NOVEMBER 2019

DEAR SIR / MADAM,

RE: SUBMISSION OF COMMENTS ON PROPOSED NHI

1) The Health Products Association of Southern Africa (HPA) is appreciative of the opportunity to comment on the NHI Bill.
2) The Health Products Association of Southern Africa (HPA) has been serving South Africa's health interests since it was founded in 1976.
3) As the primary voice of the health products industry, the HPA is committed to developing and maintaining standards that support and foster the quality, safety and efficacy of Natural Health Products, Nutritional Dietary Supplements and Complementary and Alternative Medicines (CAMs). The Association strives to establish an ethical, credible, relevant and vibrant health products industry in South Africa.
4) The HPA plays a crucial role in ensuring the long-term sustainability of this market and works to provide a fertile environment for industry growth. To achieve this the HPA has developed Self-regulatory Codes of Practice and Standards, and guides members in correct practice and procedures.
5) Despite mounting global regulatory and economic pressures, the Natural Health Products, Nutritional Dietary Supplements and CAMs international market continues to expand. The HPA has decades of experience in this field and, as the most respected body in Southern Africa, it is perfectly positioned to lead this sector into the future.

PRIMARY CONCERN FOR HPA MEMBERS:

1) TAX BURDEN
    a. The HPA is concerned that taxpaying South Africans would not be able to afford to pay an additional tax in the form of NHI.
    b. The HPA is concerned about how far taxation for the NHI could go and if this taxation would be ringfenced?
    c. The HPA is would like to know how the NHI tax will be taxed in relation to other costs e.g. free higher education, etc?

2) SINGLE EXIT PRICE
    a. One of the primary concerns of our Members is the proposed new Single Exit Price system that the Bill seeks to introduce. This system will in effect create an NHI price which would apply, even if products were not available, or sold in the NHI and therefore will apply to all Schedule 0 products (S0's') for both Category A and D Medicines.
    b. The HPA is of the opinion that the current exemption would cease to exist, and it's Members would be expected to sell all medicines including S0 Category A and S0 Category D Medicines at a Single Exit Price. The unintended consequences for S0's Category A and Category D Medicines could be extensive. Access to these products will be severely restricted.
    c. As an industry, we cannot afford SEP. The majority of our members fall into the small and medium sized categories of business within the CAMs industry and the anticipated increase in costs to implement SEP on its products will negatively affect them.
    d. This decision if implemented, would severely and negatively impact the CAMs industry in South Africa.

3) TIME FRAMES
    a. The HPA, is of the opinion that the various milestones of NHI needs to be executed in a phased in manner and that it would be unrealistic to achieve all necessary milestones with the effective go-live date of 2026.

CONCLUSION:

The Health Products Association of Southern Africa (HPA) is appreciative of the opportunity to comment on the NHI Bill.

The HPA remains supportive of achieving universal healthcare coverage for all South Africans and most notably look to its member companies in the health and wellness space to play a meaningful role in this regard.

The HPA welcomes the opportunity for further engagement on this Bill given its significance and look forward to all relevant comments and views being taken into account as part of this parliamentary process. The HPA is of the opinion that the attainment of universal healthcare coverage cannot be left to government alone and as the private sector, the HPA welcomes constructive dialogue and engagement on this very significant Bill.

The HPA is of the opinion that it needs to be appreciated that as Complementary Medicines (CAMs) have been listed as 'health-related' products, that the HPA's voice needs to be heard as it relates to CAMs forming a part of the NHI system for healthcare delivery.

In this regard, the HPA is of the opinion that the CAMs industry cannot be subjected to allopathic/pharmaceutical terms as it relates to procurement, listing and access.

Yours Sincerely

MARIA ASCENCAO
Chairman
Health Products Association

HPA DETAILED COMMENTS

SECTION	COMMENTS
To achieve universal access to quality health care services in the Republic in accordance with section 27 of the Constitution; to establish a National Health Insurance Fund and to set out its powers, functions and governance structures; to provide a framework for the strategic purchasing of health care services by the Fund on behalf of users; to create mechanisms for the equitable, effective and efficient utilisation of the resources of the Fund to meet the health needs of the population; to preclude or limit undesirable, unethical and unlawful practices in relation to the Fund and its users; and to provide for matters connected herewith.	• The **HPA** supports the promotion of universal healthcare coverage for all citizens, people in the country. • The **HPA** is also of the view that CAMs has a direct role to play in the provision of healthcare in South Africa. • As the **HPA**, our concern is around the '**How**' – the implementation framework for NHI and the role that the CAMs industry will play in the delivery mechanism for NHI. Now that the CAMs industry has been categorised as 'medicines' as an industry association we need to for the Department of Health (as the custodian of NHI and the NHI Fund) to both engage and inform the CAMs industry on this impact. • Further to this, the operational roadmap for implementation needs to be shared – the perceived notion is that there are 'grey' areas that require additional clarification, given the current healthcare system for the funding and delivery of healthcare services within the public sector. • Given the country's current macro-economic challenges (possible downgrade to junk status, failing performance of certain SoEs and possible IMF support which may be required in the immediate to midterm), this again raises the question of **sustainable affordability** for the country for the funding of NHI. • South Africa's middle class is having to absorb all financial 'blows' and this is becoming unsustainable. Currently there are 7.6 million registered taxpayers in South Africa supporting a population of 58.6 million people. • A fundamental concern is the extent to which the private healthcare sector will play in the delivery of NHI. • With reference to *"complementary services"* - the private healthcare sector cannot perform a function of top-up alone as it relates to the delivery of NHI. This will severely and negatively impact if not significantly diminish the value that the private sector can provide in support of an NHI.

