament and not the Minister because this guarantees a more open and democratic process.  Clarity is needed as to the funding of advisory committees. The NHI Bill should state that should such committees be established, for purposes of assisting the Fund, then the Fund should fund such committees to deliver on its mandate.  These powers should be centralized in the Board, or the fiduciary duties set out in the PFMA to which accounting authorities are subject should be extended to the CEO. The Financial Sector Conduct Authority (FSCA) should be expressly afforded powers of supervision over the Fund, to ensure an additional measure of fiscal control and management.  Good governance requires legal frameworks that are enforced by an impartial regulatory body, for the full protection of stakeholders. The extensive powers of the Minister should be reviewed. It is advised that appropriate representatives from suppliers should be included to provide input on their experiences on the Stakeholder Advisory Committee.  It is proposed that clause 31(1) provides that the Minister and provinces are co-stewards of health. |  |
| **Clause 32: Role of Department** | Clause 32(1)(c) does mention health care services rendered by districts and Municipalities. It is unclear whether this is referring to Municipal Health Services.  In clause 32(2)(a) it is unclear what provinces are management agents of. Provinces should be playing a stewardship role.  In clause 32(2)(b) it is unclear who will have oversight over the hospitals as designated.  Clause 32(2)(c) states that Minister may ‘establish District Health Management Offices as government components’. The role of provinces is once again not clear. This should be the role of the Provinces in terms of establishment and oversight. | The non-personal healthcare services as mentioned under clause 32(2)(c) should be clearly spelt out to remove confusion in the interpretation. | Clause 32(1): Suggested edit: delete clause 32(1) (a - e), because the functions of the NDoH are outlined in the NHA and the Constitution.  Clasue 32(1)(c) *“*co-ordinating health care services rendered by the Department with the health care services rendered by provinces, districts and municipalities, as well as providing such additional non-personal health services as may be necessary to establish an integrated and comprehensive national health system;” |
| **Clause 33: Role of Medical Schemes** | There are concerns as to what would happen to medical schemes, as most patients will not be able to afford both the NHI and medical scheme contributions.  The complementary nature of NHI and medical scheme benefits needs to be clarified, in line with the Medical Schemes Act Amendment Bill. There are significant uncertainties in the nature of coverage between medical schemes and the NHI.  Clarity is needed regarding what benefits medical schemes will be permitted to cover. There is significant risk of increased out of pocket payments if medical schemes are prohibited from funding services.  It will be critical to ensure that the complimentary services of medical schemes do not encompass essential population health needs that would limit the Fund’s capacity to achieve equity in access and ultimately UHC.  There is a lack of clarity on the roles of the Fund, medical schemes and private health insurance.  The Bill should provide for purchasing complementary health service benefits that are not covered by the Fund through a voluntary medical insurance scheme registered in terms of the Medical Schemes Act. Furthermore, the same should apply to private health insurance to ensure that services (i.e. oncology) are also provided for in this category and to prevent challenges as previously experienced in the public health sector.  The prohibition on medical schemes to provide cover in parallel to the NHI by the NHI formularies and national standardization of care through procurement and national pathways will lead to health care potentially being reduced for some patients.  Limiting the role of medical aid schemes will not be sustainable.  Submissions were opposed to the prohibitions and limitations on private medical scheme cover for services rendered by the NHI as indicated in clauses 6(o) and 33 of the NHI Bill. This has a number of negative consequences. Clause 33 has vast implications for the South African economy, in general, and the private health sector, in particular.  A key assumption is that medical scheme members will be willing to switch from healthcare provided via the private sector and financed through medical schemes to healthcare services provided by the NHI. It is unlikely that medical scheme members would consider these two goods as substitutes. Indeed, the HMI provisional report finds that currently “the public health sector does not pose a significant competition constraint to the private sector for patients or service providers.” This assumption that healthcare received in the private sector and the public sector are substitutes is therefore unfounded.  For NHI to work there is a need for a single-purchaser model where the Government is the only institution that can buy services. All other insurances should supplement what the NHI does not offer.  There are fewer details around the role of the medical aids presented in the NHI Bill in comparison to the White Paper. It will be critical to ensure that these complementary services do not encompass essential population health needs that would limit the Fund’s capacity to achieve equity in access and ultimately UHC.  Clause 33 refers to the role of medical schemes, but there is no reference in the NHI Bill to other funders of health care in South Africa.  In its current format, clause 33 of the NHI Bill probably constitutes an unconstitutional infringement on the right to healthcare as contemplated in section 27 of the Constitution.  It would be substantially more useful to use the establishment of the NHI framework as an opportunity to improve the way that medical schemes function and to create an integrated medical schemes system capable of supporting the NHI Fund in facilitating access to quality healthcare.  The prohibition of medical schemes to provide cover in parallel to the NHI would limit patient access to health care and could be regarded as regressive.  It is unclear to what extent the medical aid-related services currently available under the COIDA regime, will be available under the NHI. | Medical Schemes should be allowed to continue to offer the same benefits covered by the NHI Fund.  A gradual phasing of the medical scheme tax rebate is recommended.  This clause should be amended so that it does not only deal with complementary services.  There is a need for certification and/or monitoring of all establishments and practitioners to provide healthcare services irrespective of whether they contract with the NHI fund or not, and related support for the achievement of this end, as well as incentives for contracting with the NHI fund.  Private medical schemes should co-exist with the public sector to deliver UHC.  It is recommended that the impact of reducing the role of medical schemes to complementary cover in the NHI implementation be assessed from a legal perspective.  The health service benefits and Formulary under the NHI Bill should take into account the medical aid and related benefits provided under COIDA to ensure that there is no coverage gap for injured employees.  There were calls for the publication of draft Regulations to be expedited for stakeholders to have a clear understanding of the legal framework that will govern NHI and that stakeholders should be allowed sufficient time to comment on these Regulations. |  |
| **Clause 34: National Health Information System** | Record keeping processes for continuity of care are required. Currently, there are numerous challenges with data collection, patient record keeping and transfer of information between the different tiers of the health care system.  Data management in the health system is fragmented, which makes it difficult to monitor and evaluate health services and to facilitate good decision-making; therefore, submissions support the development of a unique robust health information system in SA.  Health care workers, including therapists, have limited access to computers at the district or rural level and therefore it is unclear how this system will be implemented without the required infrastructure, human and financial resources to enable this national health information repository and data system.  Clinical information in most public hospitals that is not electronic is a challenge.  The NHI Bill does not provide clear guidance on the new biometric system required or the coverage required of the IT system that will track registration, provide electronic record keeping and manage transferable records.  There is a lack of specificity regarding the extent of development of this health information system and a lack of recognition that the current constraints to the collection of data are as a result of staffing shortages, particularly at primary care levels.  The National Health Information System envisaged in clause 34(3) must be strengthened to ensure that in addition to provisions of the NHA, it must also comply with the requirements of this Act.  The system developed should be an intelligent digital health care system that is compatible with the various platforms in current use by practitioners. | There is a need to create a national health information system first, to ensure that everybody is enrolled in the system as the initial stage. The country must move to digitize health care. NHI must invest in technology to run effectively.  It is suggested that the NHI Fund ring-fence budget for this purpose and appoint a highly-professional team to ensure its design and maintenance.  Health care workers, health care providers and persons in charge of health establishments must comply with provisions of the NHA and provisions of clause 40 of the NHI Bill in relation to access to health records and the protection of health records.  To ensure that information is easily provided and done in standardised electronic formats, the Health Patient Registration System should be aligned with the national health information system. |  |
