health
Department:
Health
REPUBLIC OF SOUTH AFRICA

NATIONAL DEPARTMENT OF HEALTH RESPONSE TO THE COMMENTS AND DISCUSSION ON THE NATIONAL HEALTH INSURANCE BILL

DATE: 30 NOVEMBER 2022

BILL SECTION	CLAUSE IN BILL	NDOH POSITION	NDOH RECOMMENDATIONS
PREAMBLE	**RECOGNISING—** • the socio-economic injustices, imbalances and inequities of the past; • the need to heal the divisions of the past and to establish a society based on democratic values, social justice and fundamental human rights; and • the need to improve the quality of life of all citizens and to free the potential of each person; **BEARING IN MIND THAT—** • Article 12 of the United Nations Covenant on Economic, Social and Cultural Rights, 1966, provides for the "right of everyone to the enjoyment of the highest attainable standard of health"; • Article 16 of the African Charter on Human and People's Rights, 1981, provides for the right to enjoy the best attainable state of physical and mental health, and requires States Parties to take the necessary measures to protect the health of their	• The Department notes the recommendations from stakeholders to add a phrase that refers to the *social and economic determinants of disease* as part of the Preamble to the Bill. It must be appreciated that while the social and economic determinants have a direct and indirect bearing on the health and well-being of the population, the NHI Fund is being created to focus on a narrower scope of services, namely personal health care services to assist with achieving the progressive realisation of the right of access to quality personal health care services within a strengthened public and private health system. • The comment to include *quality personal health care services* as a separate point is a nuanced one because the Bill contains reference to the NHI Fund accrediting and contracting providers of personal health care services, with quality being a central tenet of the accreditation requirements.	**No change recommended**

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	people and to ensure that they receive medical attention when they are sick; • the rights to equality and human dignity are enshrined in the Constitution in sections 9 and 10, respectively; • the right to bodily and psychological integrity is entrenched in section 12(2) of the Constitution; • in terms of section 27(1)(a) of the Constitution everyone has the right to have access to health care services, including reproductive health care; • in terms of section 27(2) of the Constitution the State must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of the right of access to health care services; • in terms of section 27(3) of the Constitution no one may be refused emergency medical treatment; and • section 28(1)(c) of the Constitution provides that every child has the right to basic health care services; **AND IN ORDER TO—** • achieve the progressive realisation of the right of access to quality personal health care services; • make progress towards achieving Universal Health Coverage; • ensure financial protection from the costs of health care and provide access to quality health care services by pooling public revenue in order to actively and strategically purchase health care services based on the principles of universality and social solidarity; • create a single framework throughout the Republic for the public funding and		

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	purchasing of health care services, medicines, health goods and health related products, and to eliminate the fragmentation of health care funding in South Africa; • promote sustainable, equitable, appropriate, efficient and effective public funding for the purchasing of health care services and the procurement of medicines, health goods and health related products from service providers within the context of the national health system; and • ensure continuity and portability of financing and services throughout the Republic, **BE IT THEREFORE ENACTED** by the Parliament of the Republic of South Africa, as follows—		
Clause 1: Definitions		The Department notes the recommendation to refine the definition of primary health care services and recommends that the definition for "primary health care" be refined to include the following: *"primary health care" means addressing the main health problems in the community through providing promotive, preventive, curative, palliative and rehabilitative services.* It is noted that an input was made to the effect that "personal health care service benefits" under "complementary cover" must be defined. The proposed definition is as follows: *"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*	The Department proposes that the word "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.** The Department proposes that the word "health product" must be defined. The proposed definition is: **"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**

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		health care practitioner or within the setting of a health care organisation. To address the deficit noted by stakeholders in the definitions for *"health goods and health related products"*, 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.* Furthermore, the Department does not support the recommendations to revise the following definition for "provider payment" in that it should exclude the phrase *"in a way that creates appropriate incentives*", as this might be interpreted as perverse. We also do not support that the definition for "provider payment" should exclude the word *"uniform*" to allow for flexibility in the development of different reimbursement models. This suggestion is not appropriate as one of the core intentions of NHI is to eliminate the fragmentation in provider reimbursement regimes as they currently are inefficient, disjointed and create perverse incentives in some instances. Finally, the Department notes the proposal that the word "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.*	**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.**

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	CHAPTER 1		
Clause 2: Purpose of Act	**Purpose of Act** **2.** The purpose of this Act is to establish and maintain a National Health Insurance Fund in the Republic funded through mandatory prepayment that aims to achieve sustainable and affordable universal access to quality health care services by— *(a)* serving as the single purchaser and single payer of health care services in order to ensure the equitable and fair distribution and use of health care services; *(b)* ensuring the sustainability of funding for health care services within the Republic; and *(c)* providing for equity and efficiency in funding by pooling of funds and strategic purchasing of health care services, medicines, health goods and health related products from accredited and contracted health care service providers.	The Department supports **Clause 2** of the Bill as it provides clarity for the purpose of the Act and no further changes are recommended. **Clause 2** is consistent with the provisions of the Constitution as well as other relevant Acts such as the National Health Act, hence it is consistent with the obligations placed on the State to progressively meet the health entitlements of South Africans in an equitable and effective manner	
Clause 3: Application of Act	**Application of Act** **3.** (1) This Act applies to all health establishments, excluding military health services and establishments. (2) This Act does not apply to members of— *(a)* the National Defence Force; and *(b)* the State Security Agency. (3) If any conflict, relating to the matters dealt with in this Act, arises between this Act and the provisions of any other law, except the	The Department does not agree with the recommendation by the Competition Commission, and other stakeholders, that the Fund should not be exempted from the Competition Act. Therefore, Clause 3(5) should not be deleted, but instead amended to ensure that: Only the Fund should be exempt from the Competition Act. However, all accredited and contracted heath care providers, health establishments 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 or any other business. The	**Clause 3 (5)** amended to read: "The Fund must be exempted from the provision of the Competition Act, 1998 (Act No. 89 of 1998) ~~is not applicable to any transactions concluded in terms of this Act~~."

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	Constitution and the Public Finance Management Act or any Act expressly amending this Act, the provisions of this Act prevail. (4) The Act does not in any way amend, change or affect the funding and functions of any organs of state in respect of health care services until legislation contemplated in sections 77 and 214, read with section 227, of the Constitution and any other relevant legislation have been enacted or amended. (5) The Competition Act, 1998 (Act No. 89 of 1998), is not applicable to any transactions concluded in terms of this Act.	proposed amendment in the schedule of the bill to the Competition Act achieves this. Specifically, the Department recommends that Clause 3 (5) on the Competition Act must be reformulated to exempt the Fund but not the providers and suppliers of health care services. This is undesirable as it may promote collusion amongst providers and suppliers. The clause must be amended to read as follows: ***"The Fund must be exempted from the provision of the Competition Act"*** It is the Department's informed view that such an arrangement is not Constitutionally invalid as is suggested by some comments.	
CHAPTER 2			
Clause 4: Population coverage	**Population Coverage** **4.** (1) The Fund, in consultation with the Minister, must purchase health care services, determined by the Benefits Advisory Committee, on behalf of— *(a)* South African citizens; *(b)* permanent residents; *(c)* refugees; *(d)* inmates as provided for in section 12 of the Correctional Services Act, 1998 (Act No. 111 of 1998); and *(e)* certain categories or individual foreigners determined by the Minister of Home Affairs, after consultation with the Minister and the Minister of Finance, by notice in the *Gazette*.	The Department notes the comments and recommendations submitted by stakeholders. However, it must also be emphasised that the creation of the Fund is intended to create a unified health system that meets the personal health care needs of South Africans, with appropriate dispensations allowing for different categories of people i.e., tourists, immigrants, refugees and asylum seekers, etc to still meet their health needs as per existing legal prescripts in the Immigration Act as well as internationally ratified agreements. Specifically, the Department recommends that: **Clause 4 (2)** must not be amended. Instead, the section must be improved through inclusion of a sentence that reads: To provide a more comprehensive service to asylum seekers and undocumented migrants	**Clause 4 (3)**: **<u>Illegal migrant</u>** replaced with **<u>illegal foreigner</u>** as articulated in the Refugees Act. "(3) All children, including children of asylum seekers or illegal ~~migrants~~ **<u>foreigners</u>**, are entitled to basic health care services as provided for in section 28(1)(c) of the Constitution."

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	(2) An asylum seeker or illegal foreigner is only entitled to— *(a)* emergency medical services; and *(b)* services for notifiable conditions of public health concern. (3) All children, including children of asylum seekers or illegal migrants, are entitled to basic health care services as provided for in section 28(1)*(c)* of the Constitution. (4) A person seeking health care services from an accredited health care service provider or health establishment must be registered as a user of the Fund as provided for in section 5, and must present proof of such registration to the health care service provider or health establishment in order to secure the health care service benefits to which he or she is entitled. (5) A foreigner visiting the Republic for any purpose— *(a)* must have travel insurance to receive health care services under their relevant travel insurance contract or policy; and *(b)* who does not have travel insurance contract or policy referred to in paragraph *(a)*, has the right to health care services as contemplated in subsection (2).	**Clause 4 (3)**: Amend the term “illegal migrant” to “illegal foreigner”. Furthermore, despite the many objections indicated, the Department is certain that the benefits for all children are in line with the Constitution and are not to be amended. A child, including children of asylum seekers and illegal foreigners will be registered automatically at birth and presenting to an accredited service provider should be for the purpose of allocating a user to a provider who is accredited. The Department appreciates the Legislative responsibility placed on the Minister of Home Affairs on matters pertaining to population Registration and the stewardship role on the methods to be used to identify foreign nationals. The Minister of Health has the Legislative responsibility of providing a stewardship role of how health care services are to be accessed and provided in the country.	
Clause 5: Registration of users	**Registration of users** (6) The Minister, in consultation with the Minister of Home Affairs, may prescribe any further requirements for registration of foreign nationals contemplated in section 4(1)*(e)*. (7) Unaccredited health establishments whose particulars are published by the Minister in the *Gazette* must, on behalf of the Fund, maintain a	To ensure that the Fund’s user registry is credible it must be linked to the Population Register as maintained by the Department of Home Affairs. The relevant mechanisms for ensuring this happens and executed with precision are part of the user registration capabilities that are being incorporated into the Health Patient Registration System. The Fund must endeavour to ensure the population registration process is automated and linked to the Department of Home Affairs database. Presenting to	**Clause 5 Subclause (7)** Change the wording 'unaccredited' to **'accredited'**; **Clause 5 Subclause (8)** consider **'proof of identity'** rather than 'proof of registration' (because registration happens at first engagement with the system, then not again)

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	register of all users containing such details as may be prescribed. (8) A user seeking health care services purchased for his or her benefit by the Fund from an accredited health care service provider or health establishment must present proof of registration to that health care service provider or health establishment when seeking those health care services.	an accredited service provider should be for the purpose of allocating a user to a provider who is accredited. This will enhance the planning process including for determination of reimbursement strategy such as capitation for providers at PHC level. All health establishments whether accredited or not accredited by the NHI Fund are subject to legal prescripts of the National Health Amendment Act (12 of 2013) as an enabling Act of the Office of Health Standards Compliant where establishments are required to maintain user records for a specified period, and the registers are managed and kept confidential in terms of Section 14, 15 and 17 of the National Health Amendment Act of 2013. The Department disagrees with the assertion the Bill lacks transparency as to what services will be available and; hence, there is nothing to prevent the State from withholding a reasonable standard of care under the "available and appropriate" clause. Instead, it must be noted that Clause 10(1) (i) requires the Fund to collate utilisation data and implement information management systems to assist in monitoring the quality and standard of health care services, medicines, health goods and health related products purchased by the Fund. This shows transparency.	"(8) A user seeking health care services purchased for his or her benefit by the Fund from an accredited health care service provider or health establishment must **register whereafter the user must** present proof of ~~registration~~ **identity** to that health care service provider or health establishment when seeking those health care services."
Clause 6: Rights of users	**Rights of users** **6.** Without derogating from any other right or entitlement granted under this Act or under any other law, a user of health care services purchased by the Fund is entitled, within the State's available and appropriated resources— *(a)* to receive necessary quality health care services free at the point of care from an	The Department notes all comments made regarding the Rights of users. Users will be entitled to comprehensive health care services that will be determined through the advice received by the Fund and the Minister from the Benefits Advisory Committee (BAC). This BAC will consist of various experts in the various domains of health care provision including amongst others medicine, public health, allied disciplines, nursing, epidemiology and the	**Proposed changes to Subclause 6(o)**

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	accredited health care provider or health establishment upon proof of registration with the Fund; *(b)* to information relating to the Fund and health care service benefits available to users; *(c)* to access any information or records relating to his or her health kept by the Fund, as provided for in the Promotion of Access to Information Act, in order to exercise or protect his or her rights; *(d)* not to be refused access to health care services on unreasonable grounds; *(e)* not to be unfairly discriminated against as provided for in the Constitution and the Promotion of Equality and Prevention of Unfair Discrimination Act, 2000 (Act No. 4 of 2000); *(f)* to access health care services within a reasonable time period; *(g)* to be treated with a professional standard of care; *(h)* to make reasonable decisions about his or her health care; *(i)* to submit a complaint in accordance with section 42 regarding— (i) poor access to or quality of health care services; or (ii) fraud or other abuses by a health care service provider, a health establishment, a supplier or the Fund; *(j)* to request written reasons for decisions of the Fund; *(k)* to lodge an appeal against a decision of the Fund in accordance with section 43; *(l)* to institute proceedings for the judicial review of any decision of the Appeal Tribunal;	users of health care services. The BAC will also receive inputs from experts in Health Technology Assessment and the Health Products Procurement Unit. This is to ensure that the services covered will be comprehensive and evidence-based. Users will not be denied access to health care services because of transport costs or lack of accreditation of health care facilities. It is envisaged as supported by proposed amendments to Clause 39 (2) that health care facilities in rural, remote and deprived communities who do not meet the standards and norms of the Office of Health Standards compliance will be supported through the National Quality Improvement Plan (NQIP) to reach these standards in readiness for inspection and certification within a specified time frame. There OHSC is developing a framework for progressive certification linked to facilities that are going through the NQIP. The Fund will take this into account in order to provide a qualified conditional accreditation for such facilities. Furthermore, should public health establishments in remote and rural areas continue to fail to meet the certification criteria for the OHSC, to qualify for accreditation, they will continue to receive a global budget to allow them to continue to serve those communities. The reasonableness or unreasonableness of the grounds will be a function of the BAC as it advises the Minister and the Fund on what should inform the comprehensiveness of health care services to be purchased by the Fund. The health care component of Occupational Health Diseases whether in mining or in occupations in the overall economy currently falling under the ODIMWA	**On Subclause 6(o), the Department** proposes: DELETE 'any other private health insurance scheme' because the aim would be to have only schemes under the Medical Schemes Act providing complementary cover. Also propose addition of private insurance covering international traveller with short-term or work visa. *"6(o)* to purchase 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, **private insurance covering an international traveller with short-term or work visa, ~~any other private health insurance scheme~~** or out of pocket payments, as the case may be."