	• Further to this fundamental concern is the costing mechanism (a SEIAS needs to be done by the DPME coupled with a full financial costing by National Treasury in order to ascertain whether or not South Africa can **afford** to implement universal healthcare coverage.) The **HPA** are of the firm view that the funding and financing mechanism for NHI ought to be separated out and managed by either Treasury or the Department of Finance in order to ensure effective and good governance. • The ripple effects of making system mandatory (middle class unaffordability) would be huge. • The risk of putting the entire country on a fund based on payroll and income tax could result in economic downturn. • National Treasury needs to have greater involvement with the NHI and its funding – the NHI funding model would be a Money Bill that only National Treasury and the Minister of Finance can prescribe. • The Bill should be aligned with the provisions of the National Health Act, 2004 - particularly with regards to the expectation of delivery of a quality healthcare service. • The Governance framework for NHI implementation must be shared with all stakeholders as part of the parliamentary process (King IV guidelines regarding structure and operations). • Innovation and access to healthcare is imperative and should not be comprised by a cost driven agenda which does not encourage access to innovation and potentially could present a barrier to entry. • Further to this, the **HPA** are of the firm view that the objective cannot be isolated to obtaining access to healthcare alone but more importantly the objective ought to be based on achieving and improving healthcare outcomes in the country. • Given the fact that CAMs is a player in the wellness space, we would want to ensure that a wellness angle is incorporated into the ethos and application of NHI. The Bill does not address wellness and we remain concerned that healthcare outcomes can only be achieved if wellness as a concept for healthcare redress is placed in the epicentre of this NHI system. Our concern is, how will this be achieved, if at all? And what role would the CAMs industry play in this regard?

	Within the wellness (CAMs) market, there are different categories of wellness approaches, these include: • Wellness - Prevention rather than cure • Increased responsibility for personal health • Perceived high cost of health services • Safety and low incidence of side effects • Ease of access • Increased awareness of its benefits • Rewards by loyalty programs to keep healthy **There are different categories of CAMs and these need to be integrated into the wellness ethos of NHI:** • African Traditional Medicine • Aromatherapeutic Essential Oils • Auyrvedic Medicine • Biochemical Medicines & Salts • Chinese Medicine • Energy Substance • Herbal Medicine • Homoeopathic Medicine • Nutraceuticals • Sowa Rigpa Medicine • Unani-Tibb Medicine As the **HPA** we need to be engaged by the Department of Health on this aspect which is currently omitted from this Bill.

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;	• Once again here, the **HPA** recognises the need for equitable, quality healthcare in the country. The **HPA** subscribes to the 'moral good', and on this basis would like to engage on ensuring that this provision of healthcare services under the banner of NHI is equitable and of a good quality. • Our concern is that the NHI lowers the level of care available to the majority of citizens as opposed to the progressive realisation of the right to healthcare that the Bill aspires to. • The principle of social solidarity is embraced and accepted – however, it should not have the unintended consequence of reducing the private sector benefits of care, since this would negatively impact quality of care provided. • The **HPA** are of the firm view that this system intended for universal healthcare coverage is one that incentivises all stakeholders (funders, suppliers, providers) to want to meaningfully participate in the realisation and implementation of NHI.
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 physical and mental 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 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;	• As it relates to the Infringement of one's Constitutional Right to Freedom of Association, in terms of the NHI Bill, a *'user'* is simply defined as *"a person registered as a user in terms of Section 5."* Accordingly, Clause 4 of the NHI Bill deals with the persons that are eligible to join the fund. However, importantly, the Bill does not contain a clause that compels any of the categories of persons, referred to in Clause 4, to belong to the fund - therefore on the face of the NHI Bill as it is currently proposed, there is **no mandatory** requirement for South Africans or any other persons to join the fund. This is our fundamental understanding and this is what we support in this regard.

● 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 realization 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)© of the Constitution provides that every child has the right to basic health care services;	
SCHEDULE **REPEAL AND AMENDMENT OF LEGISLATION AFFECTED BY ACT**	
Definitions **1.** In this Act, unless the context indicates otherwise—	
''accredited'' means to be in possession of a valid certificate of accreditation from the Fund as issued in terms of section 39;	• The process of accreditation should not be a barrier to the provision of quality healthcare.
''ambulance services'' means ambulance services as contemplated in Part A of Schedule 5 to the Constitution;	**HPA Questions:** • How is this going to be incorporated into a central system? • Is this to be a function of the CUPs or district structures? • Ambulance services are the function of provinces.

''Appeal Tribunal'' means the Appeal Tribunal established by section 44;	
''asylum seeker'' has the meaning ascribed to it in section 1 of the Refugees Act;	
''Benefits Advisory Committee'' means the Benefits Advisory Committee established in terms of section 25;	
''Board'' means the Board of the Fund established by section 12;	
''central hospital'' means a public hospital designated as such by the Minister as a national resource to provide health care services to all residents, irrespective of the province in which they are located, and that must serve as a centre of excellence for conducting research and training of health workers;	**HPA Questions:** • What would constitute a *"central hospital"* under the NHI? • Where will the cost for such research be found and allocated to - as this can become a very significant driver for cost escalation? • **Within the wellness (CAMs) market, there are different categories of wellness approaches, these include:** • Wellness - Prevention rather than cure • Increased responsibility for personal health • Perceived high cost of health services • Safety and low incidence of side effects • Ease of access • Increased awareness of its benefits • Rewards by loyalty programs to keep healthy Given the different categories of CAMs, are we going to ensure that such health and wellness practitioners are integrated into the NHI framework for delivery at Central Hospitals, as an example?
''certified'', in respect of a health establishment, means to be in possession of a valid certificate issued by the Office of Health Standards Compliance as provided for in the National Health Act;	**HPA Questions:** • How does a CAMs service provider become certified? • What does *"establishment"* refer to – buildings, practices, individuals, individual practices?

''Chief Executive Officer'' means the person appointed in terms of section 19;	
''child'' means a person under the age of 18 years as defined in section 28(3) of the Constitution;	
''complementary cover'' means third party payment for personal health care service benefits not reimbursed by the Fund, including any top up cover offered by medical schemes registered in terms of the Medical Schemes Act or any other voluntary private health insurance fund;	**HPA Questions:** • What would complementary and/or top-up cover under NHI entail? • What would this be informed by? • Does this imply a compulsory diminishing role for medical schemes as benefits under the NHI Fund increase? If so, does this not impinge on consumers' rights or choice should they wish to continue being covered by private medical aid? • As a player in the health and wellness space, the HPA on behalf of its members, requires clarity on what *"complementary"* means in relation to different forms of private healthcare cover that are currently legislated – medical aid schemes and personal health insurance. • As the **HPA**, we remain extremely concerned around the perceived diminishing role of medical aid schemes, suppliers, funders, providers. • Further to this, as a segment of the healthcare market wholly focused on wellness, this omission is going to ensure that the relevant healthcare outcomes desired by Government will not be realized in the mid to long term**.**
"complementary formulary"	**HPA Questions:** • What is the definition of a "*complementary formulary"?* The Bill makes reference to them but there is no definition provided for. • Will CAMs form part of this formulary or not?
''comprehensive health care services'' means health care services that are managed so as to ensure a continuum of health promotion, disease prevention,	**HPA Questions:** • As *"comprehensive healthcare services"* relates to the Scheme, how will it be administered?