| **Clause 35: Purchasing of health care services** | Clause 35(1) states that the NHI Fund must purchase health care services “in accordance with need”. This phrase gives rise to concern as it could lead to endless litigation to determine what the need is and not according to the benefit, it covers.  On strategic purchasing, there are no provisions that define the concept or describe how it is to be implemented and undertaken by the Fund.  Further on clause 35(2), if facilities did not receive accreditation due to factors related to funding or support (e.g. inadequate infrastructure etc.), what will the funding/financing arrangement be to ensure that these facilities can be improved to meet accreditation standards?  There is concern about the impact of using a Diagnosis-Related Groups funding model, as it fails to take into account outpatient expenses.  The reimbursement strategy must consider the total cost of providing a particular service. In the private sector, health service providers and health establishments are responsible for all their overheads, e.g. rental of rooms, purchasing of equipment, hiring of staff, obtaining professional indemnity cover, etc. Hence, reimbursement must be sufficient to cover these overheads. | The provisions regarding the purchasing of health care services, and the roles of the District Health Management Offices and the Contracting Units for Primary Health Care, and their relationships, are convoluted and need to be elaborated with clear lines of reporting and accountability.  The strategic purchasing model needs to be clarified and it is unclear on what basis “need” will be determined.  Clause 35(2): Clarity is required on the position of private hospitals and private medical specialists as well as other practitioners not part of CUPs. In addition, Fund transfer timelines should be provided as prescribed in regulation under the PFMA.  Clause 35(2) should be removed, as it has the potential to benefit the private healthcare sector. Currently, there is no Diagnosis-Related Group in public healthcare, hospitals are one-stop shops for everything.  Clause 35(4)(a): It is suggested that the remuneration mechanisms not be predetermined but left to the Pricing Committee and Board to determine the most appropriate mechanisms. Clarity is also requested on whether this would include fees payable to suppliers, or only to “service providers”.  Clause 35(4)(a) must be amended. There is a need to improve government services instead of privately owned companies.  Clause 35(4)(a): A definition for “capped case-based fee”, as well as what this comprises is requested.  Clauses 35 (4)(a) and (b) are disputed as they create disparities and do not strengthen government resources. They must not only be reimbursed on a capped fee but also be authorized. The authorization must come from a central hub controlled by the NHI.  Provisions should be made for consideration of small- and medium-sized suppliers for procurement even when they may not have national capability.  The procurement process must be clear, efficient and effective and suppliers must be timeously reimbursed. | Clause 35(1): Purchasing must be aligned to the requirements of the PFMA and the NHI Bill should make specific reference to this. Suggested edit: “The Fund must actively and strategically purchase health care services on behalf of users in accordance with need, *and in alignment with requirements as per the PFMA.”*  Clause 35(3) - Suggested edit: “The Fund must transfer *the agreed reimbursement* for primary healthcare services *directly to contracted* Contracting Units for Primary Health Care at the sub-district level as outlined in clause 37.”  Clause 35(4)(b): on public ambulances services…This provision may be in conflict with 35(4)(a) and should be deleted. |
| **Clause 36: Role of District Health Management Office** | The NHI Bill does not adequately explain the reason for District Health Management Offices or Contracting Units for Primary Health Care. It also does not set out their role, how they will be governed and to whom they will be accountable.  There are concerns with the DHMO’s capacity to oversee mental health care within primary care settings; especially given the primary care systems central role in referrals.  Performance-based financing such as targets for personal preventative services (screening, health talks, etc.) must be included.  It is submitted that this clause is not aligned with the proposed amendments to the NHA included in the Schedule to the NHI Bill.  This is an area of strategic importance, as this is where the current public sector primary healthcare system starts to engage with GP’s in the private sector. Hence, it requires wide consultation with the private sector and relevant stakeholders. The management teams appointed at this interface need to be suitably qualified for this critical role.  There is concern with the relevance of this structure as it will add another layer of expenditure to bureaucrats instead of service delivery.  Concerning clause 36 and 37, it is argued that the insertion in the NHA is in conflict with the substantive provisions of the NHI Bill. Moreover, the establishment of these entities does not create the legal persons that are required to enter into contracts with the NHI Fund. | DHMOs and CUPs are unnecessary and will add unjustifiable layers of administrative costs to the system.  The mandate of the district health system should be extended to manage district clinical specialist teams, which should consider the inclusion of, at a minimum, a psychiatrist, occupational therapists, psychologists, social workers, and psychiatrically trained medical officers. |  |
| **Clause 37: Contracting Unit for Primary Health Care** | Clause 37 refers to the Contracting Units for Primary Health Care and the focus on primary health care in the NHI Bill is clear.  In instances where primary healthcare is provided by local government, it is not clear whether the CUPs will contract services individually or via the provincial administration.  In addition, the NHI Bill is generally silent on the role of the private sector with regard to CUPs. | It is suggested that the CUPs’ functions and establishment are dealt with under the proposed amendments to the NHA in the Schedule to the Bill. Clause 37 is not aligned with these proposed amendments. Hence, it is unnecessary to include these provisions in the NHI Bill.  Clause 37 should be revised to introduce a phased process for the creation of CUPs once certain cooperative governance milestones have been reached. This would require revision to the proposed new clause 31B of the NHA to ensure more equitable provision and financing of health care services.  Clause 37(2)(d) needs to be expanded to deal with suppliers of goods, as well as the inclusion of PFMA and any other relevant procurement legislation. The NHI Bill refers to a centralized procurement system, yet clause 35 mentions the disbursement of funds at various levels. | Clause 37(1)(b) Suggested edit: “is the preferred organisational unit with which the Fund contracts for the provision of primary healthcare services within a specified geographical area. *The Fund is not precluded from contracting directly with primary healthcare service providers based on need.”*  Suggested inclusion to clause 37(2) *“A Contracting Unit is comprised of a district hospital, clinics and, or community health centres and ward-based outreach teams, private primary service providers organized in horizontal networks within a specified geographical sub-district area and with the support of the District Public Health Medicine Specialist, must assist the Fund to-…”* |