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	(m) to the protection of his or her rights to privacy and confidentiality, in accordance with the Protection of Personal Information Act, 2013 (Act No. 4 of 2013), in so far as he or she must grant written approval for the disclosure of personal information in the possession of or accessible to the Fund, unless the information— (i) is shared among health care service providers for the lawful purpose of serving the interests of users; or (ii) is utilised by the Fund for any other lawful purpose related or incidental to the functions of the Fund; *(n)* to have access to information on the funding of health care services in the Republic; and *(o)* to purchase 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.	and COIDA dispensations will be covered under services to be purchased under the NHI Fund. The Fund will purchase a comprehensive set of health care benefits from accredited and contracted providers. The NHI is introducing a purchaser-provider split so that the State as a provider of health care services (such as in public clinics and hospitals) can be held accountable for the quality of services that it will providing. The purpose of strategic purchasing is to ensure that these checks and balances are kept in place to protect the rights of users to have access to needed services. There has been clarity sought on Clause 6(f) on who is responsible for determining standards in the health establishments. The OHSC makes recommendations to the Minister on Norms and Standards of Quality for health establishments that must be complied with, and Minister approves these in a Gazette. These standards are monitored through inspections and certification to be undertaken by the OHSC. Furthermore, to improve transparency in the functioning of the Fund, Clause 10(1) (i) requires the Fund to collate utilisation data and implement information management systems to assist in monitoring the quality and standard of health care services, medicines, health goods and health related products purchased by the Fund. Clause 32(1) (a) states the Department of health has a function of “issuing and promoting guidelines for norms and standards related to health matters”. If services are delayed unreasonably, the recourse for the users is the right to complain and the complaint mechanisms are set in Chapter 9 of the Bill. Concern raised about retention of specialist services for pre-existing conditions has been noted. However,	

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		what is important to note is that all providers, including specialists must be certified, accredited and contracted to continue serving their patients under NHI. Furthermore, access to specialists should follow a referral pathway following an upward and downward referral system whose detail will be contained in Regulations. Questions raised about Clause 6 (o) are noted. Health care services and medicines that are not included in the National Formulary (and there is likely to be an exceptions process as there currently in the public sector) can also be accessed through a voluntary complementary cover through medical schemes registered by the Council for Medical Schemes. The Department however does not support instances where duplication is created to cover healthcare services that are covered in the basket of services covered by the NHI Fund. The Department however proposes that a further amendment be made to Clause 6 (o) to provide for tourists and international travellers with short-term or work visa. These traveller will not be entitled to coverage under NHI Fund but must be covered through private insurance that can purchase health care services on their behalf.	
Clause 7: Health care services coverage	**7.** (1) Subject to the provisions of this Act, the Fund, in consultation with the Minister, must purchase health care services, determined by the Benefits Advisory Committee, for the benefit of users. (2) Subject to subsection (4)— *(a)* a user must receive the health care services that he or she is entitled to under this Act from a health care service provider or health	There have been concerns that the BAC has been given unfettered powers to determine a package without reference to reality of health care needs of society. The purpose of establishing the NHI Fund as contained in Clause 2 (c) is to provide for equity and efficiency in funding when purchasing needed health care services	**No change recommended.**

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	establishment at which the user had registered for the purposes of receiving those health care services; *(b)* should a user be unable to access the health care service provider or health establishment with whom or at which the user is registered in terms of section 5, such portability of health services as may be prescribed must be available to that user; *(c)* should a health care service provider or health establishment contemplated in paragraph *(a)* or *(b)* not be able to provide the necessary health care services, the health care service provider or health establishment in question must transfer the user concerned to another appropriate health care service provider or health establishment that is capable of providing the necessary health care services in such manner and on such terms as may be prescribed; *(d)* a user— (i) must first access health care services at a primary health care level as the entry into the health system; (ii) must adhere to the referral pathways prescribed for health care service providers or health establishments; and (iii) is not entitled to health care services purchased by the Fund if he or she fails to adhere to the prescribed referral pathways; (e) the Fund must enter into contracts with accredited health care service providers and health establishments at primary health care and hospital level based on the health needs of users and in accordance with referral pathways; and	and goods. The function of the BAC will be underpinned by this consideration. Clause 25(2) outlines what skills the BAC will consist of, namely various experts in the domains of health care provision including amongst others medicine, public health, allied disciplines, nursing, epidemiology and the users of health care services. The BAC will also receive inputs from experts in Health Technology Assessment and the Health Products Procurement Unit. Furthermore, Clause 25 (5) requires the BAC to review detailed and cost-effective treatment guidelines that take into account emergence of new technologies. A panel of experts will guide the development of clinical protocols for the entitlements that users will access including with regards to the National Formulary (EML, EEL and other technologies and even key consumables). These protocols are not intended to impinge on the autonomy of clinicians as these protocols will be developed by their peers in the various disciplines and they will be evidence-based protocols. Concerns that referral pathways as contained in Clause 7(2)(d)(iii) will hamper access are noted but are not valid. Adhering to referral pathways is an important component of strategic purchasing and addressing efficiencies in the delivery of health care that ensures that users enter the health system at the correct entry point and that allocation of funds for the purpose of reimbursement of providers are clearly accounted for. It is very wasteful and ineffective for users to access the health system at higher levels of care instead of the primary health care level. No user will be denied access in the case of emergency as clearly articulated in Section 27 of the Bill of Rights. All health establishments will be required to have a triage mechanism to assess if a user is in an emergency situation and in line with the Constitutional	

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	(f) in order to ensure the seamless provision of health care services at the hospital level— (i) the Minister must, by regulation, designate central hospitals as national government components in accordance with section 7(5) of the Public Service Act, 1994 (Proclamation No. 103 of 1994); (ii) the administration, management, budgeting and governance of central hospitals must be made a competence of national government; (iii) the management of central hospitals must be semi-autonomous with certain decision-making powers, including control over financial management, human resource management, minor infrastructure, technology, planning and full revenue retention delegated by the national government; and (iv) central hospitals must establish cost centres responsible for managing business activities and determine the cost drivers at the level where the activities are directed and controlled. (3) For the purpose of subsection (2)(b), ''portability of health care services'', in respect of a user, means the ability of a user to access health care services by an accredited health care service provider or at an accredited health establishment other than by the health care services provider or at the health establishment with whom or at which that user is registered in terms of section 5. (4) Treatment must not be funded if a health care service provider demonstrates that— (a) no medical necessity exists for the health care service in question; (b) no cost-effective intervention exists for the health care service as determined by a health technology assessment; or	provisions, no-one can be denied care in such instances. The Department has also noted concerns raised about Clause 7 (2) (f) that provides for the Minister to designate central hospitals as national government components in accordance with Public Service Act. Concern has been raised by some stakeholders on this provision that the designation of central or tertiary hospitals to national administration will negatively affect the district health system, separating central hospitals from the burden of disease within the community. Central hospitals are national assets and the services, training platform and research and innovation conducted in these establishments must benefit the entire country and not to be confined to individual provinces. The Constitution also assigns health as a concurrent function but it is the National Health Act that assigns functions to provinces. The NHI Act will allow the Minister to delegate functions that are listed in the NHA if the provisions in the Act are not working to the benefit of the country. Stakeholders should also note that the National Health Act, 2003, Section 41 (Subsection 4 & 5) provides for the Minister to appoint the Board of Central Hospitals and that the functions of the Boards of Central hospitals are to be prescribed by the Minister. Central hospitals are national referral centres to which lower levels of care refer. They do not form part of the District health system. Their migration to the national sphere will not impact negatively on the provision of services within a district. There are presently 10 hospitals designated in the Regulations and they are funded at least 65% through national conditional grants.	

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	(c) the health care product or treatment is not included in the Formulary, except in circumstances where a complementary list has been approved by the Minister. (5) If the Fund refuses to fund a health care service, the Fund must— (a) provide the user concerned with a notice of the refusal. (b) provide the user with a reasonable opportunity to make representations in respect of such a refusal. (c) consider the representations made in respect of paragraph (b); and (d) provide adequate reasons for the decision to refuse the health care service to the user. (6) A user who is dissatisfied with the reasons for the decision contemplated in subsection (5)(d) may lodge an appeal in terms of section 43.		
Clause 8: Rights of Users	**Rights of Users** **8.** (1)A user of the Fund is entitled to receive the health care services purchased on his or her behalf by the Fund from an accredited health care service provider or health establishment free at the point of care. (2) A person or user, as the case may be, must pay for health care services rendered directly, through a voluntary medical insurance scheme or through any other private insurance scheme, if that person or user— *(a)* is not entitled to health care services purchased by the Fund in terms of the provisions of this Act; *(b)* fails to comply with referral pathways prescribed by a health care service provider or health establishment;	The Department has noted comments and concerns on Clause 8. The intention of this Clause is to ensure that in line with principles of a single purchaser NHI, users are not required to pay when they need to access health care services and that they are not exposed to out-of-pocket payments and financial hardship as a result of the need to access health care. Improving financial protection can be achieved with: (a) increasing government expenditure on health; (b) reducing out-of-pocket payments (OOP) in the broader funding context; (c) implementing national measures of financial protection; (d) ensuring the poor are not left behind; and (e) supporting positive trends in financial protection. This Clause does not restrict a person's freedom to pay for health care services as they would have a choice to	**Clause 8(2)** be amended to read: "(2) A person or user, as the case may be, must pay for health care services rendered directly, or through a voluntary medical scheme registered under the Medical Schemes Act or **through a private insurance covering an international traveller with short-term or work visa, or** out of pocket payment ~~or any other private insurance scheme."~~ • Propose that **Clause 8(2)(b)** be DELETED because it creates a loophole to bypass the NHI. There are several provisions in

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	(c) seeks services that are not deemed medically necessary by the Benefits Advisory Committee; or (d) seeks treatment that is not included in the Formulary.	pay out of pocket should the wish not to use the services covered under NHI. However, there will be no opting out of paying the mandatory NHI taxes for those that are eligible to make these payments, and no prepayment through a medical scheme, which will not be allowed to cover NHI benefits. The choice lies in whether a user chooses to access these services using the NHI Fund or not. Therefore, access to health care services is not restricted. The constitutional right to freedom of association is not restricted as the right to access health care for all people in the population as enshrined in Section 27 of the Bill of Rights is superior to a right to freedom of association. The BAC will not have the operational presence or reach to implement clause 8(2)(c) of the NHI Bill. There is no violation of the Constitution with the usage of the word "must" as legislative writing uses this word as a matter of emphasis. It is not the intention of Clause 8(2) to exacerbate anti-selection, and as a result, increase the cost associated with medical scheme membership as the role of medical schemes will change to schemes providing complimentary cover for services not covered by NHI the reasons provided. What is important is that the medical schemes must be regulated by the Medical Schemes Act which has specific provisions for anti-selection. This is the reason why the Department is of the view that amendments proposed to Clause 8 (2) which aim to delete to use of the words "private insurance schemes" should be supported because these are schemes are not regulated by the Medical Schemes Act and are likely to implement anti-selection practices. The Department is mandated by the National Health Act in Section 90 (u & v) on Regulations to determine	the Bill for referrals, including for emergencies that will be used to elaborate on this • **Clause 8 (2) (c) to be** amended to read: *"(c) seeks services that are not deemed medically necessary by the Benefits Advisory Committee or* ***that are not covered by the Fund as promulgated in Regulations approved by the Minister****".*

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		prices in the health sector. Together with provisions of Clause (10 (1) (g-h) and Clause 26 (3) on the functions of the Health Care Benefits Pricing Committee in the NHI Bill, all costs in the sector will be controlled through these modalities. The Department concurs with, and is in support of, comments that have raised caution that Clause 8 (2) creates duplicative coverage by medical schemes and that Clause 8(2)(b) will encourage non-adherence to the referral pathway and will create a parallel system by undermining referral pathways. It also concurs with the concern raised that Clause 8 (2) (c) may require changes to strengthen Clause 33. Consequently, the Departments proposes amendments to this Clause.	
CHAPTER 3: NATIONAL HEALTH INSURANCE FUND			
Clause 9: Establishment of the Fund	**Establishment of Fund** 9. The National Health Insurance Fund is hereby established as an autonomous public entity as contained in Schedule 3A to the Public Finance Management Act.	The Department has noted all the comments arising out the provisions of Clause 9. The Department is in agreement that the required capacity and resources require adequate time to be built until the Fund is fully functional. It is for this reason that the Department is capacitating itself to incubate some of the capacities and functions that are required for the normal functioning of a health system that is geared towards achieving the intermediate long term objectives of UHC as described by the WHO. These would achieve equitable resource distribution, efficiency, accountability, transparency, quality, monitoring of utilisation and determining need, as well measuring financial protection of the population. Where a purchaser-provider mechanism has been implemented, as the intention is with NHI, funds must follow functions.	**No change recommended.**

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		The centralisation of the function of delivering health care that has until now been undertaken by the provinces does not infringe on their Constitutional mandate. Provincial health functions are assigned in Section 25 of the National Health Act. The Amendments to Section 25 of the NHA in the Schedule amends these assigned functions. Clause 32 (2)(a-b) also makes provision for these functions to be delegated to provinces or designated to autonomous legal entities. The NHI is a health policy modality that is accounting to the Minister of Health as per the Constitutional provisions. The role of the Minister of Finance is not in Health Policy but in ensuring that the Policy is funded. The Minister of Finance will therefore play a crucial role in ensuring that funding is mobilised to allow the NHI Fund to execute its mandate. The Department is in agreement that it is important to entrench accountability. The Department is satisfied that the provisions in the Bill, supported by the PFMA, as a Schedule 3A entity accounting also to Parliament, is adequate to address this concern.	
Clause 10: Functions of Fund	**Functions of Fund** 10.(1) To achieve the purpose of this Act, the Fund must— a) take all reasonably necessary steps to achieve the objectives of the Fund and the attainment of universal health coverage as outlined in section 2; b) pool the allocated resources in order to actively purchase and procure health care services, medicines, health goods and	The Department notes the inputs of stakeholders on Clause 10 of the Bill. The Department has studied a vast array of health financing systems globally. Many countries that have recently pursued similar health system reforms e.g., South Korea and Estonia, have found it advisable not to fragment purchasing capacity given that very specific and scarce skill set that is required for this function. Centralised purchasing can achieve the cost containment benefits of monopsony purchasing power	**No change recommended.**

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	health related products from health care service providers, health establishments and suppliers that are certified and accredited in accordance with the provisions of this Act, the National Health Act and the Public Finance Management Act; c) purchase health care services on behalf of users as advised by the Benefits Advisory Committee; d) enter into contracts with accredited health care service providers based on the health care needs of users; e) prioritise the timely reimbursement of health care services to achieve equity; f) establish mechanisms and issue directives for the regular, appropriate and timeous payment of health care service providers, health establishments and suppliers; g) determine payment rates annually for health care service providers, health establishments and suppliers in the prescribed manner and in accordance with the provisions of this Act; h) take measures to ensure that the funding of health care services is appropriate and consistent with the concepts of primary, secondary, tertiary and quaternary levels of health care services; i) collate utilisation data and implement information management systems to assist in monitoring the quality and standard of health care services, medicines, health goods and health related products purchased by the Fund; j) c) develop and maintain a service and performance profile of all accredited and contracted health care service providers, health establishments and suppliers;	and can also more easily address the problems associated with cross-district use of health services. The Fund will be self-administered and, where appropriate, skill sets that are not in the Fund will be identified without outsourcing the administration of the Fund. Concerns raised about Clause 10 (1)(g) and its potential to manipulate the market are unfounded. The NHI Fund in consultation with the Minister will determine its own pricing and reimbursement mechanisms as also provided for in Section 90 (u-v) of the NHA. As a single purchaser, the Fund must determine the rates that it can afford within the budget envelope. Acting as a single-payer and single purchaser, the NHI Fund will be able to reap the efficiency benefits of monopsony purchasing power and economies of scale and ensure that incentive structures for healthcare providers are integrated and coherent. There is concern that the Fund should not issue directives. The Department does not agree with the notion that only regulatory bodies can issue directives as was the case during the COVID-19 pandemic when directives were issued in the management of the pandemic. The Fund will be drafting Regulations for the Minister to publish in pursuit of its objectives. Directives will provide the Fund with flexibility to issue instructions for compliance with aspects of implementation and administration of the Act. Directives will not be contradictory to the spirit of the Act, may not contradict Regulations, and are reviewable and are not punitive but would allow regulated establishments under this Act to comply within specified time frames.	

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	k) ensure that health care service providers, health establishments and suppliers are paid in accordance with the quality and value of the service provided at every level of care; l) monitor the registration, license or accreditation status, as the case may be, of health care service providers, health establishments and suppliers; m) account to the Minister on the performance of its functions and the exercise of its powers; n) undertake internal audit and risk management; o) undertake research, monitoring and evaluation of the impact of the Fund on national health outcomes; p) liaise and exchange information with the Department, statutory professional councils, other government departments and organs of state as and when appropriate or necessary in order to achieve the purpose outlined in section 2; q) maintain a national database on the demographic and epidemiological profile of the population; r) protect the rights and interests of users of the Fund; s) enforce compliance with this Act; t) take any other action or steps which are incidental to the performance of the functions or the exercise of the powers of the Fund; and u) operate in accordance with the provisions of this Act and other applicable law at all times. (2) The Fund must perform its functions in the most cost-effective and efficient manner possible and in accordance with the values		

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	and principles mentioned in section 195 of the Constitution and the provisions of the Public Finance Management Act. (3) The Fund performs its functions in accordance with health policies approved by the Minister. (4) The Fund must support the Minister in fulfilling his or her obligation to protect, promote, improve and maintain the health of the population as provided for in section 3 of the National Health Act.		
Clause 11	**Powers of Fund** **11.** (1) *(a)* employ personnel and must comply with all applicable labour laws; (b) purchase or otherwise acquire goods, equipment, land, buildings, and any other kind of movable and immovable property; (c) sell, lease, mortgage, encumber, dispose of, exchange, cultivate, develop, build upon or improve, or in any other manner manage, its property; (d) in the prescribed manner and subject to national legislation, invest any money not immediately required for the conduct of its business and realise, alter or reinvest such investments or otherwise manage such funds or investments; (e) draw, draft, accept, endorse, discount, sign and issue promissory notes, bills and other negotiable or transferable instruments, excluding share certificates; (f) insure itself against any loss, damage, risk or liability which it may suffer or incur;	The Department supports the proposed amendments to Clause 11 (1)(i)(vi) The Department does not support the concerns raised about Clause 11(1)(h) which provides for the Fund to investigate complaints against itself. The fund must have that internal capacity to investigate complaints lodged against it first. Furthermore, Clauses 42, 43 and 44 outline other mechanisms available to stakeholders to complain, lodge complaints and appeal the decisions of the Fund. The addition of another Health Ombuds as the National Health Act has already established a Health Ombuds through the amendments of the 2013 NHA is also duplicative. The price-setting mechanism contemplated in clause 11(2)(e) is critical in ensuring that NHI as a Strategic Purchasing entity will leverage the provision of efficient and quality services through linking provider payment to their performance and compliance with accreditation criteria. The reimbursement system will be regularly reviewed and refined taking into account implementation experiences and budget impact assessments. The price-setting process will be guided	**Clause 11 (1)(i)(iv)** to be amended: "(iv) receiving and collating of all required data from **health care service** providers, **health establishments and suppliers** for the efficient running of the Fund;"

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	(g) improve access to, and the funding, purchasing and procurement of, health care services, medicines, health goods and health related products that are of a reasonable quality; (h) investigate complaints against the Fund, health care service providers, health establishments or suppliers; (i) identify, develop, promote and facilitate the implementation of best practices in respect of— (i) the purchase of health care services and procurement of medicines, health goods and health related products on behalf of users; (ii) payment of health care service providers, health workers, health establishments and suppliers; (iii) facilitation of the efficient and equitable delivery of quality health care services to users; (iv) receiving and collating of all required data from health care service providers, health establishments and suppliers for the efficient running of the Fund; (v) managing risks that the Fund is likely to encounter; (vi) fraud prevention within the Fund and within the national health system; (vii) the design of the health care service benefits to be purchased by the Fund, in consultation with the Minister; and (viii) referral networks in respect of users, in consultation with the Minister; (j) undertake or sponsor health research and appropriate programmes or projects designed to facilitate universal access to health care services;	by the outputs of the Health Benefits Pricing Committee and is also informed by Section 90 (u-v) of the National Health Act. 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 the Bill are complementary as both the SEP and the objectives of the Bill are aimed at driving down the costs of medicines. The Performance Monitoring Unit of the NHI Fund is provided for in Clause 20 (3)(h) under the Functions of the CEO.	