diagnosis, treatment and management, rehabilitation and palliative care services across the different levels and sites of care within the health system in accordance with the needs of users;	• How would a person arrive at a comprehensive EEL and EML? • What about the current PMBs? Would they be included? • Who makes that determination? • Will there be an EDL and how will access be granted? • The definition provided is not very clear. • Definitions of *"care pathways per level"* and *"sites of care"* are required. • Clarification on the decision matrix in order to evaluate formularies to be included in the Primary Health Care Package as defined by CMS vs EDL, is needed. • The elements of the *"comprehensive health care services"* need to be defined. • More importantly how will CAMs be incorporated into this?
''comprehensive health care services'' means health care services that are managed so as to ensure a continuum of health promotion, disease prevention, diagnosis, treatment and management, rehabilitation and palliative care services across the different levels and sites of care within the health system in accordance with the needs of users;	**HPA Questions:** • As *"comprehensive healthcare services"* relates to the Scheme, how will it be administered? • How would a person arrive at a comprehensive EEL and EML? • What about the current PMBs? Would they be included? • Who makes that determination? • Will there be an EDL and how will access be granted? • The definition provided is not very clear. • Definitions of *"care pathways per level"* and *"sites of care"* are required. • Clarification on the decision matrix in order to evaluate formularies to be included in the Primary Health Care Package as defined by CMS vs EDL, is needed. • The elements of the *"comprehensive health care services"* need to be defined.
''Constitution'' means the Constitution of the Republic of South Africa, 1996;	
''Contracting Unit for Primary Health Care'' means a Contracting Unit for Primary Health Care referred to in section 37;	• The **HPA** expresses concern as this relates to how these will be contracted, the quantum, as well as inconsistencies as it applies to district management systems and the Contracting Unit for Primary Healthcare. Based on our understanding of this Section in the Bill, they

	are not separate legal entities hence cannot contract - thereby substantially limiting their operational flexibility.
''Department'' means the National Department of Health established in terms of the Public Service Act, 1994 (Proclamation No. 103 of 1994);	
''District Health Management Office'' means a District Health Management Office referred to in section 36;	**HPA Questions:** • How will this be managed under the NHI? Different responsibilities will be divided across spheres of government. Based on our understanding of this section of the Bill, they are not separate legal entities hence cannot contract, thereby substantially limiting their operational flexibility.
''emergency medical services'' means services provided by any private or public entity dedicated, staffed and equipped to offer pre-hospital acute medical treatment and transport of the ill or injured;	
"evidence-based medicine"	**HPA Questions:** • What is definition of *"complementary formulary"*? • What does *complementary* mean with regards to medical aids? Does it mean supplementary to what is provided by NHI in a disease area, or only address disease areas not addressed by NHI - e.g. rare diseases?
''financial year'' means a financial year as defined in section 1 of the Public Finance Management Act;	
''Fund'' means the National Health Insurance Fund established by section 9;	
''health care service'' means— *(a)* health care services, including reproductive health care and emergency medical treatment, contemplated in section 27 of the Constitution;	**HPA Questions:** • How does "*healthcare service"* differ from *"primary care",* if at all? There are varying definitions of *healthcare* and *healthcare services*, which is unclear and confusing.

(b) basic nutrition and basic health care services contemplated in section 28(1)*(c)* of the Constitution; *€* medical treatment contemplated in section 35(2)*€* of the Constitution; and *(d)* where applicable, provincial, district and municipal health care services;	
''health care service provider'' means a natural or juristic person in the public or private sector providing health care services in terms of any law;	• Clarification is needed when referring to *accreditation* and *suppliers.* • *"any law"* needs clarification.
''health establishment'' means a health establishment as defined in section 1 of the National Health Act;	
''health goods'', in respect of the delivery of health care services, includes medical equipment, medical devices and supplies, health technology or health research intended for use or consumption by, application to, or for the promotion, preservation, diagnosis or improvement of, the health status of a human being;	
''health related product'' means any commodity other than orthodox medicine, complementary medicine, veterinary medicine, medical device or scheduled substance which is produced by human effort or some mechanical, chemical, electrical or other human engineering process for medicinal purposes or other preventive, curative, therapeutic or diagnostic purposes in connection with human health;	**HPA Questions:** • How do health related products, like CAMs make their way onto NHI, as this falls currently out of scope of public healthcare provision? This is an important question as it speaks to nutrition based and wellness-based products. Will these products form part of a separate, clearly defined prevention and wellness list?

"Health Technology Assessment (HTA)"	• The Bill makes reference to HTA, but does not provide a definition for it upfront. • According to the WHO, HTA is the systematic evaluation of properties, effects, and/or impacts of health technologies and interventions. It covers both the direct, intended consequences of technologies and interventions and their indirect, unintended consequences. The approach is used to inform policy and decision-making in healthcare, especially on how best to allocate limited funds to health interventions and technologies. HTAs should be independent from funders to ensure their scientific and economic credibility, and should be implemented in a manner which has a direct link to decisions rated to enabling patient access.
''health research'' means health research as defined in section 1 of the National Health Act;	
''hospital'' means a health establishment which is classified as a hospital by the Minister in terms of section 35 of the National Health Act;	
''Immigration Act'' means the Immigration Act, 2002 (Act No. 13 of 2002);	
''mandatory prepayment'' means compulsory payment for health services before they are needed in accordance with income levels;	**HPA Questions:** • Does this apply to all eligible users or only to registered users?
''medical scheme'' means a medical scheme as defined in the Medical Schemes Act;	
''Medical Schemes Act'' means the Medical Schemes Act, 1998 (Act No. 131 of 1998);	**HPA Questions:** • What about other forms of private healthcare funding, such as health insurance cover regulated by the Insurance Act? • These should also be defined.
''medicine'' means medicine as defined in section 1 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965);	