| **Clause 38: Office of Health Products Procurement** | There were views that the functions of the Office of Health Products Procurement overlap heavily with those of SAHPRA, and the well-established processes for the development and implementation of Standard Treatment Guidelines, which include requirements for related products.  Clause 38(1): Clarity is requested on whether the current Office of the Chief Procurement Officer will be absorbed into this office and how the draft Procurement Bill, which has been submitted to Cabinet, will align with these provisions.  The scope and ambit of clause 38(3)(b) is currently unclear with regards to the benefits to be provided by the Fund. There is an undertaking of “comprehensive health care services”, but no criteria on the limitation of the package on grounds that are reasonable, and that will determine the scope and breadth of cover.  Clause 38(3)(b): Clarification is required as to how, when and against what criteria this list will be developed. Wide consultation with relevant stakeholders is also needed.  Clause 38(3)(d): Will product choice be according to the preference of the end-user?  Clause 38(3)(h): What will qualify as a high-cost device; and will these not be included in the product list as per clause 3(b)?  Clause 38(4): The Office of Health Products Procurement must support the Benefits Advisory Committee in the development and maintenance of the Formulary and lists. It is argued that this is an operational, technical function that should be exercised by the functionaries of the Fund, and not the Minister.  If the provisions of clause 38(4) are adopted, many patients who currently have access to non-EML, and also to non-tender medicines in the public sector, will no longer have access to these.  Clause 38(5): The Office of Health Products Procurement must support the review of the Formulary annually, or more regularly if required, to take into account changes in the burden of disease, product availability, technological developments, price changes and disease management for approval by the relevant committee, and the Board.  There seems to be no option for procuring outside the Formulary. Clause 38(6) notes that the Formulary includes supplies. The Formulary creates a predicament for patients, as certain vulnerable patients may not fall within the confines of the Formulary list, as they would suffer harm because of having used such treatments or experience adverse effects after having used the treatments on the Formulary lists. Clause 8(2) states that out of Formulary treatment will not be funded by the NHI.  Procurement in the public health care sector is currently managed and controlled by National Treasury. It is not clear how the proposed procurement system in the NHI Bill will be aligned with the existing processes and systems in view of the establishment of the Office of Health Products Procurement within the NHI Fund.  Is there going to be some regulation of costs for health care services being purchased? Health care should not be commercialised.  Clauses 38 and 38(2) seem contradictory to the definition of health-related products, which expressly excludes “orthodox medicine”.  A new, separate, Office of Health Products Procurement as it is outlined may be inappropriate and wasteful, and therefore not required.  The NHI Bill is contradictory in terms of how it would set prices (clause 10(10)(g), clause 39(8)(g)) or negotiate prices (clause 11(2)(e)).  Some views do not support a price-setting system, but would support a negotiation system as per the recommendations of the Health Market Inquiry.  The role, powers and functions of the Office of Health Products Procurement, in respect of price setting and procurement of medicines lacks clarity. The current procurement legal framework does not ensure access to medicines, the ongoing sustainability of the pharmaceutical industry and its ability to sustain supply long-term.  The provision relating to pricing, fees and payment are fundamentally at odds in various parts of the NHI Bill, leading to uncertainty as to what the future holds for patient access to products in the NHI market. The definition of "employee" in section 1 of COIDA includes the category of migrant workers, while it is not clear what is meant by “certain categories of individual foreigners” under the NHI Bill.  The role of the local health establishment vis-á-vis the Office of Health Products Procurement, in procurement decisions, ordering and supply are not clear in the NHI Bill. More clarity is required as to who would be authorised to procure from the Formulary, i.e. who are the contracted health care service providers and health establishments. On a primary care level, clarity is sought on which component of the CUPs would be authorised to procure from the Formulary and how the NHI Fund would track procurement to ensure reimbursement.  Although the NHI Bill provides some insight into how health services will be purchased at different levels, it contains no specific details on how medical technology will be procured, purchased or reimbursed. The proposed centralised mechanism of procurement will have practical implications on staff training, product maintenance and technical support (e.g. availability of spare parts and technicians); which are best arranged and provided locally, not centrally. The role of the local facility within the NHI framework, in procurement and procurement decisions, as well as in ordering and supply is not clear.  The role and function of the public sector depots in the NHI system are not clear and whether those would still be under the control of the provinces. The cost of medicine is expected to increase, to cater for this requirement.  An additional complication that could lead to an increase in medicines supply cost, is the obligation placed on successful bidders to contribute to the National Industrial Participation Programme (NIPP).  There is no guarantee that monopsony buying power will result in decreased prices from healthcare providers.  There appears to be a conflict between the contemplated mechanisms for the pricing of medicines. Furthermore, the unforeseen knock-on effect to medicines pricing is not covered by the Fund.  It submitted that the NHI Bill and Memorandum are in conflict regarding the establishment of the OHPP. | Clause 38(1): There is no need to consult the Minister to discharge a function for which the Board is responsible.  Clause 38(4) must be redrafted to ensure that, although the core, medicines available in the NHI cannot be exclusive to what is on the EML. The NHI medicines access and supply system must therefore cover, over and above the Formulary, as criteria for the complementary list referred to in clause 7(4)(c).  Clause 38(4) should specifically state that the function of this Office is to develop and maintain a Formulary and that it is responsible for the regular review of this list as contemplated in subsection (5), including the developments in new technology. Once again, the Minister and the NHC need not approve the list. This is a function of the Board.  It is suggested that clause 38(6) should be aligned with clause 38(3)(e).  Where treatments are not approved on the NHI List, accredited facilities should maintain the ability to procure according to patient need in the interest of optimizing the most appropriate health outcomes. There should be consideration for access to these treatment options within alternative supplementary reimbursement mechanisms.  There is a need for alignment in procurement between the responsible parties as capital equipment and consumables are not always interchangeable. The NHI Procurement System should recognize the complexity of medical technology especially in comparison to pharmaceuticals. Medical technology improvement cycles should be considered. Procurement should support and recognize the value of innovation in medical technology to patients, clinicians and the healthcare system, and should reward features that bring new capabilities, improved efficiencies and options to the clinical pathway. |  |
| **Clause 39: Accreditation of service providers** | The accreditation of facilities funded by the NHI is not clear.  There are concerns about the licensing requirements for facilities and providers of care. The move towards purchasing services from public and private institutions as a means to improve access and equity is supported. However, there are concerns that the proposed accreditation approach appears to force providers to choose to contract with the NHI entirely or not at all. This may in turn limit the pool of private providers who may wish to use at least part of their time providing services to the NHI, presumably at comparatively lower prices, which will constrain improvements in access.  Given the state of many rural facilities, which are characterised by infrastructure decay and understaffing, there is a risk that many rural facilities will take a long time to meet the accreditation criteria. The NHI Bill does not clearly indicate what will happen to the facilities that do not immediately meet the criteria.  There is concern that the accreditation process will render the majority of public sector facilities ineligible to be contracted by the NHI Fund, therefore resulting in a heavily private sector dependent delivery model.  Clarity is needed on the purchasing of health services and the accreditation of service providers. The criteria for accreditation are unclear and many stakeholders feel that accreditation will be costly, time-consuming and duplicate the work of other regulatory bodies. The view is that it would be impossible to achieve the conditions stipulated.  The NHI Bill provides for the accreditation and contracting of suppliers. However, there is no indication of what the accreditation requirements, process and period of accreditation for suppliers’ entail.  The definition of “accredited” in clause 1 of the NHI Bill refers to clause 39, which is only applicable to service providers. Accreditation of suppliers should be relevant and provide, among others, for the range of products offered by different suppliers, the size of the supplier, geographical distribution and support services being available in all areas.  There is no mention of private providers of Environmental Health/ Municipal Health Services in this section. In Environmental Health, one will find experts in the field of Air Quality, Chemical Laboratory services, etc. There is no provision for these in the NHI Bill.  