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	(k) discourage and prevent corruption, fraud, unethical or unprofessional conduct or abuse of users or of the Fund; (l) obtain from, or exchange information with, any other public entity or organ of state; (m) conclude an agreement with any person for the performance of any particular act or particular work or the rendering of health care 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; (n) institute or defend legal proceedings and commence, conduct, defend or abandon legal proceedings as it deems fit in order to achieve its objects in accordance with this Act; and (o) make recommendations to the Minister or advise him or her on any matter concerning the Fund, including the making of regulations in terms of this Act. (2) The Fund may enter into a contract for the procurement and supply of specific health care services, medicines, health goods and health related products with an accredited health care service provider, health establishment or supplier, and must— (a) purchase such services of sufficient quantity and quality to meet the needs of users; (b) take all reasonable measures to ensure that there may be no interruption to supply for the duration of the contract; (c) conduct its business in a manner that is consistent with the best interests of users; (d) not conduct itself in a manner that contravenes this Act; and (e) negotiate the lowest possible price for goods and health care services without		

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	compromising 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** **12.** A Board that is accountable to the Minister is hereby established to govern the Fund in accordance with the provisions of the Public Finance Management Act.	The Board of the Fund must be accountable to the Minister of Health as the Executive Authority responsible for the health sector. This is consistent with other similar such entities that are established for other sectors. The National Health Act places responsibility for the health sector on the Minister of Health. This responsibility cannot be assigned to any other entity as it will undermine the Constitution. Parliament will exercise oversight over the NHI Fund as per the norm and practice for other health sector statutory entities such as NHLS, CMS and MRC. Other similar entities also have their Boards accounting to Parliament through their Ministers. Inputs to have the Commissioner of COIDA represented on the Board of the Fund are noted and will be factored into amendments The accountability for establishment of the Board should not reside with Parliament or an Independent Judicial Panel rather than an individual (Minister) as the Fund is not a Chapter 9 institution but rather a PFMA Schedule 3A public entity. Instead, Cabinet, as part of the Executive should be tasked with that responsibility.	
Clause 13: Constitution and Composition of Board	13. (1) The Board consists of not more than 11 persons appointed by the Minister who are not employed by the Fund and one member who represents the Minister.	The powers of the Minister are conferred through Section 92(2) of the Constitution and the responsibilities of the Minister to Parliament are contained in Section 92 (3) (b) of the Constitution. The role of Parliament is to amend the Constitution and pass legislation as stated in Section 44 of the	**13 (3)(a) – (b) to be amendment as follows** "(3) An ad hoc advisory panel appointed by the Minister must— *(a)* conduct public interviews of shortlisted candidates; and

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	(2) Before the Board members contemplated in subsection (1) are appointed, the Minister must issue in the Gazette a call for the public nomination of candidates to serve on the Board. (3) An ad hoc advisory panel appointed by the Minister must— (a) conduct public interviews of shortlisted candidates; and (b) forward their recommendations to the Minister for approval. (4) The Minister must, within 30 days from the date of confirmation of the appointment of a Board member, give notice of the appointment in the Gazette. (5) A Board member is appointed for a term not exceeding five years, which is renewable only once, and must— (a) be a fit and proper person; (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; (c) be able to perform effectively and in the interests of the general public; (d) not be employed by the State; and (e) not have any personal or professional interest in the Fund or the health sector that would interfere with the performance in good faith of his or her duties as a Board member. (6) The Chief Executive Officer is an ex officio member of the Board, but may not vote at its meetings.	Constitution. Parliament can therefore not be the arm of government that appoints the Board. The Board of the Fund will be accountable to Parliament through the Minister of Health as the Executive Authority responsible for the health sector. To address the concerns raised about the transparency of the appointment of the Board, it is proposed that the *ad hoc* panel must be appointed by Minister and the full procedure of recruitment and selection plus recommended names must be **approved by Cabinet.** The Minister will issue in the Gazette and national news media a call for the public nomination of candidates who comply with the criteria in subsection 13(5), to serve on the Board. The Minister will also publish a list of nominees received in response to such invitation, which list shall include the names of the nominators; and will publish the process by which members of the public may make submissions on nominees, which submissions will be considered by the ad hoc advisory panel. The composition of the Board must broadly reflect the diversity of the country, including in relation to age, race, gender and disability. It is also standard practice that the Boards of health sector entities have a ministerial representative. This allows for alignment between the entity and ministerial sector priorities. It is also standard practice that whenever a position on the Board becomes vacant before the expiry of the term of office as referred to in subsection 13(5), the Minister may appoint any other competent person, who meets the criteria listed in section 13(5) of the Act, to serve for the unexpired portion of the term of office of the previous member irrespective of when the vacancy occurs.	*(b)* forward their recommendations to the Minister for **approval by Cabinet."** **Clause 13(5) to be amendment as follows:** **"(f) composition of the Board must broadly reflect the diversity of the country, including in relation to age, race, gender and disability".** **Clause 13(5) to be amendment as follows:** **"(5)A Whenever a position on the Board becomes vacant before the expiry of the term of office the Minister may appoint any other competent person, who meets the criteria listed in section 13(5) of the Act, to serve for the unexpired portion of the term of office of the previous member irrespective of when the vacancy occurs".**

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	(7) A Board member may resign by written notice to the Minister. (8) The Minister may remove a Board member if that person— (a) is or becomes disqualified in terms of any law; (b) fails to perform the functions of office in good faith, in the public interest and in accordance with applicable ethical and legal prescripts; or (c) becomes unable to continue to perform the functions of office for any other reason. (9) (a) Subject to paragraph (b), the Minister may dissolve the Board on good cause shown only after— (i) giving the Board a reasonable opportunity to make representations; and (ii) affording the Board a hearing on any representations received. (b) If the Minister dissolves the Board in terms of this subsection, the Minister— (i) may appoint acting Board members for a maximum period of three months to do anything required by this Act, subject to any conditions that the Minister may require; and (ii) must, as soon as is feasible, but not later than three months after the dissolution of the Board, replace the Board members in the same manner that they were appointed in terms of this section.	The removal or resignation of members of the Board cannot be approved through Parliament as Parliament is not the appointing arm of government. The Minister must, after inquiry and approval by Cabinet, dissolve the Board on account of failure to discharge its fiduciary duties; poor or non-performance of its duties as contemplated; or abuse of power. It is also normal practice for the Chief Executive Officer (CEO) to be an ex-officio member of the Board.	**Clause 13(9)(a) to be amendment as follows:** (9) (a) Subject to paragraph (b), the Minister may dissolve the Board ~~on good cause shown~~ only after **inquiry and approval by Cabinet.** — ~~(i) giving the Board a reasonable opportunity to make representations; and~~ ~~(ii) affording the Board a hearing on any representations received.~~
Clause 14: Chairperson and Deputy Chairperson	**Chairperson and Deputy Chairperson** 14. (1) The Minister must appoint a Chairperson from amongst the members of the Board as contemplated in section 13(1).	This is normal practice as is the case with all other entities reporting to the Minister of Health i.e. NHLS, CMS, MRC, HPCSA as the Executing Authority (EA) to which these entities report to. Therefore, as the EA to which the Fund accounts, the same must apply and be	**Clause 14**(1) **to be amendment as follows:** "The Minister must, **after consultation with Cabinet**, appoint a

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	(2) The Board must appoint a Deputy Chairperson from amongst the members of the Board as contemplated in section 13(1). (3) Whenever the Chairperson and Deputy Chairperson of the Board are absent or unable to fulfil the functions of the Chairperson, the members of the Board must designate any other member of the Board, to act as Chairperson of the Board during such absence or incapacity.	implemented for the NHI Fund. It is proposed that the Minister after consultation with Cabinet must appoint the Chairperson from amongst members of the Board. Similarly, the representative of the Minister in the Board is to ensure that there is alignment between the overall health policy and the activities of the Fund	Chairperson from amongst the members of the Board as contemplated in section 13(1)."
Clause 15: Functions and Powers of the Board	**Functions and Powers of the Board** **15.** (1) The Board must fulfil the functions of an accounting authority as required by the Public Finance Management Act and is accountable to the Minister. (2) The entire Board as appointed in terms of sections 13 and 14 must meet at least four times per year, excluding any special meetings and sub-committee meetings that may be called from time to time as is necessary. (3) The Board must advise the Minister on any matter concerning— *(a)* the management and administration of the Fund, including operational, financial and administrative policies and practices; *(b)* the development of comprehensive health care services to be funded by the Fund through the Benefits Advisory Committee; *(c)* the pricing of health care services to be purchased by the Fund through the Health Care Benefits Pricing Committee of the Board; *(d)* the improvement of efficiency and performance of the Fund in terms of strategic	The Board will be required to exercise oversight in line with prescripts of good governance as contained in laws such as the PFMA and other governance prescripts of Schedule 3A entities. Details about quorums can be provided for in Regulation. Remuneration will be in line with National Treasury Regulations and will be approved by Minster of Health after consultation with Minister of Finance. The NHI Fund is not a Chapter 9 Institution nor can the Board be categorised as consisting of Public Office Bearers. The Board can establish Technical Committees but will not be in a position to co-opt advisors since its establishment is prescribed in law. It is not the function of the Board to set prices. Health Benefits and health prices will be recommended to the Minister by the Benefits Advisory Committee and the Health Benefits Pricing Committee which are Advisory Committees appointed to effect such a task as provided for in Clause 15. It is proposed that this clause be amended to ensure that the Board advises the Minister on any matter concerning policies related to financial and	**Clause 15(3) to be amended** to exclude Minister engaging in operations but should retain issues related to policies. "(3) The Board must advise the Minister on any matter concerning— ~~(a) the management and administration of the Fund, including operational,~~ **financial and administrative policies of the Fund** ~~and practices~~"; Clause 15 to be AMENDED to ADD (5): **"(5) The Board and the CEO of the Fund must meet with the Minister and Director-General of Health at least twice per year in order to exchange information necessary for the Board to carry out its responsibilities".**

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	purchasing and provision of health care services; *(e)* terms and conditions of employment of Fund employees; *(f)* collective bargaining; *(g)* the budget of the Fund; (h) the implementation of this Act and other relevant legislation; and (i) overseeing the transition from when this legislation is enacted until the Fund is fully implemented. (4) For the purposes of subsection (1), the Board— (a) may examine and comment on any policies, investigate, evaluate and advise on any practices and decisions of the Fund or the Chief Executive Officer under this Act; (b) is entitled to all relevant information concerning the administration of the Fund; (c) may require— (i) the Chief Executive Officer to submit a report concerning a matter on which the Board must give advice; or (ii) any Fund employee to appear before it and give explanations concerning such a matter; and (d) must inform the Minister of any advice it gives to the Chief Executive Officer.	administrative functions of the Fund. Furthermore, the Board with the CEO must meet the Minister at least twice a year to exchange information of the functioning of the Fund.	
Clause 16: Conduct and Disclosure of Interests	**Conduct and Disclosure of Interests** 16. (1) A member of the Board may not engage in any paid employment that may conflict with the proper performance of his or her functions. (2) A member of the Board may not—	The Department notes the inputs that have been made on Clause 16 and the concern raised that it should be carefully constructed to guard against conflict, corruption and capture to include any direct or indirect conflict of interest, including paid employment and should include indirect material interest to avoid clever restructuring of financial and money interests.	**No changes recommended.**

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	(a) be a government employee or an employee of the Fund; (b) attend, participate in, vote or influence the proceedings during a meeting of the Board or of a committee thereof if, in relation to the matter before the Board or committee, that member has an interest, including a financial interest, that precludes him or her from acting in a fair, unbiased and proper manner; or (c) make private use of, or profit from, any confidential information obtained as a result of performing his or her functions as a member of the Board. (3) For purposes of subsection (2)(b), a financial interest means a direct material interest of a monetary nature, or to which a monetary value may be attributed.	It is the Departments assertion that these provisions are consistent with standard Board practices implemented by entities of the Fund's nature and factored in the interests raised by these stakeholders.	
Clause 17: Procedures	**Procedures** **17.** The Board must determine its own procedures in consultation with the Minister.	This provision is consistent with standard Board practices implemented by entities of the Fund's nature where these procedures are determined in consultation with the Minister. The provision allows for the Board to establish the Fund's vision, mission and values as per the provisions of the Act. This includes delegating necessary functions to management and exercising accountability to the Minister, Parliament and other relevant stakeholders	**No changes recommended.**
Clause 18: Remuneration and reimbursement	**Remuneration and reimbursement** **18.** The Fund may remunerate a Board member and compensate him or her for expenses as determined by the Minister in consultation with the Minister of Finance and in line with the	This provision is consistent with standard Board practices implemented by entities of the Fund's nature where Boards are remunerated as per applicable Treasury prescripts and in compliance with the provisions of the PFMA. Members of the Board cannot be remunerated using the Independent Commission for the Remuneration of	**No changes recommended.**

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	provisions of the Public Finance Management Act.	Public Office-Bearers and they are not elected public office-bearers	
CHAPTER 5: CHIEF EXECUTIVE OFFICER			
Clause 19: Appointment	**Appointment** **19.** (1) A Chief Executive Officer must be appointed on the basis of his or her experience and technical competence as the administrative head of the Fund in accordance with a transparent and competitive process. (2) The Board must— *(a)* conduct interviews of shortlisted candidates; and *(b)* forward their recommendations to the Minister for approval by Cabinet. (3) The Minister must, within 30 days from the date of appointment of the Chief Executive Officer, notify Parliament of the final appointment and give notice of the appointment in the *Gazette*. (4) A person appointed as Chief Executive Officer holds office— *(a)* for an agreed term not exceeding five years, which is renewable only once; and *(b)* subject to the directives and determinations of the Board in consultation with the Minister. (5) The Board may recommend to the Minister the removal of the Chief Executive Officer if that person— *(a)* is or becomes disqualified in terms of the law;	The Department notes the concerns raised by stakeholders about the perceived excessive powers and influence by the Minister who must approve the recommendation of the Board in appointing the CEO that could undermine the autonomy of the CEO. The fact that the Fund is a Schedule 3A entity that is subject to the PFMA, the CEO will be expected to execute his or her fiduciary duties as prescribed in the PFMA. The Chief Executive Officer of the Fund must be appointed through a process that is initiated by the Board with the Minister having the final say in the approval of the appointment of the Chief Executive Officer. This is similar to how other health sector entities' CEOs are appointed and reflect the need for the Minister to retain oversight over key entities and their functions to reflect the priorities and objectives of the health sector.	