''Minister'' means the Cabinet member responsible for health;	
''National Health Act'' means the National Health Act, 2003 (Act No. 61 of 2003);	
''national health system'' has the meaning ascribed to it in section 1 of the National Health Act;	
''Office of Health Standards Compliance'' means the Office of Health Standards Compliance established by section 77 of the National Health Act;	
''permanent resident'' means a person having permanent residence status in terms of the Immigration Act;	
''personal information'' means personal information as defined in section 1 of the Promotion of Access to Information Act;	
''pooling of funds'' means the aggregation of financial resources for the purpose of spreading the risk across the population so that individual users can access health services without financial risk;	
''prescribed'' means prescribed by regulation made under section 55;	
''primary health care'' means addressing the main health problems in the community through providing promotive, preventive, curative and rehabilitative services and— *(a)* is the first level of contact of individuals, the family and community with the national health system, bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing healthcare process; and	

(b) in the public health sector, is the clinic, and in the private health sector, is the general practitioner, primary care nursing professional, primary care dental professional and primary allied health professional, through multi-disciplinary practices;	
''procurement'' has the meaning ascribed to it in section 217(1) of the Constitution;	
''Promotion of Access to Information Act'' means the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000);	• It must be enforced that all patient records remain confidential.
''provider payment'' means the payment to providers in a way that creates appropriate incentives for efficiency in the provision of quality and accessible health care services using a uniform reimbursement strategy;	• Payment terms are of concern. These need to be clearly defined. • "*incentives"* needs to be clarified.
''public entity'' means a national public entity as reflected in Schedule 3 to the Public Finance Management Act;	
''Public Finance Management Act'' means the Public Finance Management Act, 1999 (Act No. 1 of 1999);	
''referral'' means the transfer of a user to an appropriate health establishment in terms of section 44(2) of the National Health Act;	
"referral pathways"	• The Bill makes reference to "*referral pathways"* but does not define them upfront. This definition is needed as "*referral pathways"* are critical to the definition of- and access to benefits.
''refugee'' has the meaning ascribed to it in section 1 of the Refugees Act;	
''Refugees Act'' means the Refugees Act, 1998 (Act No. 130 of 1998);	

''Republic'' means the Republic of South Africa;	
''social solidarity'' means providing financial risk pooling to enable cross-subsidisation between the young and the old, the rich and the poor and the healthy and the sick;	
''strategic purchasing'' means the active purchasing of health care services by the pooling of funds and the purchasing of comprehensive health care services from accredited and contracted providers on behalf of the population;	
''this Act'' includes any regulation promulgated, directive or rule made or notice issued by the Minister in terms of this Act; and	
''user'' means a person registered as a user in terms of section 5.	
CHAPTER 1 **PURPOSE AND APPLICATION OF ACT**	
2. Purpose of Act	
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 *©* 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.	
3. Application of Act	
(1) This Act applies to all health establishments, excluding military health services and establishments.	**HPA Questions:** • It therefore would include prisoners. • Will the Department of Correctional Services contribute to this Fund?
(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; *©* refugees; *(d)* inmates as provided for in section 12 of the Correctional Services Act, 1998 (Act No. 111 of 1998); and *©* certain categories or individual foreigners determined by the Minister of	**HPA Questions:** • With a shrinking tax base[1], how is the funding mechanism for the NHI going to be sustained? • This is particularly important if the Fund intends on providing comprehensive healthcare services as stated in the Bill; and has implications for both companies and employees – possibly resulting in disinvestment and/or legal challenges. • As the **HPA**, we remain concerned about the total cost of healthcare and sustainability thereof as per the population pool described.

[1] https://businesstech.co.za/news/finance/337593/south-africas-tax-base-is-shrinking/amp/

Home Affairs, after consultation with the Minister and the Minister of Finance, by notice in the *Gazette*.	
(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)*©* 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).	

5. Registration as users	
(1) A person who is eligible to receive health care services in accordance with section 4 must register as a user with the Fund at an accredited health care service provider or health establishment.	**HPA Questions:** • Is registration mandatory? The Bill is silent on whether there will be mandatory membership (a departure from previous versions), but remains very clear on mandatory payment – is this intentional? • What is the potential for opting out? • As the **HPA**, we require clarity on whether all users as defined in the Act will be compelled to register.
(2) *(a)* A person as contemplated in subsection (1), must register his or her child as a user with the Fund at an accredited health care service provider or health establishment. *(b)*A child born to a user must be regarded as having been registered automatically at birth.	**HPA Questions:** • Why do people need to register? Surely a South African Identity Document is enough to get a person onto the system? This therefore contributes towards creating an additional administrative burden and protection of information risk.
(3)A person between 12 and 18 years of age may apply for registration as a user if he or she is not registered as a user in terms of subsection (2).	
(4) *(a)* A supervising adult as contemplated in section 137(3) of the Children's Act, 2005 (Act No. 38 of 2005), must register a child in the child-headed household concerned. *(b)* If no adult has been designated in terms of section 137(2) of the Children's Act, 2005 (Act No. 38 of 2005), any employee of an accredited health care service provider or health establishment must assist the child to be so registered.	

(5) When applying for registration as a user, the person concerned must provide his or her biometrics and such other information as may be prescribed, including fingerprints, photographs, proof of habitual place of residence and— *(a)* an identity card as defined in the Identification Act, 1997 (Act No. 68 of 1997); *(b)* an original birth certificate; or € a refugee identity card issued in terms of the Refugees Act.	
(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)€.	
(7) Unaccredited health establishments whose particulars are published by the Minister in the *Gazette* must, on behalf of the Fund, maintain a register of all users containing such details as may be prescribed.	**HPA Questions:** • What constitutes "*accreditation*"? How will CAMs be addressed as part of this? • Does this imply that facilities have the option to 'opt-out' and not be accredited? • Will unaccredited institutions still have a license to operate and treat patients privately? • Could we envisage CAMs facilities to form a part of this system?
(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.	
6. Rights of users	
HPA Questions: • What does a 'reasonable' time period entail? What does this mean?	