Clause 39(4), will there be a prescribed minimum or maximum volume linked to the duration contained in the contract? Furthermore, what does “volume” entail? In this regard, will a contracted service provider be expected to accept a certain number of patients? Can the provider refuse to accept any more / other patients when the limit has been reached?  Clarity is requested on what is meant by “performance expectation” in clause 39(4).  Clause 39(5) refers to information submission requirements for accreditation and reimbursement. This section would more appropriately located in clause 34 (National Health Information System). The reference to ‘recording on the Health Patient Registration System’ is too restrictive. A more consistent wording would be ‘recording on the national health information system’, as referred to in clause 34.  While the NHI Bill states in clause 39(7) that the Fund must renew the accreditation of service providers every five years on the basis of compliance with the accreditation criteria. It does not explicitly state whether facilities not accredited at the time of purchasing may be able to reapply for accreditation at a later period. This clause makes no provision for how service delivery in the private sector will be catered for. A public health approach to ensure that the lowest categories of staff, who can provide quality service within their scope of practice, are used.  Accreditation by the OHSC introduces the risk of creating an open market for the private sector, as there is a very real concern that if relatively few public facilities achieve accreditation, the NHI would result in de facto privatisation of the public health system.  There is an assumption that there are adequate service providers, and that those service providers will be accredited to provide required services. There are no contingency plans in place, should this not be the case. Of particular concern, would be the small rural towns, where facilities, may not be adequately managed.  It is important that the requirements to obtain this Certificate of Need are clear and discussed with interested parties.  It is submitted that if certification is required for accreditation and currently only 0.7% of public health establishments are certified compliant then the timeline set for implementation of the NHI is unrealistic, even if the transitional arrangements in phase 1 are considered.  Further detail is required on how quality assessment/control of services provided by each establishment will be conducted and how participating facilities will be reimbursed for services provided.  There is no reflection on the need to strengthen primary health services to be accredited for contracting. | Suggestion: Add a subsection to include the services rendered by a medical specialist and other practitioners and allied professionals operating within alternative frameworks.  It is recommended that public health facilities be assisted to gain accreditation earlier in the process to counter the potential for monopoly power in private providers.  The NHI Bill must contain a subsection explaining the implications and procedure where accreditation is not obtained by a health care service provider or health establishment. The section should also explain what mechanisms would be put in place to support unaccredited parties until they meet the accreditation requirements.  The accreditation process should not be duplicated by the OHSC.  It is recommended that a process of upgrading or improving non-compliant facilities be provided for or be put in place to ensure people’s rights to access health care services. Clear guidelines should be put in place for clear referral pathways. Currently, the referral pathways differ per province, thus a consultative process should be undertaken to establish these pathways.  Efforts should be made to strengthen the public sector capacity to meet accreditation standards to ensure sufficient competition for service delivery.  The process for accreditation should not be a barrier to the provision of quality health care.  Cautions that there may be duplication of functions by the proposed NHI Fund, the District Health Management Offices and the CUPs, in the accreditation of service providers and the potential investigation of complaints.  In clause 39(2)(b)(i) it is suggested that publication of a “required range of services” will result in inflexible contracting. Contracts should be customised according to the service providers/ health establishments’ nature, location and structure.  In clause 39(2)(b)(iii) it is suggested that other provisions only refer to “treatment guidelines”; whereas, here “treatment protocols and guidelines” is used. It is requested that there be consistent use of terminology.  It is recommended that the Fund should also be able to contract directly with primary care services providers, other than through CUPs.  In clause 39(5)(h): it is recommended that the information to be submitted should not change frequently as it has resource and system implications and should be specified in a Government Gazette.  Clause 39(8)(c): To allow for geographical limitations and/or area of specialisation of a specific health establishment, the provision should be amended to allow for exclusions.  Clause 39(8)(k): clarity is required on what a “code of health-related ethics or relevant law” refers to. | Clause 39(2)(b)(v) - Suggested edit to ensure that information requirements are aligned to subsection (5*): “submission of information as prescribed to the national health information system to ensure portability and continuity of health care services in the Republic and performance monitoring and evaluation.”*  In Clause 39(2)(b)(vi) the terminology in use should be aligned. “Pricing regimen” has not been defined. Suggested edit*:” …. adherence to the agreed prices for services delivered.*  Provision should be made for medical specialists and other practitioners and allied professionals not operating within the frameworks given below. Suggested edit to 39(3): “*The Fund must conclude a legally binding contract with a health establishment certified by the Office of Health Standards Compliance and with any other accredited and approved health care service provider that satisfies* the requirements listed in subsection (2) to provide—“  Clause 39(2)(b)(iv): Suggested edit: referring patients in accordance with stipulated referral pathways.  Suggested edit to 39(5): *“In order to be accredited and reimbursed by the Fund, a health care service provider or health establishment must submit information to the Fund for the recording of user data on the National Health Information System, including—“*  Clause 39(5)(e): Suggested edit to ensure consistent use of terminology: *“length of stay of an inpatient in a health establishment.”*  Clause 39(5)(f) Suggested edit: *“facility or practitioner to which a user is referred if relevant.”*  In clause 39(8)(a): it is suggested that “comprehensive” be removed to align with other provisions in the NHI Bill.  Clause 39(8)(g) - Terminology used should be consistent. Suggested edit: *“fails to adhere to the contracted prices for services delivered.”*  Clause 39(9)(a): It is recommended that written reasons must also be provided as contemplated in the Promotion of Administrative Justice Act. Suggested edit: *“provide a health care service provider or health establishment with written notice of the decision as well as reasons for the decision.”*  Clause 39(9)(d): It is suggested that this provision be combined with subsection (9)(a). Suggested edit: “*provide adequate written reasons for the decision to withdraw or refuse the renewal of accreditation to a healthcare service provider or health establishment, as the case may be”.* |
| **Clause 40: Information platform of Fund** | The NHI Bill elaborately addresses the importance of a National Health Information System for the implementation of the Fund but does not delve into how this will interface with the Home Affairs Information System or how the data from the Fund will be made accessible for research purposes.  Given the already burdensome regulatory requirements on healthcare professionals, care should be taken that the NHI and Medical Schemes Amendment Bill do not create additional layers of regulatory compliance, which would simply place onerous requirements for information to be submitted by healthcare professionals. Rather, a single database should be compiled, and all relevant stakeholders should have access to the information contained therein.  Medical schemes already collect significant member information – rather than the NHI seeking to create its own database, it might be advisable to rather obtain an exemption from the provisions of the POPI Act and allow members’ information to be shared with the NHI and the Council for Medical Schemes.  Where there is a proper sharing of patient data, subject to the protection of medical information (which could still exist on a single database, but only accessible by those healthcare practitioners who treat the patient), there would be a greater opportunity to render more efficient and effective healthcare services, with enhanced patient care. | Clause 40(2): It is recommended that this subsection be aligned with the prescribed information submission requirements set out in subsection 39(5).  Clause 40(4): The provision of personal information by third parties such as private medical schemes must be within the provisions of the POPI Act. In addition, these provisions already appear in the NHA. Hence, there is no reason to include them in this Bill. Provisions must be aligned.  Clause 40(5): it is submitted that “information architecture” specifically refers to the structural design of shared information environments and specifically to the organising and labelling of information. It does not relate to fraud and risk management and; therefore, cannot act as a preventative mechanism. Hence, this clause should be rewritten with the appropriate input from information security professionals.  Clause 40(5) should provide clarity on the envisaged fraud and risk management mechanism.  All public hospitals must be equipped with the health technology and information technology needed to connect to other hospitals across the country. This will be to the benefit of migrant workers and pensioners and patients travelling between provinces seeking health care as some provinces do not have academic and specialized hospitals. | Clause 40(3)(4) - Suggested edit: *“Information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment is confidential and no third party may disclose information contemplated in subsection (2), other than as provided for in the National Health Act and the Protection of Personal Information Act, unless-“*  In clause 40(4)(f) the word “disclosure” should be substituted with “disclose”.  Clause 41(4)(b) delete “an individual health worker”. Suggested edit: determine mechanisms for the payment of the health care provider; and- |