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	(b) fails to perform the functions of his or her office in good faith, in the public interest and in accordance with applicable ethical and legal prescripts; or *(c)* becomes unable to continue to perform the functions of his or her office for any other reason.		
Clause 20: **Responsibilities**	**Responsibilities** 20. (1) The Chief Executive Officer as administrative head of the Fund— (a) is directly accountable to the Board; (b) is responsible for the functions specifically designated by the Board; (c) takes all decisions as contemplated in terms of subsection (6); and (d) must report to the Board on a quarterly basis and to Parliament on an annual basis. (2) Subject to the direction of the Board, the responsibilities of the Chief Executive Officer include the— (a) formation and development of an efficient Fund administration; (b) organisation and control of the staff of the Fund; (c) maintenance of discipline within the Fund; (d) effective deployment and utilisation of staff to achieve maximum operational results; and (e) establishment of an Investigating Unit within the national office of the Fund for the purposes of— (i) investigating complaints of fraud, corruption, other criminal activity, unethical business practices and abuse relating to any matter affecting the Fund or users of the Fund; and	The Department notes the need for clarity to be provided in the role definition between the different committees and some units to be established by the CEO in terms of clause 20(3). The Units established will support the functioning of the BAC and Benefits Design Unit; Provider Payment Mechanisms and Rates and the Provider Payment Unit will support the Health Care Benefits Pricing Committee. There was a concern raised that the Investigative Unit of the Fund will have powers to investigate cases of corruption and maladministration against the NHI Fund, and that this function must be conducted by an independent body. The Department is of the view that the fund must have that internal capacity to investigate complaints lodged against it first. Furthermore, Clauses 42, 43 and 44 outline other mechanisms available to stakeholders to complain, lodge complaints and appeal the decisions of the Fund. The addition of another Health Ombuds as the National Health Act has already established a Health Ombuds through the amendments of the 2013 NHA is also duplicative.	**No amendments proposed.**

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	(ii) liaising with the District Health Management Office concerning any matter contemplated in subparagraph (i). (3) Subject to the direction of the Board, the Chief Executive Officer must establish the following units in order to ensure the efficient and effective functioning of the Fund: (a) Planning; (b) Benefits Design; (c) Provider Payment Mechanisms and Rates; (d) Accreditation; (e) Purchasing and Contracting; (f) Provider Payment; (g) Procurement; (h) Performance Monitoring; and (i) Risk and Fraud Prevention Investigation. (4) Subject to the direction of the Board, the Chief Executive Officer is responsible for— (a) all income and expenditure of the Fund; (b) all revenue received from the National Treasury established by section 5 of the Public Finance Management Act or obtained from any other source, as the case may be; (c) all assets and the discharge of all liabilities of the Fund; and (d) the proper and diligent implementation of financial matters of the Fund as provided for in the Public Finance Management Act. (5) The Chief Executive Officer must submit to the Board an annual report of the activities of the Fund during a financial year as outlined in section 51, which must include— (a) details of the financial performance of the Fund, as audited by the Auditor-General, including evidence of the proper and diligent implementation of the Public Finance Management Act;		

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	(b) details of performance of the Fund in relation to ensuring access to quality health care services in line with the health care needs of the population; (c) the number of accredited and approved health care providers; and (d) the health status of the population based on such requirements as may be prescribed. (6) The Chief Executive Officer must perform the functions of his or her office with diligence and as required by this Act and all other relevant law.		
Clause 21: Relationship of Chief Executive Officer with Minister, Director-General and Office of Health Standards Compliance	**Relationship of Chief Executive Officer with Minister, Director-General and Office of Health Standards Compliance** **21.** (1) The Chief Executive Officer of the Fund must meet with the Minister, Director-General of Health and the Chief Executive Officer of the Office of Health Standards Compliance at least four times per year in order to exchange information necessary for him or her to carry out his or her responsibilities. (2) Notwithstanding subsection (1) the Chief Executive Officer remains accountable to the Board.	The Department notes the comment by stakeholders that there is a blurring of lines between the Minister as the Executive Authority responsible for health and the administrative structures of the Fund i.e., CEO and the Board. However, the Department is of the view that the provisions outlined in Clause 21 (1) are important as they allow for collaborative policy and priorities alignment between the Minister, Department of Health, Office of Health Standards Compliance and the NHI Fund. This creates the mechanisms necessary for sharing the necessary information and creating platforms that align health system planning, implementation of programmes and alignment of requirements in areas such as provider accreditation and the setting of norms and standards. The provision in Clause 21(2) entrench accountability for the performance of the NHI Fund must remain with the Chief Executive Officer, whose performance is assessed by the Board according to plans submitted to	The Department proposes consideration of Clause 15(5) to provide for the Minister to have fixed points of receiving reports from Board (e.g. no less than twice a year). The Department proposes consideration that the NHI Fund has separate meetings with OHSC and CMS (without the Minister) to harmonise NHI Fund implementation and activities. 21. (1) The Chief Executive Officer of the Fund **and the Board** must meet with the Minister, Director-General of Health and the Chief Executive Officer of the Office of Health Standards Compliance at least four times per year in order to exchange information necessary for him or her to carry out his or her responsibilities.

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		and approved by the Minister of Health on an annual basis.	
Clause 22: Staff at executive management level	**Staff at Executive Management Level** **22.** The Chief Executive Officer may not appoint or dismiss members of staff at executive management level without the prior written approval of the Board.	The Department is of the view that provisions in Clause 22 provide a clear mechanism for strong and accountable management linked to the oversight function of the Board. Clause 22 will allow for clear and transparent processes to be implemented for the appointment or dismissal of the Fund's executives, without creating a process that is unilaterally implemented by the Chief Executive Officer without the knowledge of the Board, and to the detriment of the Fund's stability and ability to achieve its mandate. It also enables the Board to effectively exercise its mandated oversight function over the Fund and its activities.	**No changes recommended.**
CHAPTER 6: COMMITTEES ESTABLISHED BY BOARD			
Clause 23: Committees of Board	**Committees of Board** **23.** (1) The Board may establish a committee and, subject to such conditions as it may impose, delegate or assign any of its powers or duties to a committee so established. (2) Each committee established in terms of subsection (1) must have at least one Board member appointed in term of section 13(1) as a member of that committee.	The Department notes the various comments and suggestions made by stakeholders with regards to the Committees of the Board and the numerous additional committees that should be established as part of the Board per the King Report. However, not all the Committees are mentioned because it is considered standard practice that a Board of the Fund's nature should have committees that focus on Audit & Risk, Remuneration and Finance to mention the main ones. Additionally, the Bill only specifies core Committees, and the Board is allowed sufficient flexibility to add further committees should it deem them necessary, but	**Clause 23 (5) to have an ADDITION** **"(5) A member of such a committee must—** **a) act in a way that is impartial and without fear, favour or prejudice** **b) not expose himself or herself to any situation in which the risk of a conflict between his or her official responsibilities**

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	(3) Committees of the Board as established in subsection (1) must meet at least four times per year in order to report to the meeting of the full Board and may convene special meetings to discuss urgent matters when necessary. (4) The Board may dissolve or reconstitute a committee on good cause shown.	in consultation with the Minister due to financial and operational costs that may arise as result of setting up such committees. The Department deliberately did not draft the Bill in a prescriptive manner for this specific reason. To strengthen the clarity of the clauses in this section of the Bill, the Department recommends the following inclusion to Clause 23 (5) *"A member of such a committee must—* *a) act in a way that is impartial and without fear, favour or prejudice* *b) not expose himself or herself to any situation in which the risk of a conflict between his or her official responsibilities and private interests may arise; or* *c) use his or her position, or any information entrusted to him or her, for self-enrichment or to improperly benefit any other person."* This inclusion will address some of the recommendations made by stakeholders on requiring clarity on the criteria to be applied when considering a person for appointment to a Committee. The technical work to be performed by such committees is likely to be influenced by vested interests from providers, suppliers, users and other business interests. It is very important that members of such committees are not encumbered with possible conflicts of interest that may also be of a financial or ethical nature.	**and private interests may arise; or** **c) not use his or her position, or any information entrusted to him or her, for self-enrichment or to improperly benefit any other person."**
Clause 24 Technical Committees	**Technical Committees**	The NHI Fund requires a number of interrelated but focussed Technical and operational Committees to address the various roles and functions that enable the Fund to achieve its legislated mandate. To this effect, the Department supports the provisions that allow for	Propose consideration of **ADDITION of similar provisions to Clause 24(4) as Clause 23 (5)**

BILL SECTION	CLAUSE IN BILL	NDOH POSITION	NDOH RECOMMENDATIONS
	24. (1) *(a)* The Board may establish such number of technical committees as may be necessary to achieve the purpose of this Act. *(b)* The provisions of section 29 apply to paragraph *(a)* with the changes required by the context. (2) A committee established in terms of subsection (1)(a) must perform its functions impartially and without fear, favour or prejudice (3) A person appointed as a member of such a committee must— (a) be a fit and proper person; (b) have appropriate expertise or experience; and (c) have the ability to perform effectively as a member of that committee. (4) A member of such a committee must not— (a) act in any way that is inconsistent with subsection (2) or expose himself or herself to any situation in which the risk of a conflict between his or her official responsibilities and private interests may arise; or (b) use his or her position, or any information entrusted to him or her, for self-enrichment or to improperly benefit any other person.	the Board to be capable of establishing technical committees that will provide guidance in areas such as partnerships and collaboration with local and international entities in areas of research, Health Technology Assessments, Pricing and Benefits design, provider payments, accreditation, purchasing and contracting, performance monitoring and risk and fraud prevention. Where necessary, and through clearly outlined operating procedures, the Fund can draw on additional expertise as and when required, with due consideration by the Board on the financial implications of such decisions and the transparent, accountable and autonomy of the Fund in its planning and decision making processes. As the Fund will be subject to the Public Finance Management Act, the remuneration of such Committees will be in line with National Treasury Regulations and prescripts as applicable from time to time. The recommendation that the exact detail and numbers of who will be appointed to each committee should be stated in the Bill is noted. However, the Department's view is that such detail should not necessarily be contained in the founding Act for the NHI Fund. It would be too prescriptive to include such detail in the Act. Instead, the Minister can gazette this information in stipulated regulations, which will be subject to stakeholder comments and inputs before finalisation. The functioning of the Technical Committees must be guided by clearly articulated Terms of Reference to ensure objective support to the Board and Administration in pursuit of the purposes of the Fund	
CHAPTER 7: ADVISORY COMMITTEES ESTABLISHED BY MINISTER			

BILL SECTION	CLAUSE IN BILL	NDOH POSITION	NDOH RECOMMENDATIONS
Clause 25 Benefits Advisory Committee	**Benefits Advisory Committee** **25.** (1) The Minister must, after consultation with the Board and by notice in the *Gazette*, establish a committee to be known as the Benefits Advisory Committee as one of the advisory committees of the Fund. (2) 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. (3) A person appointed in terms of subsection (2)— *(a)* serves for a term of not more than five years and may be reappointed for one more term only; and *(b)* ceases to be a member of the Committee when he or she is no longer a member of the institution that nominated him or her or when he or she resigns. (4) A vacancy in the Benefits Advisory Committee must be filled by the appointment of a person for the unexpired portion of the term of office of the member in whose place the person is appointed, and in the same manner in which the member was appointed in terms of subsection (2). (5) The Benefits Advisory Committee must determine and review— (a) the health care service benefits and types of services to be reimbursed at each level of care at primary health care facilities and at district, regional and tertiary hospitals; (b) detailed and cost-effective treatment guidelines that take into account the emergence of new technologies; and	The Department notes that indeed the Benefits Advisory Committee (BAC) is an important Committee of the NHI Fund in that the advice it provides to the Minister will ensure that health care services covered by the Fund are inclusive and do not disadvantage any communities in improving the health outcomes of the population. The detailed cost-effective guidelines will form the basis of progressively determining the costing of benefits to be covered by the NHI Fund. A process of priority-setting and health technology assessment (HTA) will be used to inform the decision-making processes of the BAC to determine the benefits to be covered. The range of services will be regularly reviewed using the best available evidence on cost-effectiveness, allocative, productive and technical efficiency and HTA. It must also be noted that the appointment of the BAC is aligned with Section 91 of the National Health Act on the appointed of Ministerial Advisory Committees. In line with the recommendations by some Portfolio Committee members, the Department supports the position that Clause 25(3)(b) be amended as follows: "*ceases to be a member of the Committee ~~when he or she is no longer a member of the institution that nominated him or her or~~ when he or she resigns".* This recommendation is based on the position that no member should be appointed to the BAC on the basis of institutional membership, but rather purely because of their individual skills and expertise. Nominating individuals based on their institutional affiliation will expose the BAC, and the Fund, to avoidable institutional vested interests and lobbying.	**Clauses 25 (3)(b) to be amended as follows:** "(b) ceases to be a member of the Committee ~~when he or she is no longer a member of the institution that nominated him or her or~~ when he or she resigns".

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	(c) in consultation with the Minister and the Board, the health service benefits provided by the Fund. (6) The Minister must appoint the chairperson from amongst the members of the Committee. (7) The Minister must, by notice in the Gazette, publish the guidelines contemplated in subsection (5)(b) and may prescribe additional functions to the Benefits Advisory Committee.		
Clause 26 Health Care Benefits Pricing Committee	**Health Care Benefits Pricing Committee** **26. (1)** The Minister must, after consultation with the Board and by notice in the *Gazette*, establish a Health Care Benefits Pricing Committee as one of the advisory committees of the Fund, consisting of not less than 16 and not more than 24 members. **(2**) The Health Care Benefits Pricing Committee consists of persons with expertise in actuarial science, medicines, epidemiology, health management, health economics, health financing, labour and rights of patients, and one member must represent the Minister. (3) The Committee must recommend the prices of health service benefits to the Fund. (4) The Minister must appoint the chairperson from amongst the members of the Committee.	The Department emphasises that the establishment of a Health Care Benefits Pricing Committee (HCBPC) is critical as it will advise the Minister and the Fund to ensure financial protection from the costs of health care and also provide access to quality health care services by determining the most affordable prices to be reimbursed by the Fund. The Fund will pay using a uniform reimbursement strategy and there will be no balanced or split billing. As a strategic purchaser, it is important that the Fund pays providers in a way that creates appropriate incentives for efficiency and for the provision of quality and accessible care. As was noted by a number of stakeholders, the Department agrees that this Committee is critical for the Fund's ability to determine provider payment mechanisms that must contribute to a responsive health system through ensuring that delivery of healthcare services is efficient, affordable and sustainable. It is important that people with the appropriate skill are appointed to ensure robust and reliable mechanism for the determination of prices for the reimbursement of accredited providers within the Fund's allocated budget.	**No changes recommended.**
Clause 27: Stakeholder	**Stakeholder Advisory Committee**	The Department notes the recommendation that business be specifically mentioned as an additional	**No changes recommended.**

BILL SECTION	CLAUSE IN BILL	NDOH POSITION	NDOH RECOMMENDATIONS
Advisory Committee	**27.** The Minister must, after consultation with the Board and by notice in the *Gazette*, appoint a Stakeholder Advisory Committee comprised of representatives from the statutory health professions councils, health public entities, organised labour, civil society organisations, associations of health professionals and providers as well as patient advocacy groups in such a manner as may be prescribed.	stakeholder to be included in the Stakeholder Advisory Committee. The recommendation to include brokers, supply chain managers and other such stakeholders is also noted. However, the Department disagrees with this approach as it is too prescriptive – once the approach of nominating and including Stakeholder Advisory Committee is opened up to such a prescriptive approach, it is impossible to draw the line on who not to mention or include. The broad, in principle, approach currently outlined in Clause 27 is deemed sufficient for inclusion in a Bill of this nature. Any such inclusions as may be deemed necessary can be provided for and elucidated further in enabling regulations that will be gazetted by the Minister of Health. These regulations will be developed to address procedures by which this Committee will operate. The Department is convinced that the composition of the Stakeholder Advisory Committee addresses the concerns raised by a number of stakeholders who had expressed an interest in being specifically named as a stakeholder to be included in this Committee In response to the recommendation regarding further clarity on the role of the Stakeholder Advisory Committee, the Department would like to indicate that this Committee will not have any decision-making powers and that its advisory recommendations will not have a binding effect on the operations and functioning of the Fund.	
Clause 28	**Disclosure of interests** **28.** A member of a committee established by the Minister in terms of this Act who has a personal or financial interest in any matter on which such committee gives advice, must disclose that interest when that matter is	The Department would like to indicate that the processes indicated in Clause 28 are consistent with those of the PFMA and are in line with good governance principles as it promotes transparency and accountability. Additionally, they are important as they help ensure that Committee members take decisions that will benefit the public interest instead of personal interest or associated/affiliated organisational	**No changes recommended.**

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	discussed and be recused during the discussion	interests. This is why it is recommended that no person be nominated based on their institutional or organisational affiliation. All nominations and appointments must be based on individual skills and expertise only.	
Clause 29: Procedures and remuneration	**Procedures and remuneration** **29.** When establishing a committee under this Chapter, the Minister must determine by notice in the *Gazette*— *(a)* its composition, functions and working procedures; *(b)* in consultation with the Minister of Finance, the terms, conditions, remuneration and allowances applicable to its members; and *(c)* any incidental matter relating to the committee.	The Department does not agree with the suggestion that the Board must unilaterally be capable of determining the procedures and remuneration of Committees. The Minister as the Executive Authority has power vested in him or her to issue such gazettes, and this power cannot be unilaterally usurped via inclusion of such a provision in the Bill. The current provisions are consistent with other processes of appointing Ministerial Advisory Committees using the provision of Section 91 of the National Health Act. They allow for the Minister to comply with the provisions of the National Health Act. Additionally, as is the procedure for all entities falling under the PFMA, the remuneration of Board members and the various committees indicated in the Bill will be as per the provisions of the PFMA, and according to National Treasury regulations and prescripts as published and updated from time to time.	**No changes recommended.**
Clause 30: Vacation of office	**Vacation of Office** **30.** A member of a committee established in terms of this Act ceases to be a member if— *(a)* that person resigns from that committee; *(b)* the Minister terminates that person's membership for adequate reason; or	To strengthen the clarity of the clauses in this section of the Bill, the Department recommends the following inclusion (similar to those proposed for Clause 23 (5)) where a member may be disqualified should they be found to: *act in a way that is not impartial and with fear, favour or prejudice in the interest of specific parties or stakeholders;*	Clause 30 to be amended by adding the following subclauses: **(d)** **"act in a way that is not impartial and with fear, favour or prejudice in the interest of specific parties or stakeholders;** **(e)** **deliberately exposes himself or herself to any**