• What will constitute a *"professional standard of care"*? Given the sheer volume of patients the **HPA** remains concerned that lodged appeals may suffer a similar fate to SAHPRA backlogs. This will inevitably result in patients becoming prejudiced, discriminated against, which are against the provisions of the Constitution. • This also relates to the purchase of healthcare which falls outside of the Fund. What will these be? Essentially, what does the Fund cover? These must be known to patients upfront and not only become known during the process of healthcare provision. • Would the NHIF have the authority to insure itself (with regards to citizens being allowed the choice of cover through a PMB-based health insurance), given the generally applicable government policy of not insuring itself, and if so, how costly an exercise would this be and how would it impact health benefits? • Definition is needed for *"unreasonable grounds".* • An individual's choice to purchase comprehensive health benefits, inclusive of CAMs products should be preserved. According to the HMI chaired by Justice Sandile Ngcobo, previous Chief Justice of the Constitutional Court, the report remarked as	

follows (ref. p.91): *76. "The HMI considers that PMBs are an essential component of universal health coverage and the most successful mechanism to prevent catastrophic expenditure".* Given the NHI's purpose *"… to achieve sustainable and affordable universal access to quality healthcare services",* the PMBs support the Bill's main aim as articulated by the HMI report. • **It is on this basis, that CAMs needs to be integrated onto either PMB and or an alternative listing with specific reference to CAMs which fall under the ambit of NHI**. In addition, as stated above, the Bill proposed funding of the NHI through three taxation means – any individual choosing to purchase comprehensive PMB-based health insurance after having contributed to the NHIF through the above, should be allowed the choice. This could also decrease the burden on the NHIF. • The SEIAS published by the DPME, dated 26 June 2019, identifies a pertinent risk – namely that the funding of NHI and a transformed health system will rely on the ability to raise taxes, which may be constrained during recessions and periods of economic downturn. • The associated mitigating measure of innovative budgeting requires clarity. In the event that medical schemes play a much	

smaller role, or none at all, in the health system, it would make the entire population solely dependent on the fiscus. This is a significant risk, not only to the rights of health users, but also to national health outcomes.	
7. Health care services coverage	
(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 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; *€* 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	**HPA Questions:** • Will the current doctor-to-patient ratio of 40.7:10000[2] not worsen under NHI? • How does this then translate into measures to safe guard against possible abuse? • How do we also ensure that doctors have the freedom to provide patients with the best care possible, based on their ethical code of practice? • As the **HPA**, we need to raise a concern with regards to accessing quality healthcare at the point of entry - which is PHC. • Better understanding is also needed to the referral pathways and at which point the decision to refer or not is taken by the healthcare provider. • It needs to be ensured that the patient is not prejudiced in any way as part of this journey and/or process and does not result bottlenecks. Given the additional volumes of patients, we remain concerned of the doctor-to-patient ratio and the impact this may have on improving healthcare outcomes.

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; *€* 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 *(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 *©* 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	**HPA Questions:** • What will inform the EEL and EML? • Where will CAMs feature? • Additionally, what will inform HTA? • What about the provision of secondary, tertiary and quaternary care? At what point will the patient be referred? • Who determines medical necessity, and what are the guidelines/matrix to be used?
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; *€* 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.	
8. Cost coverage	
(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; *€* seeks services that are not deemed medically necessary by the Benefits Advisory Committee; or *(d)* seeks treatment that is not included in the Formulary.	• Clarity is needed on the usage of the terms "*scheme*" vs "*insurance*" in this Section, as these two terms are different in law (from different Acts) and need to be defined properly. • It is good to note however, that access to private and or medical insurance is explicitly mentioned.
CHAPTER 3 NATIONAL HEALTH INSURANCE FUND	

9. Establishment of Fund	
The National Health Insurance Fund is hereby established as an autonomous public entity, as contained in Schedule 3A to the Public Finance Management Act.	**HPA Questions:** • What is the role of Minister of Finance in this regard? • What is the role of the Office of Health Standards Compliance in the execution of the Fund? • Is centralisation of the Fund the best option in the delivery of National Health Insurance? • From a Corporate governance perspective, the **HPA** are of the view that the Minister of Health's powers need to be scaled back, as cited in King IV type arrangements in the structure. • The **HPA** would like to put forward the Malaysia model as an example. To this end, the DPME play an oversight role, as well as provide for regular report back sessions. Having said this, we are acutely aware of DPME resource constraints. What is categorically required is the ability to remain both capable and both independent in the delivery of relevant oversight. • The centralisation of the function of the Provinces in delivering healthcare, which is the second-largest function of all the Provinces, at a national level infringes on their Constitutional mandate.
10. Functions of Fund	
(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 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;	• Concern is raised with regards to the ability for the state to provide healthcare administration and management. • The central funding system remains a cause for concern. • The role of intergovernmental departments to enable universal healthcare coverage requires prioritisation. There are far too many examples where a system has collapsed due to a lack of prioritisation and support. In order for NHI to work, it requires 'seamless' integration. • To this end, a digitised, automated IT system is required as the functional backend of NHI. • There must be defined timelines for payment of healthcare services. • As it stands now, doctors are paid "same day" by the patient, and it is the responsibility of the member of the medical aid to get reimbursed by the medical aid. Alternatively, for "in hospital" treatments, the hospitals receive a pre-authorisation which "guarantees"

€ 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; € 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)* develop and maintain a service and performance profile of all accredited and contracted health care service providers, health establishments and suppliers; *(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;	reimbursement. Currently, the financial burden/risk resides with the patient and the available "out of pocket" funds. If the NHI services are "free" at the point of service, then the doctors are at risk of not being paid by NHI after patient treatment or waiting for long periods of time. • This view is also expressed by the National Treasury on the oversight role of the government over SoEs, in noting that *"Government's role as regulator is more focused on the industry within which the SOE operates or which the SoE serves.* • Given the potential pricing role of the supply-side regulator, an independent HTA Agency could be housed in such a body, as there would also be a direct correlation to price and the benefits package.

(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; € 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 and principles mentioned in section 195 of the Constitution and the provisions of the Public Finance Management Act.	• There needs to be a balance between costs vs patient outcomes. • The Fund must perform its mandate informed by the principles of outcomes/value-based healthcare.
(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.	
11. Powers of Fund	
(1) In order to achieve the purpose of the Act and to perform the functions outlined in section 10, the Fund may— *(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; € 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; € 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; *(g)* improve access to, and the funding, purchasing and procurement of, healthcare services, medicines, health goods and health related products that are of a reasonable quality;	• Central financing, funding and procurement is highly problematic. This needs to be separated out in order to ensure effective governance. • Definition is needed for the term "*otherwise*". • Definition is needed for the term *"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 collate all required data from providers 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; *(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; *€* 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	**HPA Questions:** • How can security of supply be ensured? • If the Fund procures as tenders are typically awarded in the current circumstance, South Africans face the risk that some suppliers will exit the market given that they do not have a deep private sector to support their local presence. This will create the risk of sustainability of supply for the NHI and possibly compromise its ability to negotiate cost effective access. • The procurement of medicines and medical devices should be guided by principle of value-based healthcare, including: • The value for money that the product provides, i.e. the inherent value for money of a product encompasses its clinical benefits, but also the patient experience and health economic benefits; and