| **Clause 41: Payment of health care service providers** | Clause 41(1) states that the NHI Fund in consultation with the Minister will determine the nature and mechanism of provider payment. Clause 20(3)(c) places the function of setting up a unit of providing payment in the jurisdiction of the CEO. The view is that this is vague and leaves a lot to the discretion of the Fund and the Minister, with no indication as to the criteria that will be used to determine appropriate payment levels for providers.  Clarity is requested on what is meant by “additional mechanisms” in clause 41(1).  The NHI Bill provides no information about the accreditation of suppliers as required by clause 41(2).  Clause 41(3)(b) is unclear and not aligned with other related provisions. Hence, it raises the question of what does “all-inclusive” mean. Who will be paid, the service provider, the establishment or the supplier?  It is submitted that since the law of contract applies, it is unclear what legislative purpose clause 41(4)(c) provides.  There is uncertainty relating to how service providers will be compensated and how private practices would fit into the implementation of the NHI.  The lack of clarity on the payment of providers is concerning, considering that health care providers will be the backbone of the NHI. Certainty on the payment of health care providers should therefore be a priority.  With limited information available on what conditions are prevalent at the different facilities, it is not clear how the costing will be done, reimbursement calculated for services provided, and health services planned for different facilities.  It is suggested that the requirement in the NHI Bill (clause 11) that the NHI Fund must “negotiate the lowest possible prices for goods and health care services” is removed. It is recognised; however, that price could be a factor once the appropriateness of medical technology for a particular patient has been confirmed.  The provision of occupational therapy and the like is often being overlooked, while the full recovery of the patient often requires occupational therapy or physiotherapy and the like, without which the patient will regress or relapse, which ultimately costs the health care system more.  Most of the reimbursement functions under the NHI are envisaged to function based on reimbursement contracts to be signed between the NHI Fund and health care providers or between intermediate structures like the District Health Management Offices and some form of organisation of health care practitioners. It is unclear where the Fund contracts with hospitals, whether doctors will be employed by these hospitals, or whether they will be contract workers. It is also not clear what the expectations of contracts in primary care will be, nor how these will involve doctors in capitation arrangements. None of these contracting mechanisms has yet been tested, yet the government is turning in them into law.  Clarity is required on the proposed amendments to the Road Accident Fund (RAF) and COIDA, as it will affect the provision of occupational therapy services through COIDA and RAF if service providers and service users lack clear information on what services will be funded and how reimbursement for services will occur.  It is proposed that all NHI benefits are set on the principles of “evidence-based practise” and not “medical necessity”.  The tariffs set by the NHI Fund in terms of the NHI Bill must take into account the realistic and reasonable costs incurred by health care providers in rendering the service and should be in line with the current industry tariffs. The NHI Bill contains no clear provisions on how reimbursement of health care providers will be managed. | Clause 41(3)(a) The provisions of the Bill need to be aligned. Case in point, contracting is a function of the Fund, so it cannot be a function of CUPs. The proposed amendments to the NHA do not provide for CUPs to have contracting functions. Hence, provision must be made for the Fund to contract and reimburse primary care providers.  Clause 41(5): It is recommended that subsection (5) be deleted and relevant definitions be included in clause 1 of the NHI Bill. Furthermore, to eliminate confusion, “health care provider” and “health care service provider” must not both be used in the NHI Bill.  It is proposed that the NHI Bill provide clarity on the meaning of “all-inclusive”, whether this includes payment to the facility, the provider and/or the supplier. Further, that a determination be made beforehand on how providers will be paid.  Regarding the recourse for non-payment, it is proposed that timeframes be established by the NHI Bill. For example, payment should be made within 30 days of the service being provided and should payment not be made on time, someone other than the Fund must be held personally accountable.  References to health insurance in the NHI Bill should clearly distinguish between insurance products and medical schemes.  The capitation vs the fee for service models of reimbursement need to be balanced with a more hybrid system to counter the effects of both under-servicing and over-servicing of patients.  Establishments and providers should autonomously determine ancillaries that go into the provisions of services. The application of the Competition Act should not be excluded and that a tender framework that caters for free-pricing and pricing negotiations should be considered. | Clause 41(1) Suggested edit: The Fund must determine the nature of provider payment mechanisms and adopt additional mechanisms. |
| CHAPTER 9: COMPLAINTS AND APPEALS | | | |
| **Clause 42: Complaints** | How will the complaints process, as described in clause 42, relate to the general role of the office of the Ombudsman as set out in the OHSC Act?  The Fund cannot both manage funds and deal with complaints regarding the management of the funds. This should be done by an external party.  The governing of fines should be regulated.  In dealing with complaints and appeals, there is significant scope for broker services. Prospective users who cannot afford professional legal representation in the complaints and appeal process should be permitted to use the services of brokers that are applicable in the private healthcare market.  The NHI Bill presents a long-winded complaints procedure that fails to appreciate the magnitude of the grievance on the life of the complainant or the affected. | Centralising the complaints function at national level is considered impractical. It is proposed that complaints are mainly managed at facility level.  Clause 42 should be redrafted because it allows the NHI to investigate a complaint against itself. This is not impartial.  It is recommended that clause 42(3) be amended to provide for a fixed period in which a complainant should be informed of the outcome, as delays may adversely affect complainants.  The NHI Bill must present a concise, reasonable and user-centred complaints procedure that appreciates the threat/magnitude of the user’s health condition at the time of lodging a complaint.  It is recommended that the complaints process be distinct from the CEO so that a forum independent from the Fund may be empowered to deal with this and be headed by a person outside the Fund so that it is empowered to make determinations and enforce those, even against the Fund or the Minister.  Structures should be in place to ensure smooth processes that will deal with complaints, as well as proactive approaches that will minimize the need for complaints, as these impacts on the state coffers due to medical litigations.  The complaints process and timelines should be included in the NHI Bill for clarity and transparency. Furthermore, the rules of natural justice must be applied and any person or entity against whom a complaint is lodged should be provided with the opportunity to respond to these complaints. | Clause 42(1) Suggested edit: “An affected natural or juristic person, namely a user, health care service provider, health establishment or supplier, may furnish a complaint with the Fund in terms of the procedures determined by the Fund ~~in consultation with the Minister~~.” The Fund must deal with such complaints in accordance with the prescribed mechanisms and timeframes.  Clause 42(4)(a) Suggested edit: “provide the entity against whom the complaint was lodged with a notice of the decision to provide the ~~health care service provider~~ respondent with a reasonable opportunity to make representations in respect of such a decision.  Clause 42(4)(c) Suggested edit: “provide adequate reason for the outcome of the decision ~~to withdraw or refuse the renewal of~~  ~~accreditation to the health care service provider~~ as it determines to the entity affected, as the case may be.” |