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	(c) the term for which the member was appointed has expired and the membership has not been renewed.	*deliberately exposes himself or herself to any situation in which the risk of a conflict between his or her official responsibilities and private interests may arise; or* *make use of his or her position, or any information entrusted to him or her, for self-enrichment or to improperly benefit any other person."* The Department notes the recommendation to make provision in case any member of a Committee passes away. The position of the Department is that standard procedures for replacing the deceased member must apply, and these must be through a process lead by the Minister of Health and through gazette.	(f) **<u>situation in which the risk of a conflict between his or her official responsibilities and private interests may arise; or</u>** **<u>make use of his or her position, or any information entrusted to him or her, for self-enrichment or to improperly benefit any other person."</u>**
CHAPTER 8: GENERAL PROVISIONS APPLICABLE TO OPERATIONS OF THE FUND			
Clause 31: Role of Minister	**Role of Minister** **31.** (1) Without derogating from any responsibilities and powers conferred on him or her by the Constitution, the National Health Act, this Act or any other applicable law, the Minister is responsible for— *(a)* governance and stewardship of the national health system; and *(b)* governance and stewardship of the Fund in terms of the provisions of this Act. (2) The Minister must clearly delineate in appropriate legislation the respective roles and responsibilities of the Fund and the national and provincial Departments, taking into consideration the Constitution, this Act and the National Health Act, in order to prevent	The department notes the comments and recommendations made by stakeholders with regards to the role of the Minister in various aspects of the Fund and its structures. We recognise that the Minister is the designated Executive Authority for the health sector and in particular, the national health system and how its functions are performed as per the various legislative and regulatory frameworks. In particular, we recognise Section 92 of the Constitution, which clearly stipulates that members of the Cabinet are accountable collectively and individually to Parliament for the exercise of their powers and performance functions. This section also provides for the Minister to report regularly to	**No changes recommended.**

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	duplication of services and the wasting of resources and to ensure the equitable provision and financing of health services.	Parliament on the performance on matters under his or her control The matters that are under the control of the Minister are in governance and stewardship of the health system as contained in Section 3 of the National Health Act which stipulates that the Minister must within the limits of available resources endeavour to protect, promote, improve and maintain the health of the population including equitable prioritisation of health care services to be provided. Therefore, the Department is comfortable with the various roles indicated for the Minister in the Bill and does not recommend any substantive changes to Clause 31.	
Clause 32: Role of Department	**Role of Department** **32.** (1) The functions of the Department are outlined in the National Health Act and the Constitution, and include— *(a)* issuing and promoting guidelines for norms and standards related to health matters; *(b)* implementing human resources planning, development, production and management; *(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 health services as may be necessary to establish an integrated and comprehensive national health system; *(d)* planning the development of public and private hospitals, other health establishments	The Department is of the view that provisions in Clause 32 of the Bill are essential to clearly delineating the functions of the Department of Health as the maker of health policy and coordinating all providers of health services, and the role of the Fund as the purchaser of personal health care services from accredited and contracted health care providers, health establishments and providers. Clause 32(2) is key to the shifting of the public health sector funds to the NHI Fund as the functions are re-aligned to enable the strategic purchasing of personal healthcare services for the population. This will occur as the purchaser/provider split is implemented and the provinces are delegated only the provider functions. The purchaser provider split that will arise from the creation of the Fund is important for creating an environment where accredited and contracted providers and suppliers of services offer cost-effective,	**No changes proposed.**

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	and health agencies as contemplated in section 36 of the National Health Act; and *(e)* integrating the annual health plans of the Department and the provincial and district health departments and submitting the integrated health plans to the National Health Council. (2) Subject to the transitional provisions provided for in section 57, the Minister may introduce in Parliament proposed amendments to the National Health Act for the purpose of centralising the funding of health care services as required by this Act, and in such cases the Minister may— *(a)* delegate to provinces as management agents, for the purposes of provision of health care services, and in those cases the Fund must contract with sections within the province such as provincial tertiary, regional and emergency medical services; *(b)* designate provincial tertiary and regional hospitals or groups of hospitals as autonomous legal entities accountable to the Minister through regulation; and *(c)* establish District Health Management Offices as government components to manage personal and non-personal health care services. (3) Without derogating from the Constitution or any other law, the functions of a provincial Department must be amended to comply with the purpose and provisions of this Act, subject to the provisions of section 57.	efficient prices and deliver quality healthcare services to the population. Additionally, Sub-clause 32(2)(c) aims to devolve greater responsibility to the districts and implement reforms that support proactive planning and management of the resources for health services from the public purse closer to the communities who are to benefit. The introduction of District Health Management Offices also allows for localised service planning and provision, thus addressing the concerns around the Fund centralising all functions to the detriment of service delivery. The Department therefore supports all the provisions outlined in Clause 32 and its accompanying sub-clauses.	

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Clause 33: Role of Medical Schemes	**Role of Medical Schemes** **33.** Once National Health Insurance has been fully implemented as determined by the Minister through regulations in the *Gazette*, medical schemes may only offer complementary cover to services not reimbursable by the Fund	The Department recognises that to achieve meaningful progress towards realising universal health coverage through the phased implementation of NHI, it is critical that the implementation agenda leverages resources in the public and private sectors. Our view is that NHI must be founded on the public sector as its backbone, and that the NHI Fund must strategically utilise its allocated resources to draw in private sector providers and suppliers to provide registered users with needed health care services. The introduction of NHI ensures that the Fund will strategically utilise its capabilities to purchase health care services on behalf of the population through utilising mechanisms that draw on all health sector resources, public and private, by promoting equity, accessibility, affordability and sustainability principles. A key aim of implementing NHI is ensuring that progressively the country eliminates the fragmentation in the mobilising and allocation of healthcare financing resources in the country. Consequently, Clause 33 is essential to achieving equity in access to the entire financial and non-financial (especially human resources for health) resources of the national health system. Clause 33 is inevitably a central tenet of the health sector reforms because the Constitution regards everyone equally before the law and enjoins the State to undertake rational and reasonable steps towards progressively ensuring that everyone, not only those with control of resources, have access to needed healthcare services. It provides that these 'services' which will be excluded from payment from the Fund may be provided to individuals through voluntary complementary cover. They will change over time as technology and the economy changes.	**No changes proposed.**

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		The Department would like to emphasise that it will take reasonable time for the NHI Fund to establish an equilibrium and settle on the benefits that it will pay for. As benefits are fully paid for by the Fund and providers are accredited to deliver the benefits to all it will be inappropriate to have a duplicate funding stream and therefore **only the Fund** will pay for those inclusive benefits while medical aid schemes will pay for excluded services. The implication of the provision is that "fully implemented" will be detailed in the Gazette that the Minister will publish at the relevant time through legally determined procedures. The requirement that the details be furnished in the Bill would make the Bill too prescriptive and potentially create legal hurdles in future. Allowing for such details to be included in the regulations provides for sufficient flexibility to outline what 'full implementation' implies as the roll-out plan progresses. The Department is of the view that Clause 33 should remain generic as is currently outlined in the Bill. This will allow sufficient regulatory provisions to be outlined as the implementation processes unfold. The Clause should not be amended into a prescriptive one.	
Clause 34: National Health Information System	**National Health Information System** **34.** (1) The Fund must contribute to the development and maintenance of the national health information system as contemplated in section 74 of the National Health Act through the Information Platform established in terms of this section	The Department notes that for NHI to be effectively and efficiently implemented in a sustainable manner, it must be based on an information system that is capable of generating robust, accurate and reliable information at all times and in the correct format for planning and decision-making at all levels of management is required. Functional, integrated and appropriately coordinated and interoperable information systems are the	**No changes proposed.**

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	(2) Subject to the provisions of the National Archives and Record Services of South Africa, 1996 (Act No. 43 of 1996), the Protection of Personal Information Act, 2013 (Act No. 4 of 2013), and the Promotion of Access to Information Act, data must be accurate and accessible to the Department and the Fund, or to any other stakeholder legally entitled to such information. (3) Health workers, health care service providers and persons in charge of health establishments must comply with the provisions in the National Health Act relating to access to health records and the protection of health records.	cornerstone of any resilient and effective health system. The development of an integrated Health Information Platform aligned to the National Digital Health Strategy of the National Department of Health is currently underway. The end goal is one electronic health record for an individual from birth. The availability of required technology to provide data and information to the fund will be a prerequisite for accreditation as a provider. Over the past 5 year the National Department of Health has distributed more than 22 000 desk top computers to Primary Health Care facilities and Public Hospitals this is over and above the supply of equipment by the individual provincial departments of Health. Another good example of this is the interoperable platform for data management, planning and decision-making that was established during the management of the COVID-19 Pandemic. This enabled the country to better track the pandemic and make timely, evidence-based decisions to mitigate against the spread through the Risk-Adjusted approach Digital Health literacy of the public and health care workers is a key requirement for the development and implementation of an integrated digital health platform. South Africa's health system needs access to readily available quality data and information for policy development, informed decision-making for health resource planning and allocation, and monitoring and evaluating service delivery access. Without this, it is impossible to properly assess the population's health needs and thus plan how best they can be met.	

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Clause 35: Purchasing of health care services	**Purchasing of health care services** **35.** (1) The Fund must actively and strategically purchase health care services on behalf of users in accordance with need. (2) The Fund must transfer funds directly to accredited and contracted central, provincial, regional, specialised and district hospitals based on a global budget or Diagnosis Related Groups. (3) Funds for primary health care services must be transferred to Contracting Units for Primary Health Care at the sub-district level as outlined in section 37. (4) *(a)* Emergency medical services provided by accredited and contracted public and private health care service providers must be reimbursed on a capped case-based fee basis with adjustments made for case severity, where necessary. (b) Public ambulance services must be reimbursed through the provincial equitable allocation.	Clauses 35 provide for mechanisms that will enable the Fund to fulfil its mandate as a strategic purchaser to meet the population health needs. Referring to World Health Organisation standards, strategic purchasing is the active, evidence-based engagement in defining the service-mix and volume, and selecting the provider-mix in order to maximise societal objectives. It requires information on a range of issues such as prioritisation, cost-effectiveness, staff and facilities, price, quality and projections on available resources. The NHI Bill provisions on the purchasing of health care services are targeted at creating mechanisms that leverage the Fund's capabilities and using these to improve the performance of the health system and progressing towards universal health coverage. By the Fund executing the role of an active purchaser that pools funds on behalf of a population and purchases health services from accredited and contracted providers including emergency medical services, it will make sure that all users have access to equitable, affordable quality health care services at all times irrespective of where they reside. By design and according to statutes, the NHI Fund will purchase health care services for all users from appropriately accredited and contracted providers, whether public or private. The Fund will reimburse accredited and contracted providers directly whether at a primary health care level or at higher levels of care without going through an intermediary. The public sector will be the backbone upon which the service provision platform will be based, but the Fund will leverage its strategic purchasing resources to determine its own pricing and reimbursement mechanisms. It must be noted that the Fund will be compliant with the requirements of the Public Finance Management Act, and other prescripts such as the	**Clause 35 (2) to be amended** to read (2) The Fund must ~~**transfer funds**~~ **reimburse payment** directly to accredited and contracted central, provincial, regional, specialised and district hospitals based on a global budget or Diagnosis Related Groups. **Clause 35 (3) to be amended** to read: "5 (3) Funds for primary health care services must be ~~transferred~~ **reimbursed directly to accredited and contracted primary health care providers and establishments** ~~to Contracting Units for Primary Health Care~~ at the sub-district level as outlined in section 37."

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		Preferential Procurement Framework thus ensuring that even small to medium enterprises are prioritised where possible. This section of the Bill is also linked to what is clearly stated in the White Paper on NHI which indicates that *"active purchasing by a single strategic purchaser, using explicit contracts that set prices; gatekeeping at a primary health care level, and provider-payment reform that moves away from a fee-for-service environment to alternative strategies for reimbursement."* This aims to improve the efficiency of the system to increase the value of the money spent. Therefore, as a strategic purchaser, it is important that the Fund establishes a purchaser-provider split that enables it to proactively determine and purchase healthcare services directly from accredited and contracted healthcare services providers.	
Clause 36: Role of District Health Management Office	**Role of District Health Management Office** **36.** A District Health Management Office established as a national government component in terms of section 31A of the National Health Act must manage, facilitate, support and coordinate the provision of primary health care services for personal health care services and non-personal health services at district level in compliance with national policy guidelines and relevant law.	The Department notes the concerns that have been raised by some stakeholders about the role of DHMOs and their governance and accountability. The Department is of the view that there is a compelling reason to establish the DHMOs. Its functions will incorporate those that are currently performed by the current DHMT. Sufficient effort and resources must be allocated towards enhancing the managerial and technical capacity of within all DHMOs. The DHMO's will be established to ensure that every South African has access to PHC services within a District. They will be responsible for all planning and co-ordination of PHC needs of the district population. The DHMO should be given the responsibility of improving the health status of the district population with clear targets set for improvement.	**No changes proposed.**

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		DHMOs will adopt a multi-sectoral approach that includes other relevant Government departments. The DHMO will integrate public and private services. DHMO will be established as national government components accountable to the national sphere following the philosophy of centralised decentralisation. The DHMOs will support the functions undertaken by District Health Councils in their governance and oversight role over health districts and to promote community participation in the planning, provision and evaluation of health care services	
Clause 37: Contracting Unit for Primary Health Care	**Contracting Unit for Primary Health Care** **37.** (1) A Contracting Unit for Primary Health Care established in terms of section 31B of the National Health Act— (a) manages the provision of primary health care services, such as prevention, promotion, curative, rehabilitative ambulatory, home-based care and community care in a demarcated geographical area; and (b) is the preferred organisational unit with which the Fund contracts for the provision of primary health care services within a specified geographical area. (2) A Contracting Unit for Primary Health Care must be comprised of a district hospital, clinics or community health centres and ward-based outreach teams and private providers organised in horizontal networks within a specified geographical sub-district area, and must assist the Fund to—	The Department notes the generally positive comments towards the establishment of Contracting Units for PHC (CUPs) and the proposal for amendments. The intention of establishing CUPs is to ensure that is to facilitate contracting of public and private healthcare providers on behalf of the Fund in a Purchaser-Provider arrangement and as a principle of Strategic Purchasing. This will ensure that the Fund has a presence in a demarcated geographic area at a sub-district level. The CUPs will be established by the NHI Fund and not the DHMO to ensure purchaser-provider split and will be accountable to the NHI Fund. The Department concurs that the establishment of the CUP should be provided for in Clause 37 of the NHI Bill instead of being provided for in proposed Section 31 (B) of the National Health Act.	**Remove from the amendment to the National Health Act in the Schedule and include relevant details in S37 of the NHI Bill and Clause 37(1) to read:** "37(1) Contracting Units for Primary Health Care must be established ~~in terms of section 31B of the National Health Act~~ **as part of the Fund to** — (a) ~~manages the provision of primary health care services~~**plan the funding of accredited and contracted health care providers and establishments for,** such as prevention, promotion, curative, rehabilitative ambulatory, home-based care and community care in a demarcated geographical area; and (b) is the ~~preferred~~ organisational unit **through which the Fund facilitates the development of**

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	(a) identify health care service needs in terms of the demographic and epidemiological profile of a particular sub-district; (b) identify accredited public and private health care service providers at primary care facilities; (c) manage contracts entered into with accredited health care service providers, health establishments and suppliers in the relevant sub-district in the prescribed manner and subject to the prescribed conditions; (d) monitor the disbursement of funds to health care service providers, health establishments and suppliers within the sub-district; (e) access information on the disease profile in a particular sub-district that would inform the design of the health care service benefits for that sub-district; (f) improve access to health care services in a particular sub-district at appropriate levels of care at health care facilities and in the community; (g) ensure that the user referral system is functional, including the transportation of users between the different levels of care and between accredited public and private health care service providers and health establishments, if necessary; (h) facilitate the integration of public and private health care services within the sub-district; and (i) resolve complaints from users in the sub-district in relation to the delivery of health care services.		**contracts to be entered into between the Fund and public and private health care providers and establishments** ~~with which the Fund contracts~~ for the provision of primary health care services within a specified geographical area.”
Clause 38: Office of Health Products Procurement	**Office of Health Products Procurement**	In line with the Constitutional mandate and provisions in the National Health Act, the Minister has overall stewardship over the health system including in	Change from ~~**Office**~~ to **UNIT** All clauses under Clause 38 and anywhere in the Bill to be changed to