€ negotiate the lowest possible price for goods and health care services without compromising the interests of users or violating the provisions of this Act or any other applicable law.	• The need to provide a sustainable environment to support ongoing innovation, which there is continued incentive to invest in new technologies and drive access to better levels of care. • It is highly unlikely in a single purchaser, single payer model can achieve the lowest price, as the erosion/elimination of competition results in monopoly and leads to higher prices in the long term.
CHAPTER 4 **BOARD OF FUND**	
12. Establishment of Board	
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.	• A credible, relevant Board, fit for purpose is required.
13. Constitution and composition of Board	
(f) 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.	
(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; *€* be able to perform effectively and in the interests of the general public; *(d)* not be employed by the State; and *€* 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.	• The **HPA** supports lifestyle audits being conducted as part of this process as well as ongoingly over the five (5) year term.
(6) The Chief Executive Officer is an *ex officio* member of the Board, but may not vote at its meetings.	• The **HPA** implores that this appointment is relevant and fit for purpose, not a politicised one.
(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	

€ 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.	
14. Chairperson and Deputy Chairperson	
(1) The Minister must appoint a Chairperson from amongst the members of the Board as contemplated in section 13(1).	
(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.	
15.Functions and powers of Board	
(f) 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; € 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 purchasing and provision of health care services;	• The **HPA** needs to raise the perceived dual responsibility of the Board, both advisory and operational, as this may not be proper and effective governance. • It is important to note that Collective bargaining must not compromise the quality of health care and must support improved patient outcomes.

€ 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; I 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.	
16. Conduct and disclosure of interests	
(f) 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— *(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 € 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.	
17. Procedures	
The Board must determine its own procedures in consultation with the Minister.	
18. Remuneration and reimbursement	
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 provisions of the Public Finance Management Act.	
CHAPTER 5 CHIEF EXECUTIVE OFFICER	
19. Appointment	
(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.	• A relevant, fit-for purpose candidate needs to be identified. • It is important for a Chief Executive Officer to be appointed with no political interference. • The competency framework needs to be detailed to all stakeholders, inclusive of the private sector.
(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; *(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 € becomes unable to continue to perform the functions of his or her office for any other reason.	
20. Responsibilities	
(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;	• Safeguarding from political interference in the duties and responsibilities of the CEO reporting into the Board is needed.

€ 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; € maintenance of discipline within the Fund; *(d)* effective deployment and utilisation of staff to achieve maximum operational results; and € establishment of an Investigating Unit within the national office of the Fund for the purposes of— (2) 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 (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; € Provider Payment Mechanisms and Rates; *(d)* Accreditation; € 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; € 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; *(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; € 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.	
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.	• This notion is highly unlikely when there is a clause in the Bill that states *"the Board will forward their recommendations to the Minister for approval by Cabinet".*
22. Staff at executive management level	
The Chief Executive Officer may not appoint or dismiss members of staff at executive management level without the prior written approval of the Board.	
CHAPTER 6 COMMITTEES ESTABLISHED BY BOARD	
23. Committees of Board	
(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.	• With the establishment of several committees and sub-committees, safeguarding is needed against possible delays in decision-making due to any potential bureaucracy.

(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.	
(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.	
24. Technical committees	
(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 *€* 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.	
CHAPTER 7 **ADVISORY COMMITTEES ESTABLISHED BY MINISTER**	
25.Benefits Advisory Committee	
(f) 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.	• With the establishment of several committees and sub-committees, safeguarding is needed against possible delays in decision-making due to any potential bureaucracy.
(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.	**HPA Questions:** • **Should this representation not be supported by ensuring that certain industries are represented: CAMs industry players, hospitals, pharma, doctors as a cross-check?** • **This would need to also include appointments of expertise in CAM therapeutic areas.**

(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 € in consultation with the Minister and the Board, the health service benefits provided by the Fund.	• Must include the role and value of CAMs products.
(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.	
26.Health Care Benefits Pricing Committee	
(f) 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.	• The **HPA** has a concern that wellness is not represented as part of this list of expertise required for the Healthcare Benefits Pricing Committee.
(3) The Committee must recommend the prices of health service benefits to the Fund.	• All annual increases need to be debated via a public process which is both transparent and broad-based consultation before the Minister approves. • This should be an independent process, with an independent appointed person in control of process via a regulator outside of the structure. • In its recommendation for good SoE governance, the SoE Network of Southern Africa recommends that there should be a clear separation between the state's ownership function and other state functions that may influence the operating conditions for SoEs, particularly with regards to legal enforcement and market regulation.

	• *concern itself with issues like pricing, consumer interest and industry issues and interest. Although the regulator is a government agency and is carrying out a government role, the relationship of a regulator with the SoE can be and should be an independent, objective, arms-length relationship with the SoE, unlike the more direct relationship that Government as shareholder and policy-maker, would have*.
(4) The Minister must appoint the chairperson from amongst the members of the Committee.	
27.Stakeholder Advisory Committee	
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.	• **This committee should be inclusive of all the relevant stakeholders in the health sector, such as the pharmaceutical, CAMs industry players, the medical devices industry, private health care entities. etc.** • In addition, there is no clear mechanism on how the deliberations of this Advisory Committee will be incorporated in the processes of the NHI, or what its primary purpose is. • The mandate of the Stakeholder Advisory Committee needs to be clarified.
28.Disclosure of interests	
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 discussed and be recused during the discussion.	
29. Procedures and remuneration	

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 € any incidental matter relating to the committee.	• The **HPA** are of the firm view that remuneration must be in line with the principle of universal healthcare coverage.
30. Vacation of office	
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 € the term for which the member was appointed has expired and the membership has not been renewed.	
CHAPTER 8 **GENERAL PROVISIONS APPLICABLE TO OPERATION OF FUND**	
31. Role of Minister	
(f) 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.	• This is of concern as it relates to the powers of the Minister of Health. Clarity on the role of Minister of Health is needed. • Protection of the integrity of the fund for the purpose in which it was created is needed, not only for current citizens, but for future generations to come (leaders appointed after this Minister). • This statement alludes to a potential separation of powers.