| **Clause 43: Lodging of appeals** | The wording under clause 43 must be broader to cover all relevant persons. It is suggested that only the persons involved in the complaint should be able to appeal a decision. |  | Clause 43 - Suggested edit: “~~A natural or juristic person, namely a user, health care service provider, health establishment or supplier~~ *The complainant or the respondent who is aggrieved by a decision of the Fund delivered in terms of clause 42 may, within 60 days after receipt of written notification of the decision, appeal against such decision to the Appeal Tribunal.”* |
| **Clause 44: Appeal Tribunal** | Clause 44(1)(a): This may be misinterpreted as Chairperson of Board of the NHI Fund.  There are concerns that there is significant potential for conflict of interest and perceptions that the process is not sufficiently neutral in its outlook. | The Appeal Tribunal should be completely independent of the Board, to ensure the credibility of the Board. The nomination and appointment process should be transparent. Invitation for nominations and the final appointments should be published in the Government Gazette.  It is argued that a 3-year term is too short. The Tribunal needs to build jurisprudence and it may well be that there has not been adequate volume or complexity of cases to build that jurisprudence in 3 years. A 5-year term is rather proposed.  Provision should be made in the NHI Bill to co-opt relevant expertise depending on the complaint.  Provision should also be made in the NHI Bill for disqualification criteria, conflicts of interest, deceased members, and termination of membership.  The Appeal Tribunal should consider a stratified approach to deal with the volume of complaints.  The NHI Bill should make provision for further eligibility criteria and grounds for disqualification that would apply to members of the Appeal Tribunal.  Additionally, the NHI Bill should also provide for the quorum requirements to the extent that a decision made by the Tribunal should be made by the Chairperson and at least two other members (one skilled in the medical field, and one in the financial field) to ensure that its decisions are fair. | Clause 44 (1)(a) which reads, “One member appointed on account of his or her knowledge of the law, who must also be the Chairperson of the ~~Board~~ Appeal Tribunal”. |
| **Clause 45: Powers of Appeal Tribunal** | The inclusion of a clause that reflects the rights of all parties appearing before the Tribunal is proposed.  Clarity is requested as to whether the Appeal Tribunal can make cost orders. | It is recommended that parties appearing before the Tribunal should have the same rights as they would in the High Court, for example, legal representation, cross-examination, etc. Hence, a clause should be included providing for these rights. Furthermore, the NHI Bill should specifically state that such powers should be exercised on reasonable grounds and for the lawful purpose of exercising the functions of the Appeal Tribunal in terms of the Act. |  |
| **Clause 46: Secretariat** | It is submitted that the Tribunal have its own staff and infrastructure since the decisions referred to it are those of the Tribunal and not the Board. | It is recommended that clause 46 be aligned with clause 47 in respect of record keeping. | Clause 46: Suggested edit: *“The Chief Executive Officer of the ~~Board~~ Fund must designate a staff member of the Fund to act as secretary of the Appeal Tribunal and the Fund must keep the minutes and all records of a decision of the ~~Board~~ Appeal Tribunal**for at least three years after the decision has been recorded.”* |
| **Clause 47: Procedure and remuneration** | Clause 47(3) provides that the Appeal Tribunal must determine the outcome of the appeal within 180 days. Submissions are of the opinion that 180 days is somewhat excessive, and have proposed that an appeal should be concluded within 90 days.  Clause 47(3) should align with clause 56 in respect of record keeping. |  |  |
| CHAPTER 10: FINANCIAL MATTERS | | | |
| **Clause 48: Sources of funding** | The legality of clause 48(b) is questioned, as all income must be paid into the National Revenue Fund.  While a mandatory prepayment system is mentioned in the NHI Bill as a source of funding for the NHI, it is not clear how this will be operationalised or what additional funding mechanisms will be provided by Treasury to support the Fund.  The NHI Bill does not provide reliable costing estimates for NHI, nor does it offer a clear picture of what impact the NHI will have on the taxpayer and whether it will be sustainable.  There are shortcomings in the NHI Bill and it is submitted that the draft regulations dealing with the budget for the Fund should have accompanied this Bill for meaningful comments and submissions to be made.  There is agreement with the source of funding that is stipulated in the NHI Bill and believe that if we are going to have quality health care someone needs to pay for it as per clause 49.  It remains unclear what the total cost of NHI implementation will be and this will largely depend on the benefit package. While the Fund will largely be based on income tax, given the large informally employed population in South Africa, particularly rural communities, it is unclear whether taxes will be sufficient to cover the NHI’s needs and whether sufficient government subsidies will be available to ensure access for vulnerable communities. Links between the country’s budget and the Fund’s expenditure are virtually absent in the NHI Bill.  The proposed taxes on employers and employees will place an already heavy tax burden on a shrinking tax base.  Clarity in the form of a Treasury policy paper is urgently required in relation to the proposed funding mechanisms for NHI and risks of earmarking payroll tax. | Clause 48(c) should be deleted as a consequential amendment to the proposal that the Fund may not be allowed to invest funds.  It is proposed that more information is provided to confirm the sustainability of the proposed NHI reforms and also that parallel alternative mechanisms for the attainment of UHC in South Africa are considered. Ideally, the 2019 SEIAS should have provided the implemented mitigation strategies and completed action points for the risks that were identified in the 2017 SEIAS and repeated in the 2019 SEIAS. There is confusion around the inclusion of extra taxes.  A solid funding plan should be put in place prior to the implementation of the NHI. South Africa cannot afford for the NHI to fail mid-flight. That would be dire to the economy of the country and users of the Fund. | Clause 48(d): Suggested edit: “any money paid erroneously to the Fund which, in the opinion of the ~~Minister~~ Board, will be refunded; |
| **Clause 49: Chief source of income** | In relation to "mandatory prepayment" and "chief source of income", the scope and meaning of these concepts should be made clear and if there is indeed a connection between the two, such connection must be clarified.  The specifics around the funding of the NHI are not clear from Chapter 10 of the NHI Bill, which deals with financial matters. What is clear is that funding for the NHI will be collected through a number of taxes, namely general tax, medical scheme tax credits and personal income tax. Such taxes can however only be levied through a “Money Bill” under section 77 of the Constitution.  The NHI Bill is silent on the system’s overall likely costs. No accurate costing was done. Revenue sources are limited. The NHI’s financing is vague or under-calculated. A comprehensive Treasury paper on NHI costs and financing has long been promised but has still to be published. It is difficult to understand and comment on a Bill where its full application and its actual eventual cost to taxpayers is unclear at this stage.  There is no indication of financial viability of the NHI Fund. This is left to regulations covering budget, fees, fund reserves, and fund investment by the DOH on their own, at some future stage.  The entire funding mechanism and prudential oversight on solvency issues of the scheme requires more clarity. | Without an accompanying Money Bill, it is difficult to determine how resources will be sourced and what the impact would be, for example, the remuneration of specialised services (i.e. Orthotics and Prosthetics).  Clause 49(2(a)(ii): Funding for medical scheme tax credits to various medical schemes should remain untouched, and should not fall within the discretion or ambit of powers for reallocation towards the funding for NHI.  Clause 49(2) should be dealt with in a dedicated financial plan with clear guidelines. It is recommended that this subsection be deleted.  Two other models that can be considered would be; the voucher system or the value-based system/Capitation. The voucher system essentially works the way medical aids work at the moment, where a voucher will be given to a citizen. He/she will then have to go to a practitioner to consult. The practitioner will then use the voucher to claim from the Fund. Under the capitation payment model, providers are paid a prospective “cap” or per member per month fee. |  |