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	38. (1) The Board, in consultation with the Minister, must establish an Office of Health Products Procurement which sets parameters for the public procurement of health related products. (2) The Office of Health Products Procurement must be located within the Fund and is responsible for the centralised facilitation and coordination of functions related to the public procurement of health related products, including but not limited to medicines, medical devices and equipment. (3) The Office of Health Products Procurement must— (a) determine the selection of health related products to be procured; (b) develop a national health products list; (c) coordinate the supply chain management process and price negotiations for health related products contained in the list mentioned in paragraph (b); (d) facilitate the cost effective, equitable and appropriate public procurement of health related products on behalf of users; (e) support the processes of ordering and distribution of health related products nationally, and at the district level with the assistance of the District Health Management Office; (f) support the District Health Management Office in concluding and managing contracts with suppliers and vendors; (g) establish mechanisms to monitor and evaluate the risks inherent in the public procurement process; (h) facilitate the procurement of high cost devices and equipment; and	providing oversight over ensuring that there is access to health products and health goods. Therefore, the Minister, in consultation (in agreement) with the National Health Council, would be the approver of the NHI Formulary. The establishment of OHPP is not a wasteful effort (as some have suggested) as it is necessary to establish a centralised procurement mechanism to be used both in public and private sectors as is the case across the world in most countries that have implemented similar reforms. OHPP is an essential component of NHI and will drive efficiencies in public health product procurement. Pooled procurement, when applied appropriately and diligently almost always reduces costs. Current procurement in the public sector has resulted on cost efficiencies evidenced but the current prices of ARVS which are the lowest in the world. On the Draft Procurement Bill, Section 3(3) states that the NHI Bill will prevail if there is conflict arising between the NHI Act and the provisions of any other law, except the Constitution and the Public Finance Management Act. It would therefore be the responsibility of the National Treasury to ensure the Bills are aligned. (Section 3(3) states that *"(3) If any conflict, relating to the matters dealt with in this Act, arises between this Act and the provisions of any other law, except the Constitution and the Public Finance Management Act or any Act expressly amending this Act, the provisions of this Act prevail.")* The role of the National Treasury Chief Procurement Officer will remain as an oversight role in managing procurement reforms across the public sector, maintaining the procurement system and overseeing the way in which government does business with the private sector. Procurement under NHI will be aligned to the Public Finance Management Act.	read: ~~The Office~~ of Health Products Procurement **<u>Unit</u>**

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	(i) advise the Board on any matter pertinent to the procurement of health related products. (4) The Office of Health Products Procurement must support the Benefits Advisory Committee in the development and maintenance of the Formulary, comprised of the Essential Medicine List and Essential Equipment List as well as a list of health related products used in the delivery of health care services as approved by the Minister in consultation with the National Health Council and the Fund. (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, price changes and disease management for approval by the Minister. (6) An accredited health care service provider and health establishment must procure according to the Formulary, and suppliers listed in the Formulary must deliver directly to the accredited and contracted health service provider and health establishment. (7) The provisions of this section are subject to public procurement laws and policies of the Republic that give effect to the provisions of section 217 of the Constitution, including the Preferential Procurement Policy Framework Act, 2000 (Act No. 5 of 2000), and the Broad-Based Black Economic Empowerment Act, 2003 (Act No. 53 of 2003).	The Medicines and Related Substances Act 101 of 1965 states in Section 2A that the objects of SAHPRA "are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, Scheduled substances, clinical trials and medical devices, IVDs and related matters in the public interest", whereas the role of the OHPP according to Section 38 of the proposed NHI Bill is to set the parameters for the public procurement of health related products. There is no contradiction in the definition of health related products and orthodox medicines. There is no legal term titled "orthodox medicine". Definitions will be aligned to other legislation based on comment received. In clarifying benefits to be covered as per the provisions in Clause (38 (3)(b), the National Health Products List will be aligned to the health care service benefits and types of services to be reimbursed, as well as the treatment guidelines, as determined by the Benefits Advisory Committee as contained in Clause 25(5) of the Bill. There has been concern that the Bill is silent on defining the criteria that will be used to limit the health care services packages. It should be noted that the health care services to be covered will be determined by the Benefits Advisory Committee in consultation with the Minister and the Board of the NHI Fund. There will not be a positive list of services but a list that outlines services that are not going to be covered will be published in a Gazette and these will be regularly reviewed taking into account the changing burden of disease and changes and developments in technology. On concerns raised that there will be no product choice according to user preference, the National Health Products List will be aligned to the health care benefits	

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		and will be applied in a similar way to the way in which the Essential Medicines List is applied currently in the public Sector and the prescribed minimum benefits in the private sector. The detail of what will be categorised as high cost devices will be provided in the regulations published in terms of the Bill. It is not possible to guarantee access to treatments that do not appear on the National Health Products List. Non-EML drugs may still be accessed but will be for the patient's account and will not be covered by the Fund. Provisions will also be made for exceptions to procure outside of EML for vulnerable patients not falling within confines of Formulary. However, it will not be possible to fund treatment for every disease. The NHI Fund will aim to cover as comprehensively as possible a basket of services related to the majority of disease burden in South Africa. The details on price regulation for medicines will be provided for in Regulations. However, international best practices are being considered in the development of models for price regulation and consequential amendments will be made as necessary to applicable legislation. Furthermore, a price-setting approach is used across numerous countries to drive equitable access to health products. The role and function of public sector depots under NHI will be defined by the public sector in their own supply chain model, which may include depots.	
Clause 39: Accreditation of service providers	**Accreditation of service providers**	The Department notes the comments from stakeholders in respect of seeking clarity about accreditation.	It is proposed that amendments be made to ensure that public sector facilities are not excluded from the accreditation process, leaving

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	(2) In order to be accredited by the Fund, a health care service provider or health establishment, as the case may be, must— *(a)* be in possession of and produce proof of certification by the Office of Health Standards Compliance and proof of registration by a recognised statutory health professional council, as the case may be; and *(b)* meet the needs of users and ensure service provider compliance with **prescribed specific performance criteria**, including the— (i) provision of the minimum required range of personal health care services specified by the Minister in consultation with the Fund and published in the Gazette from time to time as required; (ii) allocation of the appropriate number and mix of health care professionals, in accordance with guidelines, to deliver the health care services specified by the Minister in consultation with the National Health Council and the Fund, and published in the Gazette from time to time as required; (iii) adherence to treatment protocols and guidelines, including prescribing medicines and procuring health products from the Formulary; (iv) adherence to health care referral pathways; (v) submission of information to the national health information system to ensure portability and continuity of health care services in the Republic and performance monitoring and evaluation; and (vi) adherence to the national pricing regimen for services delivered.	The Department also notes the additions to the clauses as per the recommendations of stakeholders and are in support of these additions. The Department does not support the deletion of the term "comprehensive" as contained in Clause 39 (8)(a) as contracted providers will be required to deliver comprehensive services in line with the provisions of the contract that they have entered into. In clarifying the concerns raised about duplication of functions between the Office of Health Standards Compliance (OHSC) and the NHI Fund, the following explanation is provided as clarification: (a) The OHSC is mandated to "inspect and certify health establishments as compliant or non-compliant with the norms and standards. (b) A certificate of compliance issued by the OHSC is valid for a period of four years and is subject to renewal. It is also a pre-requisite for establishments that wish to be considered for engagement with the NHI Fund (c) Should a health establishment issued with a compliance certificate be inspected for any other reason and thereafter a compliance notice issued against a previously certified health establishment the validity of a certificate of compliance is suspended until the conditions set out in the said compliance notice are fulfilled The OHSC has provision for a graduated progressive approach towards certification through conditional certification of struggling health establishments. Accreditation is aimed at ensuring that health care service providers and health establishments are credentialed to deliver health care services at the appropriate level of care to users who are in need and	vulnerable communities without services. The intention is to have a phased approach to accreditation (which will be described in Regulations provided for in s55(1)(h)) in line with conditional /graded certification. Conditional accreditation aligned to the 3 grading systems that are provided for by the OHSC should underpin this phased approach to accreditation. Consider 39(2)(a): "(2) In order to be accredited by the Fund, a health care service provider or health establishment, as the case may be, must— (a) be in possession of and produce proof of **a graded** certification by the Office of Health Standards Compliance and proof of registration by a recognised statutory health professional council, as the case may be; and"

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	(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 prescribed health care service provider that satisfies the requirements listed in subsection (2) to provide— (a) primary health care services through Contracting Units for Primary Health Care; (b) emergency medical services; and (c) hospital services. (4) The contract between the Fund and an accredited health care service provider or health establishment must contain a clear statement of performance expectation and need in respect of the management of patients, the volume and quality of services delivered and access to services. (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 recording on the Health Patient Registration System, including— (a) national identity number or permit and visa details issued by the Department of Home Affairs, as the case may be; (b) diagnosis and procedure codes using the prescribed coding systems; (c) details of treatment administered including medicines dispensed and equipment used; (d) diagnostic tests ordered; (e) length of stay of an inpatient in a hospital facility; (f) facility to which a user is referred if relevant; (g) reasons for non-provision or rationing of treatment, if any; and	are entitled to health care service benefits that will be purchased by the Fund. Accreditation will be renewed on a 5-year basis and takes into account the following criteria: (a) Ability to provide a range of services that are specified for each level of care; (b) Having the appropriate number and mix of health care professionals to deliver the specified services; (c) Adherence to treatment protocols and guidelines, including prescribing from the NHIF formulary; (d) Initiating care at the primary care level and adherence to referral pathways; (e) Submission of routine information required for performance monitoring; and (f) Adherence to the pricing regimen for services delivered. Health Establishments need to be certified by the OHSC before they are accredited. Public Health care facilities located in rural and deprived areas that are struggling to meet the certification criteria will be subjected to a progressive approach to certification and will be supported through the national quality improvement plan to move towards full certification. Such facilities will be conditionally accredited to ensure that no communities are left behind and equity principles are adhered to as the country moves towards Universal Health Coverage. This will also ensure that the concern raised about de-facto privatisation of the health system is mitigated. The Department therefore supports a proposal made to use Conditional Accreditation for these disadvantaged health establishments.	**Propose amendment to Clause 39 (5):** "In order to be accredited and reimbursed by the fund, a health care provider or health establishment must submit information to the Fund ~~for recording on the Health Patient Registration System~~ **through an information platform as prescribed and accredited by the fund."**

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	(h) any other information deemed necessary by the Minister in consultation with the Fund for the monitoring and evaluation of national health outcomes. (6) The performance of an accredited health care service provider or health establishment must be monitored and evaluated in accordance with this Act and appropriate sanctions must be applied where there is deviation from contractual obligations as per the law. (7) The Fund must renew the accreditation of service providers every five years on the basis of compliance with the accreditation criteria as reflected in subsection (2). (8) The Fund may withdraw or refuse to renew the accreditation of a health care service provider or health establishment if it is proven that the health care service provider or health establishment, as the case may be— (a) has failed or is unable to deliver the required comprehensive health care service benefits to users who are entitled to such benefits; (b) is no longer in possession of, or is unable to produce proof of, certification by the Office of Health Standards Compliance and of proof of registration by the relevant statutory health professions council, as the case may be; (c) has failed or is unable to ensure the allocation of the appropriate number and mix of health care professionals to deliver the health care services specified in the Gazette; (d) has failed or is unable to adhere to treatment protocols and guidelines, including prescribing medicines and procuring health products from the Formulary;	Clause 39 (4) provides for accredited providers to submit statements in respect of performance expectations and need in respect of management of patients, the volume and quality of services delivered. Performance expectations will be based on meeting the criteria in the contract whilst the volume refers to the number of users that will be served by the accredited and contracted provider. Environmental Health and Municipal Health services are delivered as non-personal health care services and will be based on a different funding model to that covered by NHI Fund.	

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	(e) has failed or is unable to comply with health care referral pathways; (f) for any reason whatsoever, does not submit to the Fund the information contemplated in section 34(3) timeously; *(g)* fails to adhere to the national pricing regimen for services delivered; (h) intentionally or negligently breaches any substantive terms of a legally binding contract concluded with the Fund; (i) fails or is unable to perform as required by the terms of a legally binding contract concluded with the Fund; (j) delivers services of a quality not acceptable to the Fund; or (k) infringes any code of ethics or relevant law applicable in the Republic. (9) If the Fund withdraws the accreditation of a health care service provider or health establishment, or refuses to renew the accreditation of a health care service provider or health establishment, the Fund must— (a) provide a health care service provider or health establishment with notice of the decision; (b) provide a health care service provider or health establishment with a reasonable opportunity to make representations in respect of such a decision; (c) consider the representations made in respect of paragraph (b); and (d) provide adequate reason for the decision to withdraw or refuse the renewal of accreditation to a health care service provider or health establishment, as the case may be. (10) A health care service provider or health establishment who is dissatisfied with the reasons for the decision provided in terms of		

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	subsection (8)(d) may lodge an appeal in terms of section 43. (11) The Fund may issue directives relating to the listing and publication of accredited health care service providers and health establishments.		
Clause 40: Information platform of Fund	**Information platform of Fund** **40.** (1) The Fund must establish an information platform to enable it to make informed decisions on population health needs assessment, financing, purchasing, patient registration, service provider contracting and reimbursement, utilisation patterns, performance management, setting the parameters for the procurement of health goods, and fraud and risk management. (2) Health care service providers and health establishments must submit such information as may be prescribed to the Fund, taking into consideration the provisions of the Protection of Personal Information Act, 2013 (Act No. 4 of 2013). (3) The information in subsection (2) may be used by the Fund to— (a) monitor health care service utilisation and expenditure patterns relative to plans and budgets; (b) plan and budget for the purchasing of quality personal health care services based on need;	The Department notes the comments made on Clause 40. For the NHI Fund to carry out its functions effectively, it must be able to know what is happening administratively, financially, clinically and productivity or performance-wise in real-time and with easily accessible and usable information. The Fund's information platform must be used to monitor, evaluate and plan for the access and use of health care services as this will assist in identifying gaps and developing interventions to address cost escalation, service gaps and quality concerns. Clause 40 provides the framework by which the NHI Fund will be enabled to collect, collate and analyze the information that is required for decision making, proactive planning and funding decisions. The NHI Information System Architecture from its design will be using technology that would prevent fraud and in cases of fraud allow for early detection. The application of Artificial Intelligence, Machine learning and Blockchain are key technologies included in the design of the architecture to prevent fraud as far as possible. Fraud Detection will be facilitated by applying **predictive analytics** to large data sets for most operationally complex businesses and healthcare is no	**No changes recommended**

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	(c) monitor adherence to standard treatment guidelines, including prescribing from the Formulary; (d) monitor the appropriateness and effectiveness of referral networks prescribed by health care service providers and health establishments; (e) provide an overall assessment of the performance of health care service providers, health establishments and suppliers; and (f) determine the payment mechanisms and rates for personal health care services. (4) 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), unless— (a) the user consents to such disclosure in writing; (b) the information is shared among health care service providers for the lawful purpose of serving the interests of users; (c) the information is required by an accredited health care service provider, health establishment, supplier or researchers for the lawful purpose of improving health care practices and policy, but not for commercial purposes; (d) the information is utilised by the Fund for any other lawful purpose related to the efficient and effective functioning of the Fund; (e) a court order or any law requires such disclosure; or (f) failure to disclosure the information represents a serious threat to public health.	different. Utilising the Big Data Platform, the actual data generated through all phases of the patient--provider journey will be used to conduct fraud detection by applying the technology of predictive analysis. Examples can include improper referrals, improper prescriptions, or performing procedures that are not related or relevant to the diagnosis of the patient. The Department is of the view that the users must always be placed at the centre of the health information platform to support portable health records that will improve access and minimise waste when there is duplication of investigations including laboratory tests, lack of transparency and the necessity for user and provider accountability. Health Data of an individual is categorised as one of the most personal data sets and should be always protected. The advent of technology and its application and use in capturing individual's health data require very stringent measures to protect individual's personal data. Reference to POPIA as the legislation governing the protection of personal data is therefore relevant to this section. The Development and implementation of a Shared Electronic Health Record to support Clause 6 (b) for the portability and continuity of Health Care services available to the user forms part of the design of the NHI Information System Platform. The implementation of quality, continuous high speed, broadband connectivity is a specific requirement for the operationalisation of this. There is not a misalignment between clause 39(5) and clause (40) 2. Clause 39(5) refers to the requirements for accreditation for a provider to the Fund. Clause 40(2) referred to data and information that must be submitted to the fund by health service providers and health establishments – this would include among	

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	(5) The information architecture must include a fraud and risk management mechanism. (6) In order to fulfil the requirements for dissemination of information and the keeping of records, the information platform must facilitate— (a) the implementation of the objects and the effective management of the Fund; and (b) portability and continuity of health care services available to users subject to the provisions of this Act.	others – details on the services provided, operating hours, survey related data as part of the monitoring and evaluation processes. The Department agrees to amendments to be made to Clause 39 (5) so that it does not to make specific reference to the HPRS since the HPRS is the name of a solution. The following wording is proposed: As outlined in proposed changes to Clause 39 (5), in order to be accredited and reimbursed by the fund, a Health Care Provider or Health Establishment must submit information to the fund through **an information platform as prescribed and accredited by the fund. (as outlined above)**	
Clause 41: Payment of health care service providers	**Payment of health care service providers** **41.** (1) The Fund, in consultation with the Minister, must determine the nature of provider payment mechanisms and adopt additional mechanisms. 41. (1) The Fund, in consultation with the Minister, must determine the nature of provider payment mechanisms and adopt additional mechanisms. (2) The Fund must ensure that health care service providers, health establishments and suppliers are properly accredited before they are reimbursed. (3) (a) An accredited primary health care service provider must be contracted and	The Department appreciates the representations made by numerous stakeholders regarding the need for the Bill to ensure alignment between the functions of the Fund and those of the Contracting Units for Primary Health Care (CUPs). The Department agrees with the notion that the Fund, as the strategic purchaser of health care services, must be the entity that directly contracts and reimburses accredited and contracted providers. The CUPs must play the role of actively engaging and identifying needed health care providers at the local level with all accredited and contracted providers reimbursed as per the Fund's approved provider payment mechanisms for the services they provide to users. Furthermore, the provider payment mechanisms adopted by the Fund must be deliberately directed at contributing to a responsive health system through incentivising access to good quality services whilst also	**Edit terminology for consistency** Clause 41 (3)*(a) amended to read:* **"(a)** An accredited health care service provider **or health establishment providing primary health care services** ~~must be~~ **contracted through** a Contracting Unit for Primary Health Care **will be**