(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 duplication of services and the wasting of resources and to ensure the equitable provision and financing of health services.	
32.Role of Department	
(f) The functions of the Department are outlined in the National Health Act and the Constitution, and include— *(f)* issuing and promoting guidelines for norms and standards related to health matters; *(b)* implementing human resources planning, development, production and management; *€* 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 and health agencies as contemplated in section 36 of the National Health Act; and	• Centralisation of healthcare provision could result in provincial malalignment if not managed appropriately. • Health services functions are the concurrent legislative competence of both national and provincial government. • The current scope of responsibility for provinces is stated in the National Health Act. To this end, this Act would need to be amended. • There must be a smooth transition to what is being proposed. This process needs consultation and 'pilot' systems. • Definitions are needed as to who will ensure the services of municipal public health and epidemiology within the districts and municipalities.

€ 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— *(f)* 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 € 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.	
33. Role of medical schemes	
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.	**HPA Questions:** • There is a concern that the current private medical aid schemes would only serve as complementary and/or top-up services which will fall outside of the provisions of NHI. What would constitute such top-up requirements? • Who determines referral pathways? • While the Bill states that medical schemes cannot cover services "reimbursable" by the NHI, it also clearly states that to obtain reimbursement, patients will have to follow prescribed *"referral pathways"* enforced by contracted providers. If patients decline to use a contracted provider, or to follow a referral pathway, their care will not be reimbursed by the NHI. Does this mean therefore that medical schemes will be able to fund uncontracted services that are not reimbursable by the NHI, as these services would be deemed "complementary"? In addition, as stated above, the Bill proposed funding of the NHI through three taxation means – any individual choosing to purchase comprehensive PMB-based health insurance after having contributed to the NHIF through the above, should be allowed the choice. This individual choice might offer some relief to the NHIF on funding requirements, thereby contributing to its sustainability. • It needs to be noted that this could possibly violate the Bill of Rights, Section 18 – the right of association. • If medical necessity is not determined/rejected by the NHI healthcare service, it could put patients at risk of death or serious injury. • Patients could overload NHI emergency services in order to get treatment outside the referral pathways.

	• The implied limitation on the rights of citizens to purchase additional health insurance at their own cost, even after they have contributed to the NHI, is unjustifiably unconstitutional.
34. National Health Information System	
(f) 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 section 40.	• Data confidentiality and data integrity is critical here.
(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.	
35. Purchasing of health care services	
(f) The Fund must actively and strategically purchase health care services on behalf of users in accordance with need.	• Central funding for purchasing is a concern – for example, it could result in service delays.

(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.	• Emergency services are the function of provinces currently. Integration of such services into national healthcare provision needs to be flagged.
36. Role of District Health Management Office	
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.	**HPA Questions:** • How does this function link-in with the Contracting Units? There seems to be a duplication of certain functions in this section, which could lead to confusion and ineffectiveness. • Integration of this office into national healthcare provision needs to be flagged. • Definition is needed for *"non-personal health service package".*
37.Contracting Unit for Primary Health Care	

(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.	• What are the financial implications for the contracting of Primary Healthcare Units?
(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— *(f)* 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; € 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; € 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 *(f)* resolve complaints from users in the sub-district in relation to the delivery of health care services.	
38. Office of Health Products Procurement	
(f) 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.	**HPA Questions:** • Will generics be prioritised over innovative products and medicines- even CAMs products? • What about innovations in healthcare which prioritises wellness? • Will there be in opportunity to input into the EEL and EML? If so, at when, and at what stage?

(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; € 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; € 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	• Our concern as the HPA is the listing of CAMs products on a list of some sort. • The procurement of 'health-related' products (inclusive of CAMs) has unintended consequences as it relates to CAMs being subjected to Single Exit Pricing (SEP). • The primary concern to our membership is the proposed new Single Exit Price system that the Bill seeks to introduce. This system will in effect create an NHI price which would apply, even if products were not available, or sold in the NHI and therefore will apply to all S0s (both Category A and D).The current exemption would cease to exist. We will be expected to sell all medicines including S0s at a Single Exit Price. The unintended consequences for S0s are large. Access alone will be a big problem. • As an industry now classed with pharmaceutical medicines, we cannot afford SEP as the majority of our members fall into the small and medium sized categories of business within the CAMs industry.

(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.	• Formulary developments should take into account evidence-based medicines, inclusive of CAMs.

(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).	
39. Accreditation of service providers	
(f) Health care service providers and health establishments accredited by the Fund in terms of this section must deliver health care services at the appropriate level of care to users who are in need and entitled to health care service benefits that have been purchased by the Fund on their behalf.	**HPA Questions:** • In light of the proposed amendment in the NHI Bill to the Health Professions Act, 1974 which will prohibit registered practitioners from providing services not covered by the NHI Fund, can healthcare professionals choose not to become accredited by the NHI; and if they do, can they still practice privately, and can funders (medical schemes, health insurers) insure for these costs? If not, this seems Constitutionally unjustifiable. • What about ensuring the rights of not only the patient but consumer who utilizes CAMs products to manage and be in control of the wellness choices?
(2) In order to be accredited by the Fund, a health care service provider or health establishment, as the case may be, must— *(f)* 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—	**Questions requiring answers:** • How are the healthcare referral pathways determined?

(f) 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.	
(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— *(f)* primary health care services through Contracting Units for Primary Health Care; *(b)* emergency medical services; and € 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.	**HPA Questions:** • Would there be a prescribed minimum or maximum volume linked to duration contained in the contract?
(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— *(f)* 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; € details of treatment administered including medicines dispensed and equipment used; *(d)* diagnostic tests ordered; € 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 *(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— *(f)* 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	**HPA Questions:** • What happens in the events of "stock outs", and alternative measures need to be applied? What are the rights of the patient or suppliers in such cases? • Doctors should be able to prescribe medicines according to their judgement in providing the best quality care for their patients. Since the Bill makes provision for complementary/top-up cover by a medical scheme, a doctor should be able to provide medicine outside of the Formulary if such patient has a means of paying for it outside of NHI reimbursement. • A doctor should also not risk loss of accreditation in such an event.

relevant statutory health professions council, as the case may be; € 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; € 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; *(f)* 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 health related 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— *(f)* 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; € 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 subsection (8)*(d)* may lodge an appeal in terms of section 43.	**HPA Questions:** • Will there be a fee charged for lodging an appeal? This would be a potentially significant cost for the NHI.
(11) The Fund may issue directives relating to the listing and publication of accredited health care service providers and health establishments.	
40. Information platform of Fund	

(f) 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.	• This needs to be a transparent process.
(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; € 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;	

€ 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; € 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; € a court order or any law requires such disclosure; or *(f)* failure to disclosure the information represents a serious threat to public health.	• Caution is advised against the provision of personal information by third parties, such as private medical schemes, and must be within the provisions of POPIA.