| **Clause 50: Auditing** | An oversight function, beyond the Auditor-General, should be established to monitor the activities and finances of the Fund. |  |  |
| **Clause 51: Annual reports** | It is recommended that a report on health outcomes as per the Health Market Enquiry be included.  Clause 51(3)(d): It should be specified in the Bill that the lending financial institution must have a specific international rating to ensure that not any institution is used.  Clause 51(3)(e): It is recommended that this be an independent actuary to allow for information integrity. |  |  |
| **CHAPTER 11: MISCELLANEOUS** | | | |
| **Clause 52: Assignment of duties and delegation of powers** | Clause 52 circumvents the Board of the Fund by allowing the Minister or the CEO to assign any of their duties or delegate any of their power to any employee of the Fund. In terms of the principles of good governance, the delegation of authority must be subject to the approval of the Board. |  |  |
| **Clause 53: Protection of confidential information** | **No input** |  |  |
| **Clause 54: Offences and penalties** | Clause 54(2): The issuing of directives by the Fund is not supported. | Clause 54(1)(e): It is recommended that the extent of any fraud within this environment should not be limited within the Act, but should rather be determined in line with the severity of the offence.  Clause 54(1)(e): A R100 000 fine for corruption is too soft and a harsher punishment including compulsory imprisonment should be meted out. | Clause 54(1)(e): Suggested edit: “sells or otherwise discloses confidential information owned by the Fund to a third party without the prior knowledge and written consent of the Fund, is guilty of an offence and liable on conviction in a court of law to a monetary fine, or imprisonment, the value or term of sentence to be determined by the severity of the offence. |
| **Clause 55: Regulations** | Clarity is requested as to the necessity of clause 55(1)(b) when clause 41(1) provides for payment mechanisms. | It is recommended that there is a need to be more inclusive to ensure appropriate engagement from all stakeholders. Include patients and service providers, as well as appropriately qualified experts in the various sectors as required.  Clause 55(1)(h): The involvement of and contribution of traditional healers should be included under this subsection.  Clause 55(1) (i and j): It is suggested that these subsections be deleted because these are covered in the amendments to the NHA.  Clause 55(1) (p and q): It is recommended that the entire complaints and appeals procedure be included in the Regulations.  Clause 55(1)(t): Clarity is requested as to what fees are envisaged in this section, how these will be identified, evaluated and implemented.  Clause 55(1)(x): It is suggested that the various subsections dealing with funding of/ payment for services be combined and/or aligned.  Clause 55(1)(y): It is recommended that all committees should function according to Charters. The Code of Conduct is a separate item. The Board should be responsible for compiling both a Charter and a Code of Conduct.  In relation to clause 55(2), submitting notices of changes in the Gazette for a Fund that runs on a massive IT system will slow down the process of obtaining feedback. Rather, this should be integrated in the Fund’s IT system so that users are notified of proposed changes in real-time. In addition, users should have visibility of all feedback received on the proposed changes. The same should apply to Directives issued in terms of clause 56. |  |
| **Clause 56: Directives** | Clarity is sought on the scope of applicability of the directives that the NHI Fund may issue. | It is suggested that clause 56(1) be deleted. There are views that it is not acceptable for the Fund to issue directives that are binding. It is viewed to be a unilateral administrative action and does not provide for any input or comment by interested parties.  Clause 56(1 and 2): The issuing of directives by the Fund is not supported.  It is recommended that the NHI Fund may make directives for the purpose of implementation and administration of the Fund. |  |
| **Clause 57: Transitional arrangements** | Clause 57(2)(a) provides for part of a period that has already passed; hence, this implies that all actions taken in lieu of giving effect to the transitional arrangements would amount to actions that were conducted without authority under the Act, once the Bill is enacted.  Clarity is requested in clause 57(3)(a and b) on when the committees cease to exist, how will they be established and what their functions and roles will be.  Clause 57(3)(b): The role of private medical schools or private training platforms and payment for training as part of service delivery needs to be clarified.  The NHI Bill does not include a definition for HTA. No further detail is provided to describe the scope, functions or level of autonomy of the HTA Agency, nor the manner in which it will interact with the other NHI committees and units. The NHI Bill does not specify how the appointments to the Ministerial Advisory Committee on HTA for NHI or the HTA Agency Board will be carried out, or the types of stakeholders that will be represented.  On the MAC on HTA, no information is provided on the composition and decision-making processes thereof. It is critical that this be a multi-stakeholder forum with requisite skills and insights that operate transparently with regular reporting. Currently, in SA there is a shortage of HTA skills and care should be taken that the HTA process should not become a bureaucratic bottleneck that limits patient access to appropriate care as a result of insufficient experienced resources. The failures of the Medicines Control Council (the predecessor of SAHPRA) to timeously register medicines and the bottlenecks created by the National Health Laboratory Services’ initial HTA process, which led to its subsequent discontinuation, should serve as warnings in this regard.  The approach to drive cost-effectiveness as laid out in various sections of the NHI Bill is a pragmatic one but must not be misinterpreted to mean cheapest as often lowest cost is not the best value. | Clauses 57(1)(a) and 57(2) should be deleted as they do not speak to the implementation of the Act.  Clause 57(4)(g)(iii): Consideration should be given to the inclusion of pathology services when developing requirements for primary care units.  A scaled-down NHI should be considered and should form part of the transitional period to the new dispensation. The new dispensation should include a rigorous and transparent pilot project.  Clause 57(2)(iv) should be re-worded to include “people with mental and physical disabilities”.  Clause 57(4)(f) should include registered psychologists in the list of designated providers.  The NHI Bill should include a definition for HTA and recommends the establishment of an HTA Agency that should be mandated in the NHI Bill, with the MAC on HTA for NHI, steering its inception.  Further proposes that a more detailed description of the tasks and stakeholder representation is provided for the MAC on HTA for NHI. In addition, it is proposed that the NHI Bill provide more clarity on how appointments to the HTA Agency board will be made (as part of the mandate for its establishment).  It is proposed that the Terms of Reference for the MAC on HTA be published in the Government Gazette.  It is proposed that the HTA Committee not be housed within the Fund and that it be a function of independent bodies as this may open the Fund to bias.  It is proposed that a wider framework, other than just HTAs, as value assessments are not outcomes in themselves. These constitute information that a funder would consider, together with other factors such as health policy and human rights considerations.  An HTA process based on the principles of regularly reviewed, evidenced-based assessments of cost-effectiveness and efficiency as laid out in the NHI Bill is sound but further details should be included to ensure an objective, credible and transparent mechanism.  It is proposed that a review of international markets to establish best practice in the procurement of medical technology be undertaken. Examples provided included Thailand, Singapore, Australia and the United Kingdom.  Open-ended phrases in clauses such as, “where necessary” and “which may be required” should be reconsidered. |  |
| SCHEDULE | | | |