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	remunerated by a Contracting Unit for Primary Health Care. (a) An accredited primary health care service provider must be contracted and remunerated by a Contracting Unit for Primary Health Care. (b) In the case of specialist and hospital services, payments must be all-inclusive and based on the performance of the health care service provider, health establishment or supplier of health goods, as the case may be. (c) Emergency medical services must be reimbursed on a capped case-based fee basis with adjustments made for case severity, where necessary. (4) Without limiting the powers of the Minister to make regulations in terms of section 55, the Minister may make regulations to— (a) provide that payments may be made on condition that there has been compliance with quality standards of care or the achievement of specified levels of performance; (b) determine mechanisms for the payment of an individual health worker and health care provider; and (c) provide that the whole or any part of a payment is subject to the conditions outlined in a contract and that payments must only be effected by the Fund if the conditions have been met. (5) For the purposes of subsection (4), ‘‘health worker’’ and ‘‘health care provider’’ have the meanings ascribed to them in section 1 of the National Health Act.	making delivery of healthcare efficient, affordable and sustainable. The Fund must be capable of assessing and deciding on alternative reimbursement mechanisms that it will deploy when contracting accredited providers and health establishments at different levels of care. As a strategic purchaser, the NHI Fund will pay providers in a way that creates appropriate incentives for efficiency and for the provision of quality and accessible care. The selected reimbursement mechanisms must be determined in an administratively fair and transparent process and the resulting tariffs must be reasonable, take into account financial implications for the Fund and ensure the Fund remains effective, efficient and sustainable in all its operations and contractual arrangements with all types and level of health care services providers. The Department is in agreement with the position put forward by a number of stakeholders that the Fund must implement and sustain a set of reimbursement mechanisms that complement each other rather than relying on a single payment mechanism. It is for this reason that the Department proposals in the Bill emphasises that the Fund utilises capitation for primary health care services and a combination of global budgets and Diagnosis Related Groupers (DRGs) for hospitals in the main. However, over and above these two mechanisms, the Department also recommends additional tools are applied for specific service categories such as emergency medical care.	**reimbursed by the Fund using a capitation strategy.”**

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CHAPTER 9: COMPLAINTS AND APPEALS			
Clause 42: Complaints	**Complaints** **42.** (1) 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, and the Fund must deal with such complaints in a timeous manner and in terms of the law. (2) The Investigating Unit established by the Chief Executive Officer in terms of section 20(2)(e) must launch an investigation to establish the facts of the incident reported and must make recommendations to the Chief Executive Officer as to the way in which the matter may be resolved within 30 days of receipt of the complaint. (3) The complainant must be informed in writing of the outcome of the investigation launched in terms of subsection (2), and any decision taken by the Fund, within a reasonable period of time. (4) If the Fund has made a decision in terms of subsection (3), the Fund must— (a) provide the health care service provider with a notice of the decision to provide the health care service provider with a reasonable opportunity to make representations in respect of such a decision; (b) consider the representations made in respect of paragraph (a); and (c) provide adequate reason for the decision to withdraw or refuse the renewal of accreditation	The complaints processes outlined in Clause 42 are essential for the purposes of ensuring that the Fund operates in a manner that is procedurally fair and administratively just. The Department supports the provisions indicated in these Clauses because the Fund must develop and implement protocols and procedures for dealing with complaints raised by various stakeholders, including users, patients, providers and suppliers. These must be clearly communicated and readily accessible. This will ensure that the Fund's processes around addressing complaints are compliant with the Constitution as well as the provisions of the Promotion of Administrative Justice Act. The Fund must endeavour to deal with all complaints in a fair, lawful way and that the protocols and systems implemented to achieve this constitute reasonable administrative action. While the Investigation Unit that is proposed will be a Unit within the purview of the CEO, the Fund should still be capable of speedily investigating any incident reported to it and it must exercise its investigating powers in a fair, non-prejudicial and transparent manner. The outcomes of such investigations should be expediently communicated within stipulated timeframes. Under clearly defined standard operating protocols, the Unit should furnish relevant information about a specific incident to other statutory bodies for further handling. The recommendation that the Bill must stipulate timelines by when complaints are addressed is not supported. Such provisions are generally included in supporting regulations rather than founding Acts.	**No changes recommended**

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	to the health care service provider, as the case may be.	Therefore, the Department suggests that such recommendation be deferred for inclusion in the regulations that will be gazetted by the Minister at the appropriate time.	
Clause 43: Lodging of appeals	**Lodging of appeals** **43.** A natural or juristic person, namely a user, health care service provider, health establishment or supplier aggrieved by a decision of the Fund delivered in terms of section 42 may, within a period of 60 days after receipt of written notification of the decision, appeal against such decision to the Appeal Tribunal.	The Department acknowledges the need for the Fund to have in place administrative transparent and fair processes when it comes to ensuring that every registered user has access to health care benefits rendered through accredited and contracted providers and health establishments, it is inevitable that the Fund will receive complaints from various parties.	**No changes recommended**
Clause 44: Appeal Tribunal	**Appeal Tribunal** 44. (1) An Appeal Tribunal is hereby established, consisting of five persons appointed by the Minister: (a) One member appointed on account of his or her knowledge of the law, who must also be the chairperson of the Board; (b) two members appointed on account of their medical knowledge; and (c) two members appointed on account of their financial knowledge. (2) A member of the Appeal Tribunal appointed by the Minister in subsection (1) must serve as a member for a period of three years, which term is renewable only once. (3) A member ceases to be a member if— *(a)* he or she resigns from the Appeal Tribunal;	This provision is important in that it ensures that the Fund will have an Appeal Tribunal vested with the necessary power to review the decisions reached by the Fund and make the necessary determinations. The Department agrees with the suggested amendment to remove reference to the Board in Clause 44(1)(a). However, the additional details are considered to be too prescriptive and must be addressed through enabling regulations.	**Clause 44**(1) amended to read: "(1) An Appeal Tribunal is hereby established, consisting of five persons appointed by the Minister **after consultation with Cabinet:**

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	(b) the Minister terminates his or her membership on good cause; or *(c)* the term for which the member was appointed has expired and has not been renewed or after a second term may not be renewed.		
Clause 45: Powers of Appeal Tribunal	**Powers of Appeal Tribunal** **45.** (1) The Appeal Tribunal has the same power as a High Court to— *(a)* summon witnesses; *(b)* administer an oath or affirmation; *(c)* examine witnesses; and *(d)* call for the discovery of documents and objects. (2) The Appeal Tribunal may after hearing the appeal— *(a)* confirm, set aside or vary the relevant decision of the Fund; or *(b)* order that the decision of the Fund be effected.	The Department acknowledges that the provisions of Clause 45 are consistent with provisions of other Acts providing for similar structures. For instance, with the Council for Medical Schemes, the Appeal Board has the powers of the High Court to summon witnesses and based on this it is the Department's conviction it is appropriate for the Appeal Tribunal of the Fund has the powers as a High Court. The Appeals Tribunal may after the hearing confirm or vary the decision concerned or rescind it and give another decision as they seem just. These powers of the Appeal Tribunal are consistent with those outlined in Chapter 8 of the Constitution of the Republic, specifically those relating to High Courts under section 169. They are also consistent with Section 7 of the Promotion of Administrative Justice Act.	
Clause 46: Secretariat	**Secretariat** **46.** The Chief Executive Officer of the Board 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 for a period of at least	For the effective functioning of the Appeal Tribunal, it is important that there is a Secretariat that assists with records keeping and also ensures that in instances where aggrieved parties require access to specific information, they may be granted such access as per the Promotion of Access to Information Act.	**Proposal to amend Clause 46 to read as follows:** "The Chief Executive Officer of the ~~Board~~ **Fund** must designate a staff member of the Fund to act as secretary of the Appeal Tribunal

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	three years after the decision has been recorded.	Furthermore, the existence of the Secretariat will contribute to realising systems and processes that allow for the smooth functioning and operations of Appeal Tribunal. The Department concurs with stakeholders that there are indeed minor terminology changes that should be effected in the following section as highlighted: *"The Chief Executive Officer of the 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 the decisions of the Board Tribunal for a period of at least three years after the decision has been recorded"*	and the Fund must keep the minutes and all records of the decisions of the ~~Board~~ **Appeal Tribunal** for a period of at least three years after the decision has been recorded."
Clause 47: Procedure and remuneration	**Procedure and Remuneration** **47.** (1) The Minister, in consultation with the Minister of Finance and the Fund, must determine the terms, conditions, remuneration and allowances applicable to the members of the Appeal Tribunal. (2) A member of the Appeal Tribunal must recuse himself or herself if it transpires that he or she has any direct or indirect personal interest in the outcome of the appeal and must be replaced for the duration of the hearing by another person with similar knowledge appointed by the Minister. (3) The Appeal Tribunal must determine the outcome of the appeal within 180 days after the lodgement of the appeal and inform the appellant of the decision in writing, and the	The Department proposes that the principles of administrative justice that must inform the procedures and functioning of the Appeal Tribunal should be: (a) Lawful action: the decision must have been taken by an official duly authorised to do so, and must not be inconsistent with the confines of applicable legal framework; (b) Reasonableness: all decisions and ensuing actions must meet the rationality test and must be fit for purpose; and (c) Procedural fairness: the affected parties must be given reasonable notice, must be consulted and the decision making process must be impartial. The Department concurs that the current proposed period of 180 days turnaround for addressing an	

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	Secretariat appointed in section 46 must keep record of all proceedings and outcomes. (4) Nothing in this section precludes an aggrieved party from seeking suitable redress in a court of law that has jurisdiction to hear such a matter.	appeal may be too long, and consideration should be given to a shorter period such as 90 days. This would be similar to what is provided for in the Medical Schemes Act. The Fund will be subject to the provisions of the Public Finance Management Act and relevant National Treasury regulations and prescripts. This will assist in ensuring that all members of the Appeal Tribunal, including various other Committees, are reimbursed accordingly to defined criteria and using rates predetermined and communicated by National Treasury.	
CHAPTER 10: FINANCIAL MATTERS			
Clause 48: Sources of funding	**Sources of Funding** **48.** The revenue sources for the Fund consist of— (a) money to which the Fund is entitled in terms of section 49; (b) any fines imposed in terms of this Act other than by a court of law; (c) any interest or return on investment made by the Fund; (d) any money paid erroneously to the Fund which, in the opinion of the Minister, cannot be refunded; (e) any bequest or donation received by the Fund; and (f) any other money to which the Fund may become legally entitled.	The Department has noted the concerns on the legality of Clause 48 (b) regarding fines being considered under sources of funding. The Department is amenable to the deletion of this subclause. On sources of additional funding to the NHI Fund, Clause 49 (2)(a) of the Bill provides for sources of funding including the additional sources that will be mobilised. South Africa currently spends 8.8% of GDP on Health with 4.1% in the public sector serving more than 80% of the population and 4.7% in the private sector that serves less than 20% of the population. The 8.8% of GDP spending is way above what other countries of similar economic development spend on health care. Furthermore, as articulated by the WHO, while costing assumptions and scenarios may be useful for raising core policy issues regarding the sustainability of reforms, it is not useful to focus on getting the exact	**Propose the deletion of Clause 48(b)** ~~any fines imposed in terms of this Act other than by a court of law;~~

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		number indicating the estimated costs. This is because evidence has shown that countries that have gone down this path have ended up tied to an endless cycle of revisions and efforts to dream up new revenue sources, thus focusing on issues that have more to do with tax policy than health policy. Therefore, **focusing on the question of "what will NHI cost" is the wrong approach as it is better to frame the question around the implications of different scenarios for the design and implementation of reforms to move towards UHC**. The White Paper on NHI has articulated in detail how challenges of management in the public sector could be addressed. It is not appropriate for such remedial measures to be legislated as they may require ongoing review, It is not correct that the SEIAS 2017 did not provide for mitigation strategies as this is a standard requirement in the SEIAS Template as provided by the DPME The Memorandum of Objects in the Bill has also outlined the financial implications of the Bill to the State and made projection of the funding envelope requirement for the medium term. The Department supports the deletion of Clause 48(b) ~~any fines imposed in terms of this Act other than by a court of law~~; as fines that are not provided for in the Bill should not be regarded as sources of funding for the Fund	
Clause 49: Chief source of income	**Chief Source of Income** **49.** (1) The Fund is entitled to money appropriated annually by Parliament in order to achieve the purpose of the Act.	The Department notes the comments that have been made under Clause 49.	Propose consideration of **ADDITION to Clause (2)(a)(i)** such as: **"…… shifting funds from national government**

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	(2) The money referred to in subsection (1) must be— *(a)* appropriated from money collected and in accordance with social solidarity in respect of— (i) general tax revenue, including the shifting funds from the provincial equitable share and conditional grants into the Fund; (ii) reallocation of funding for medical scheme tax credits paid to various medical schemes towards the funding of National Health Insurance; (iii) payroll tax (employer and employee); and (iv) surcharge on personal income tax, introduced through a money Bill by the Minister of Finance and earmarked for use by the Fund, subject to section 57; and (b) calculated in accordance with the estimates of income and expenditure as contemplated in section 53 of the Public Finance Management Act. (3) Once appropriated, the revenue allocated to the Fund must be paid through a Budget Vote to the Fund as determined by agreement between the Fund and the Minister and subject to the provisions of the Constitution and the Public Finance Management Act.	The Department does not support the deletion of Clause 49 (2) as it is an important clause for providing for how NHI will be funded. Clause 49 (2) provides a framework that outlines the options that government must pursue in raising revenue for the NHI Fund using a mandatory pre-payment system. The definition of mandatory prepayment is contained in the definition section. Mandatory prepayment refers to paying for health care before the person is sick and this is compulsory according to income levels. Chief sources of income for the Fund could be from general tax revenue from payroll, surcharge on taxable income, and complemented by employment based levies and other taxes as determined by the National Treasury. The determination of the actual extent of the taxation will be articulated in a Monies Bill that is developed and published by the National Treasury. The revenue collected will be pooled to achieve financial and risk protection for the entire population. The 2019 SEIAS and the accompanying Memorandum of Objects in the NHI Bill has outlined the financial implications of the Bill to the State and made projections of the required funding envelope requirement for the medium term. The Department does not support an approach that proposes medical tax credits to be left untouched. This is because the tax credits on benefit those that are in a position to pay either through medical scheme coverage or out-of-pocket but do not befit the poor. The money that goes into tax-credits will be consolidated to	**departments and agencies, and** from the provincial equitable share and conditional grants into the Fund″ (as funds need to move from Correctional Services in time)

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		benefit all as the role of medical schemes and out-of-pocket payment reduces under NHI.	
Clause 50: Auditing	**Auditing** **50.** The Auditor-General must audit the accounts and financial records of the Fund annually as outlined in the Public Audit Act, 2004 (Act No. 25 of 2004).		**No changes proposed**
Clause 51: Annual reports	**Annual Reports** **51.** (1) As the accounting authority of the Fund, the Board must submit to the Minister and Parliament a report on the activities of the Fund during a financial year as determined by the Public Finance Management Act. (2) Subject to the provisions of the Public Finance Management Act, the report must include— *(a)* the audited financial statements of the Fund; (b) a report of activities undertaken in terms of its functions set out in this Act; (c) a statement of the progress achieved during the preceding financial year towards realisation of the purpose of this Act; and (d) any other information that the Minister, by notice in the Gazette, determines. (3) In addition to the matters which must be included in the annual report and financial statements as determined by section 55 of the Public Finance Management Act, the annual report must be prepared in accordance with generally accepted accounting practice and contain a statement showing—	Under the functions of the Fund in Clause 10 (1)(o), the Fund must undertake research, monitoring and evaluation of the impact of the Fund on Health outcomes. These outcomes need not necessarily be published annually as outcomes have a longer time horizon such as biannually with impact assessment being produced on a 5 yearly basis. The Fund is a Schedule 3(A) non-business entity as described in the PFMA. Therefore, it is not required of the Fund to engage with lending financial institutions as its funding will be derived from the fiscus. A valuation report of an entity is an independent exercise that is conducted by external role-players. It is therefore not necessary to amend this clause as the independency is implied.	**No changes proposed**

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	(a) the total number of users who received health care benefits in terms of this Act; (b) the total monetary value of health care benefits provided in respect of each category of benefits and level of care as determined by the Minister; (c) all loans, overdrafts, advances and financial commitments of the Fund; (d) the particulars of all donations and bequests received by the Fund; (e) an actuarial valuation report; (f) particulars of the use of all immovable and movable property acquired by the Fund; (g) any amount written off by the Fund; and (h) any other matter determined by the Minister. (4) The Minister must without delay— (a) table a copy of the report in the National Assembly; and (b) submit a copy of the report to the National Council of Provinces.		
Clause 52: Assignment of duties and delegation of powers	**Assignment of duties and delegation of powers** 52. Subject to the Public Finance Management Act— (a) the Minister may assign any duty and delegate any power imposed or conferred upon him or her by this Act, except the power to make regulations, to any person in the employ of the Fund; and (b) the Chief Executive Officer of the Fund may assign any duty and delegate any power imposed or conferred upon him or her by this Act to any employee of the Fund.	This Clause is provided for in the PFMA and is consistent with the prescripts within the PFMA and does not undermine principles of good governance.	**No changes proposed recommended**

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Clause 53: Protection of confidential information	**Protection of confidential information** 53. Nothing in this Act affects the provisions in any other legislation or law prohibiting or regulating disclosure of personal or other sensitive information accessible to or in possession of the Fund.	The Department notes that while no specific comments or recommendations are made with regards to Clause 53, it remains exceptionally important that all the information at the disposal of the Fund, whether that of users/patients or that of accredited and contracted health care services providers and suppliers is kept confidential to the highest standards and norms possible. Therefore, compliance with the provisions of Protection of Personal Information Act, 2013 will be mandatory at all times and in all instances.	**No changes proposed recommended**
Clause 54: Offences and penalties	**Offences and penalties** **54.** (1) Any person who— *(a)* knowingly submits false information to the Fund or its agents; (b) makes a false representation with the intention of obtaining health care service benefits from the Fund to which he or she is not entitled; (c) utilises money paid from the Fund for a purpose other than that in respect of which it is paid; (d) obtains money or other gratification from the Fund under false pretences; or (e) sells or otherwise discloses 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 fine not exceeding R100 000.00 or imprisonment for a	The Department emphasises that the provision of accurate and truthful information is essential to ensure accurate planning and to prevent malfeasance, fraudulent and undesirable practices in relation to the activities and functions of the Fund. It must be prohibited for anyone to purposefully provide inaccurate information that will expose the Fund to taking incorrect decisions and to impact negatively on the sustainability of the Fund. The Department notes the recommendation to insert the word *confidential* to Clause 54(1)(e) – this is in principle supported as it adds clarity with regards to nature and type of information, to prevent anyone from selling or disclosing of confidential information to third parties without due consent and permission from affected parties.	Propose insert the word “confidential” into Clause 54(1)(e) “(e) 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 fine not exceeding R100 000.00 or imprisonment for a period not

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	period not exceeding five years or to both a fine and such imprisonment. (2) Any natural or juristic person who fails to furnish the Fund or an agent of the Fund with information required by this Act or any directive issued under this Act within the prescribed or specified period or any extension thereof, irrespective of any criminal proceedings instituted under this Act, must pay a prescribed fine for every day which the failure continues, unless the Fund, on good cause shown, waives the fine or any part thereof. (3) Any penalty imposed under subsection (2) is a debt due to the Fund.		exceeding five years or to both a fine and such imprisonment.”
Clause 55: Regulations	**Regulations** **55.** (1) Without derogating from the powers conferred on the Minister by the Constitution and the National Health Act or any other applicable law, the Minister may, after consultation with the Fund and the National Health Council contemplated in section 22 of the National Health Act, make regulations regarding— *(a)* the legal relationship between the Fund and the various categories of health establishments, health care service providers or suppliers as provided for in the National Health Act; (b) payment mechanisms to be employed by the Fund in order to procure health care services from accredited and contracted health care service providers, health establishments or suppliers; (c) the budget of the Fund, including the processes to be followed in drawing up the	The implementation of National Health Insurance requires the creation of various institutional and organisational structures to enable the Fund to execute its mandate and responsibilities and effectively as per the provisions of this Bill. Clause 55 on Regulations is important because it ensures that the Minister of Health, as the Executive Authority responsible for health, has sufficient scope and flexibility in introducing various regulations to support the realisation of the provisions outlined in the Bill. With regards to the specific comment on the clarity between Clause 55(1)(b) in relation to Clause 41(1): (a) Clause 41(1) outlines the overarching framework of the types of reimbursement mechanisms that the NHI Fund will have to consider and implement for the purposes of paying appropriately accredited and contracted health care services providers. The	Proposal for **Clause 55 (4) to be deleted** ~~(4) Regulations must be tabled in the National Assembly and the National Council of Provinces for a period of one month before being finalised.~~

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	budget, in compliance with the provisions of the Public Finance Management Act; (d) information to be provided to the Fund for the development and maintenance of the national health information system by users, health establishments, health care service providers or suppliers and the format in which such information must be provided; (e) clinical information and diagnostic and procedure codes to be submitted and used by health care service providers, health establishments or suppliers for reimbursement and reporting purposes to the Fund; (f) participation by the fund in the national health information system contemplated in section 74 of the National Health Act, including the Health Patient Registration System referred to in section 39; (g) the registration of users of the Fund in terms of section 5; (h) the accreditation of health care service providers, health establishments or suppliers; (i) the functions and powers of a District Health Management Office; (j) the functions and powers of a Contracting Unit for Primary Health Care Services; (k) the relationship between the Fund and the Office of Health Standards Compliance; (l) the relationship between the Fund and the Department of Correctional Services in order to clarify the mechanisms for purchasing, within available resources, quality needed personal health care services for inmates as is required by the Correctional Services Act, 1998 (Act No. 111 of 1998); (m) the relationship between public and private health establishments, and the optional	chosen reimbursement mechanisms must be reasonable, take into financial implications and must ensure the Fund remains effective, efficient and sustainable in all its operations and contractual arrangements with providers. (b) On the other hand, Clause 55(1)(b) enables the Minister to gazette detailed regulations that to support the Fund in its efforts to establish mechanisms to implement payment mechanisms for various levels and types of contracted providers.	

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	contracting in of private health care service providers; (n) the relationship between the Fund and medical schemes registered in terms of the Medical Schemes Act and other private health insurance schemes; (o) the development and maintenance of the Formulary; (p) investigations to be conducted by the Fund or complaints against the Fund in order to give effect to the provisions of Chapter 8; (q) appeals against decisions of the Fund in order to give effect to the provisions of Chapter 8; (r) the manner in which health care service providers, health establishments and suppliers must report to the Fund in respect of health care services purchased by the Fund and the content of such reports; (s) the monitoring and evaluation of the performance of the Fund; (t) all fees payable by or to the Fund; (u) subject to the Public Finance Management Act, the nature and level of reserves to be kept within the Fund; (v) subject to the Public Finance Management Act, the manner in which money within the Fund must be invested; (w) all practices and procedures to be followed by a health care service provider, health establishment or supplier in relation to the Fund; (x) the scope and nature of prescribed health care services and programmes and the manner in, and extent to which, they must be funded; (y) the proceedings of the meetings of committees appointed in terms of this Act and a code of conduct for members of those committees;		

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	(z) the proceedings and other related matters of the Appeal Tribunal; (zA) any matter that may or must be prescribed in terms of this Act; and (zB) any ancillary or incidental administrative or procedural matter that may be necessary for the proper implementation or administration of this Act. (2) The Minister must, not less than three months before any regulation is made under subsection (1), cause a copy of the proposed regulation to be published in the Gazette together with a notice declaring his or her intention to make that regulation and inviting interested persons to furnish him or her with their comments thereon or any representations they may wish to make in regard thereto. (3) The provisions of subsection (2) do not apply in respect of— (a) any regulation made by the Minister which, after the provisions of that subsection have been complied with, has been amended by the Minister in consequence of comments or representations received by him or her in pursuance of a notice issued thereunder; or (b) any regulation which the Minister, after consultation with the Board, deems in the public interest to publish without delay. (4) Regulations must be tabled in the National Assembly and the National Council of Provinces for a period of one month before being finalised.		
Clause 56: Directives	**Directives**		

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	56. (1) The Fund may issue directives which must be complied with in the implementation and administration of this Act, and any directives so issued must be published in the Gazette. (2) Any directive issued under this section may be amended or withdrawn in like manner	The Department is of the view that the inclusion of the provisions on Directives will provide the Fund with sufficient flexibility to issue instructions for compliance with aspects implementation and administration of the Act. The Directives are not all encompassing for all sectors of the health system, but rather those that are directed at administrative and operations elements of the Fund and how users, accredited and contracted providers, and suppliers relate to it from time to time. Taking into account the Department's experiences with the COVID-19 pandemic, it is deemed necessary that the Bill includes these provisions to ensure responsiveness of the Fund to emerging risks and the need to meet population health care needs. Nonetheless, the Directives will not be contradictory to the spirit of the Act and must be reviewable to ensure administrative justice. The Directives are not intended to be punitive in nature.	**No proposed changes recommended**
Clause 57: Transitional arrangements	**Transitional Arrangements** 57. (1) (a) Despite anything to the contrary in this Act, this Act must be implemented over two phases. (b) National Health Insurance must be gradually phased in using a progressive and programmatic approach based on financial resource availability. (2) The two phases contemplated in subsection (1)(a) are as follows: (a) Phase 1, for a period of five years from 2017 to 2022 which must— (i) continue with the implementation of health system strengthening initiatives, including	The Department notes and appreciates the comments and recommendations made by stakeholders with respect to the matters indicated in the Transitional Arrangements under Clause 57. The implementation of NHI requires an intense period of ongoing legislative and policy reforms as part of the preparatory work to create the institutional and organisational structures required to enable the successful and sustainable implementation of the NHI Fund. The Fund is intended to address the personal health care services needs of the entire population in the country and so it is not necessary to implement a scaled down model as is recommended by some stakeholders. Instead, the Department will be implementing NHI through a phased process.	S57(2) The two phases contemplated in subsection (1)(a) are as follows: (a) Phase 1, for a period of five years from 2017 to ~~2022~~ **2023** which must—

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	alignment of human resources with that which may be required by users of the Fund; (ii) include the development of National Health Insurance legislation and amendments to other legislation; (iii) include the undertaking of initiatives which are aimed at establishing institutions that must be the foundation for a fully functional Fund; and (iv) include the purchasing of personal health care services for vulnerable groups such as children, women, people with disabilities and the elderly; and (b) Phase 2 must be for a period of four years from 2022 to 2026 and must include— (i) the continuation of health system strengthening initiatives on an on-going basis; (ii) the mobilisation of additional resources where necessary; and (iii) the selective contracting of health care services from private providers. (3) In Phase 1 the Minister may establish the following interim committees to advise him or her on the implementation of the National Health Insurance: (a) The National Tertiary Health Services Committee which must be responsible for developing the framework governing the tertiary services platform in South Africa. (b) The National Governing Body on Training and Development which must, amongst others— (i) be responsible for advising the Minister on the vision for health workforce matters, for recommending policy related to health sciences, student education and training,	Adopting a phased and structured process allows for the State, and stakeholders, to learn lessons and improve systems and processes as the phased implementation program unfolds. More importantly, the phasing of the implementation process taking into account available financial resources is consistent with the Constitutional obligation placed on the State to progressively realise the population's health care needs as per the provisions in the Bill of Rights. The Department notes the various suggestions made by stakeholders concerning Health Technology Assessment and that it should be part of the Transitional arrangements processes. The Department's implementation plan recognises and prioritises the need to build internal HTA capacity as part of the preparatory work for the implementation of NHI. The exact structure and form of HTA that will be implemented will be gazetted by the Minister at the appropriate time, and this will be done through regulations rather than incorporating such provisions in the Bill itself. (a) Health Technology Assessment is an important element to be undertaken as part of the processes for deciding and informing the scope of healthcare benefits and associated technology that must be included in the formulary and essential equipment list that users are entitled to. (b) Health Technology Assessment is also critical for determining the most affordable technology, using evidence-based medicine principles, which must be accessible to all users of quality healthcare services. In broader terms, instituting mechanisms that entrench health technology assessment is pivotal for ensuring that the Fund is implemented on a sustainable platform.	S57(2)(b) Phase 2 must be for a period of four years from ~~2022 to 2026~~ **2023 to 2027** and must include—

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	including a human resource for health development plan; (ii) be responsible for the determination of the number and placement of (including but not limited to) all categories of interns, community service and registrars; (iii) oversee and monitor the implementation of the policy and evaluate its impact; and (iv) coordinate and align strategy, policy and financing of health sciences education. (c) The Ministerial Advisory Committee on Health Care Benefits for National Health Insurance, which must be a precursor to the Benefits Advisory Committee and which must advise the Minister on a process of priority-setting to inform the decision-making processes of the Fund to determine the benefits to be covered. (d) The Ministerial Advisory Committee on Health Technology Assessment for National Health Insurance, which must be established to advise the Minister on Health Technology Assessment and which must serve as a precursor to the Health Technology Assessment agency that must regularly review the range of health interventions and technology by using the best available evidence on cost-effectiveness, allocative, productive and technical efficiency and Health Technology Assessment. (4) Objectives that must be achieved in Phase 1 include— (a) the migration of central hospitals that are funded, governed and managed nationally as semi-autonomous entities; (b) the structuring of the Contracting Unit for Primary Health Care at district level in a cooperative management arrangement with the	The Department would also like to bring to the Committee's attention that some of the timelines indicated in this section of the Bill require updating. This is because progress on some key areas was inevitably **affected by the COVID-19 pandemic over the period 2018 to 2021**. This has led to a status where some planned activities have to be moved forward slightly but should not hinder the finalisation of the Bill. This is consistent with what is indicated in Clause 59 (2) which indicates that subject to provisions of section 57, different dates may be fixed in respect of the coming into effect of different provisions of this Act.	

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	district hospital linked to a number of primary health care facilities; (c) the establishment of the Fund, including the establishment of governance structures; (d) the development of a Health Patient Registration System contemplated in section 5; (e) the process for the accreditation of health care service providers, which must require that health establishments are inspected and certified by the Office of Health Standards Compliance, health professionals are licensed by their respective statutory bodies and health care service providers comply with criteria for accreditation; (f) the purchasing of health care service benefits, which include personal health services such as primary health care services, maternity and child health care services including school health services, health care services for the aged, people with disabilities and rural communities from contracted public and private providers including general practitioners, audiologists, oral health practitioners, optometrists, speech therapists and other designated providers at a primary health care level focusing on disease prevention, health promotion, provision of primary health care services and addressing critical backlogs; (g) the purchasing of hospital services and other clinical support services, which must be— (i) funded by the Fund; (ii) an expansion of the personal health services purchased; and (iii) from higher levels of care from public hospitals (central, tertiary, regional and district hospitals) including emergency medical services and pathology services provided by National Health Laboratory Services; and		

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	(h) the initiation of legislative reforms in order to enable the introduction of National Health Insurance, including changes to the— (i) Medicines and Related Substances Act, 1965 (Act No. 101 of 1965); (ii) Occupational Diseases in Mines and Works Act, 1973 (Act No. 78 of 1973); (iii) Health Professions Act, 1974 (Act No. 56 of 1974); (iv) Dental Technicians Act, 1979 (Act No. 19 of 1979); (v) Allied Health Professions Act, 1982 (Act No. 63 of 1982); (vi) Medical Schemes Act, 1998 (Act No. 131 of 1998); (vii) Mental Health Care Act, 2002 (Act No. 17 of 2002); (viii) National Health Act; (ix) Nursing Act, 2005 (Act No. 33 of 2005); (x) Traditional Health Practitioners Act, 2007 (Act No. 22 of 2007); and (xi) other relevant Acts. (5) Objectives that must be achieved in Phase 2 include the establishment and operationalisation of the Fund as a purchaser of health care services through a system of mandatory prepayment.		
Clause 58: Repeal or amendment of laws	**Repeal or amendment of laws** 58. (1) Subject to this section and section 57 dealing with transitional arrangements, the laws mentioned in the second column of the Schedule are hereby repealed or amended to	To achieve legislative and regulatory harmony between the provisions of the Bill and the existing health sector and related Acts.	Separate comments on each of the eleven laws in the schedule have been presented to Portfolio Committee

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	the extent set out in the third column of the Schedule. (2) The repeal or amendment of any law by this Act does not affect— (a) the previous operation of such law or anything done or permitted under such law; (b) any right, privilege, obligation or liability acquired, accrued or incurred under such law; or (c) any penalty, forfeiture or punishment incurred in respect of any offence committed in terms of such law.	It must be noted by stakeholders that the Acts indicated here are summary of those that will require consequential amendments to assist with creating the legislative and regulatory framework for the phased implementation of NHI. Additionally, the list of Acts indicated would need to be amended to allow for the operationalisation of the various structures required to create a functional, effective and sustainable NHI Fund. The purpose of the proposed amendments is not to undermine the provisions of the indicated Acts or to reduce the entitlements of the population – instead, it is to ensure that the population's personal health care needs are accessible through a continuum that consolidates the State's health care resources, with appropriate private sector involvement, to progressive meet the health needs of the entire population.	
Clause 59: Short title and commencement	**59.** (1) This Act is called the National Health Insurance Act, 2019, and takes effect on a date fixed by the President by proclamation in the Government *Gazette*. (2) Subject to section 57, different dates may be fixed in respect of the coming into effect of different provisions of this Act.		