| **Clause 58: Repeal or amendment of laws** | The NHI Bill also proposes significant changes to other pieces of legislation which will, among other things, remove the responsibility of employers to cover the healthcare costs of workers injured on duty, fundamentally change the pricing regimen for medicines and medical devices and in-vitro diagnostics, make significant changes to the NHA, which will alter the delivery functions of healthcare, changing from the current provincial system to a District managed system. There is no clear replacement for these two systems. The implications of these repeals and amendments are not adequately explained or understood. | The interaction between the NHI Bill and all pieces of legislation outlined in the schedule to clause 58 of the Bill and the implications of the proposed amendments should be clarified.  It is proposed that instead of proposing amendments to key laws in the Schedule to the Bill, these laws should be amended through amendment Bills that follow the prescribed legal process for comment.  It is suggested that the Nursing Act be amended to enable and regulate independent practice by nurses in the private sector.  It is proposed that clause 58(2) be deleted since the Interpretation Act, 1957 regulates the effects of the repeal of laws.  The Medicines and Related Substances Act: the short title is incorrect, and clause 1(a) should be reconsidered and redrafted since concerns can be raised about the objectivity of the appointment of members of the pricing committee since the OHPP plays a role in the appointments of the pricing committee. This may create a space for price collusion.  Compensation for Occupational Injuries and Diseases Act: the words “notwithstanding paragraph (a)” in paragraph (b) of section 22(3) would after the proposed deletion of paragraph (a) be no longer necessary.  Road Accident Fund Act: Clause 1(a) is problematic since it requires that liability of the RAF or an agent regarding any tariff shall be based on the reimbursement strategy for health services contemplated in the NHI Bill in consultation with the Minister. It is submitted that if consultation is required, then the appropriate functionary is the NHI and not the Minister of Health.  Road Accident Fund Act: If the sections proposed by clause 1(b) are deleted then a consequential amendment must be made to section 17(4B) to remove reference to the deleted subsections (5 and 6).  A National Health Amendment Bill should be published, which contains all the proposed amendments and to which comprehensive comments can be submitted. |  |
| **Clause 59: Short title and commencement** | No input |  |  |
| ADDITIONAL COMMENTS FROM STAKEHOLDERS   1. **Limitations of the Bill to its objectives**  * There were views that only purchasing-and funding-related powers should be included in the Bill, whilst other reforms must be included as amendments in other laws. * It was argued that the NHI Bill appears to step into the domain of regulating and organising providers, but also into other fields that would be related to both purchasing and provisions of care, but that should be governed under those laws.  1. **Constitutional issues**  * The inclusion of emergency services, that under the Constitution must be provided and funded by the provinces. * The removal of central hospitals, and staff, as well as district health structures from their current provincial powers and employer, to the National Department of Health. * The NHI Bill may possibly be in violation of section 217 of the Constitution by excluding the Competition Act. This could be problematic and would detract from a price negotiation system that would provide flexibility in pricing and adaptability to the needs of specific populations and areas.  1. **Legal framework**  * The current version of the NHI Bill provides an inadequate framework for the infrastructure and capability needed to achieve the desired outcome of UHC. * Health providers are bound by laws such as the Protection of Personal Information (POPI) Act, 2013 and the Consumer Protection Act (CPA), 2008. It appears as if both acts are excluded from the NHI Bill in clause 3(3) as it may contradict with the provisions in the NHI Bill. This is a major concern, as the NHI Bill cannot override another law, both of which have their roots in the Constitution. * Consumers have no independent recourse within the current NHI framework.  1. **System design issues**  * There were views that there is no evidence that a single purchaser will result unequivocally in cost reduction. The NHI Bill does not propose the establishment of a single-purchaser model. Medical schemes, albeit in a complementary role, will remain purchasers; other providers of health care insurance will also remain; the State Security Agency will retain its medical scheme; the Road Accident Fund will remain a purchaser of healthcare; and the Compensation Fund remains in place. * The single-payer system vs a hybrid model: It is argued that countries such as Thailand, France and Chile adopted a hybrid model, which catered for specific population groups that were more likely to have an efficient and responsive health care system. This was in contrast to countries (Brazil, Ghana and Canada) that adopted a single-payer model system. * The single-payer system is said to disrupt South Africa’s health care market dynamics in three fundamental ways:   + Through huge buying power that will thwart any competition that comes its way;   + Through cross-subsidization of the poor by the wealthy; the sickly by the healthy and the old by the young; and   + Through per capita payments to providers as the State and through the Office of Health Products that will determine the fees that private doctors may charge their patients and restrict billable services and products.  1. **The role of Medical Schemes**  * Potential Constitutional challenges arise from limiting the ability of medical scheme beneficiaries to access services outside of NHI and to purchase cover for such services. It is incumbent upon the State to take account of different economic levels in ensuring access to healthcare. Preventing medical scheme beneficiaries from accessing healthcare services through voluntary private healthcare insurance is at odds with the responsibilities of the State. The State would need to demonstrate that there are no alternative mechanisms available and that the limitation of the rights for existing medical scheme beneficiaries can be substantiated as being rational. Refer to section 36 of the Constitution. * National health systems across the world exist alongside private health systems. Hence restrictions on the cover that medical schemes or other private health insurance schemes may offer are not supported. In a free market economy, such restrictions are not appropriate. * As the HMI report indicated that competition promotes better health outcomes. The rationale for restricting the ability of medical schemes to offer parallel cover to the NHI Fund is not clear. * Confining medical schemes to complementary services, which will prevent them from remaining in business and compel them to transfer their reserves to the NHI Fund, is inconsistent with the right to property in section 25 of the Constitution. This is deemed unconstitutional. * The reduced role of medical schemes will not address the current barriers to access health care services, which the NHI Bill seeks to address.  1. **Financing of NHI**  * Any imposition of taxes falls within the remit of the Minister of Finance and must be dealt with through a Money Bill. Foreign direct investment may be impacted by prohibitive taxes. The impact of the introduction of any additional taxes must, therefore, be carefully considered for its potential unintended consequences and specifically the impact on all the different stakeholders. * It should be noted that the Davis Tax Committee has expressed its reservations in this regard in its report to the Minister of Finance, entitled Financing a National Health Insurance for South Africa (March 2017). It was submitted that the Portfolio Committee should consult with the Davis Tax Committee to fully understand the tax implications of the proposed NHI. * It was recommended that mechanisms to contain the administrative expenditure of the NHI Fund must be prescribed to ensure that the majority of the funds are used for health care benefits and not for the operational expenditure of the Fund.  1. **Governance of the NHI Fund**  * In the NHI Bill, governance and decision-making are to a large degree centralised in the office of the Minister of Health and a limited number of committees. As a result, some important decisions are left to executive or policy decisions. This poses a risk, as it becomes a very centralised decision-making process, which is not in accordance with good governance principles. It would be concerning to vest too much power in individual decision-making in the Minister or Chief Executive Officer, regarding, for example, price setting, guidelines, and health technology assessment (HTA). * In addition, to not meeting the standards of good corporate governance as recommended, amongst others, in the King IV Report on Corporate Governance 2016 (King IV), it will also entrench significant political power which is to be avoided in the context of the current economic challenges created by political interference at State-owned entities. To avoid irregular expenditure, wastage and qualified audits, sufficient focus must be placed on good governance and the achievement of desired outcomes. Structures must be implemented that ensure checks and balances, transparency and public input. * Legal requirements and clinical elements of the system must be rational, objective and transparent and not open to political interference. * It is advisable in terms of good corporate governance standards that the governing body, i.e. the Board of the NHI Fund, should be in control of the organisation’s, functions relative to its object and purpose. In this regard, the Board of the NHI Fund must have the power to establish committees that are required for the fulfilment of its key functions, i.e. purchasing of health care services and payment of such services. | | |  |