(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— *(f)* 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.	
41. Payment of health care service providers	
(f) 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.	**HPA Questions:** • What international accreditation standards will be used? • How will suppliers be accredited? • Will accreditation be harmonised internationally?
(3) *(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	**HPA Questions:** • What international standards of performance measurements can be used? • Measures must be taken to provide clear guidance on access to critical care (emergency services) in order to prevent patients from using emergency services as a "loophole" to enter the system.

supplier of health goods, as the case may be. € 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— *(f)* 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 € 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.	• It is important to include **all** stakeholders in a consultative process.
(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.	
CHAPTER 9 COMPLAINTS AND APPEALS	
42. Complaints	

(f) 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.	• As a matter of principle, there should be an Ombud set up where complaints relating to the fund are addressed with a separate office with low- or no-cost at all to ensure accessibility, transparency and fairness for all.
(2) The Investigating Unit established by the Chief Executive Officer in terms of section 20(2) 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	

€ provide adequate reason for the decision to withdraw or refuse the renewal of accreditation to the health care service provider, as the case may be.	
43. Lodging of appeals	
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.	
44. Appeal Tribunal	
(f) An Appeal Tribunal is hereby established, consisting of five persons appointed by the Minister: *(f)* 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 € 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;	

(b) the Minister terminates his or her membership on good cause; or € the term for which the member was appointed has expired and has not been renewed or after a second term may not be renewed.	
45. Powers of Appeal Tribunal	
(1) The Appeal Tribunal has the same power as a High Court to— *(a)* summon witnesses; *(b)* administer an oath or affirmation; € 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.	
46. Secretariat	
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 three years after the decision has been recorded.	
47. Procedure and remuneration	
(f) 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 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.	
CHAPTER 10 FINANCIAL MATTERS	
48.Sources of funding	
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; € any interest or return on investment made by the Fund;	**Questions requiring answers:** • Will funding from international NGOs be a source of revenue? • Transparency on the NHI Pilot projects is needed for this process – what was invested, etc.? • How will bequests or donations be managed? • Figures from 2017 indicate that South Africa spent 8.8% of its GDP on healthcare, just over R4 trillion, while the U.S. spent 19.1% of their GDP on health and France 11.5%. The lowest spender was the UAE with 3.8%.

(d) any money paid erroneously to the Fund which, in the opinion of the Minister, cannot be refunded; € any bequest or donation received by the Fund; and *(f)* any other money to which the Fund may become legally entitled.	• The South African exchange rate (ZAR/U.S.$ depreciation) factored into the GDP gap relative to where we are, will almost 'force' a longer time period for South Africa to have a fully-fledged NHI system because of the exchange rate/GDP shortfall. • The **HPA** recommends a process similar to MDG/SDG process where targets are set, reassessed, and reset. Frameworks are then formed based on state of play at the time – based on how it is implemented, arrived at a certain point, reassessed and redefined, with a review for the next phase. • Clear pathways and formularies are not the desired process for this to be achieved. The **HPA** recommends a 'back to basics' approach, with information on the Return of Investment for NHI to be publicly shared.
49.Chief source of income	
(1) The Fund is entitled to money appropriated annually by Parliament in order to achieve the purpose of the Act	**HPA Questions:** • The **HPA** expresses a major concern as it relates to the 3 sources of funding. In the event of a shrinking tax base where will additional funds be sourced to cover any shortfalls?
(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.	
50. Auditing	
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).	
51. Annual reports	
(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.	• Treasury recognises the need for SoE's to adhere to the principles of the King IV Report. Therefore, it is recommended that the NHI Bill should have an explicit requirement for the NHIF to report in accordance with the King IV Report.
(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— *(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.	
CHAPTER 11 MISCELLANEOUS	
52. Assignment of duties and delegation of powers	
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	• Concern is raised as this relates to the overarching powers of the Minister of Health, and should include the Minister of Finance to have fiduciary control and oversight. • Good governance requires a separation of powers in this regard.
53. Protection of confidential information	
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.	
54. Offences and penalties	

(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; *©* 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 *©* 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 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.	
55. Regulations	
(d) 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— *(d)* 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; *©* the budget of the Fund, including the processes to be followed in drawing up the 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; © 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 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; *©* 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; *(z)* the proceedings and other related matters of the Appeal Tribunal; *(z*A*)* any matter that may or must be prescribed in terms of this Act; and *(z*B*)* 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.	
56. Directives	
(d) 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	
57. Transitional arrangements	
(d) (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	• The role of the private sector must not be diminished over time. If anything, the role of the private sector needs to be integral in complementing universal healthcare coverage.

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 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— *(d)* the continuation of health system strengthening initiatives on an on-going basis; (ii) the mobilisation of additional resources where necessary; and	**HPA Questions:** • Amendments to 11 other pieces of legislation might be necessary - is this timeline realistic?

(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: *(d)* 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— *(d)* be responsible for advising the Minister on the vision for health workforce matters, for recommending policy related to health sciences, student education and training, 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	• Clarity is needed on the powers of the Minister of Health initially prescribing healthcare benefits. • The development and revision of the healthcare service benefits should be preceded by a rigorous fiscal impact assessment, with systematic estimation and HTA from an independent institution. • In addition to this, there should be an assessment of the readiness of facilities and human resource needs on order to deliver the benefits to the entire population at an acceptable level of quality. This is particularly important if the Fund foresees a declining role of medical schemes as it increases benefit provision.

education. © 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	• The role of national pathology services is not made clear. Vital tests could be offered as a primary healthcare level, as well as a secondary and tertiary level. The role of diagnostic screening plays a big part in disease prevention and therapeutic monitoring – which are beneficial to patients before becoming medically necessary.

in a cooperative management arrangement with the 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 *(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.	
58. Repeal or amendment of laws	
(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 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.	

59. Short title and commencement	
(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.	
SCHEDULE **REPEAL AND AMENDMENT OF LEGISLATION AFFECTED BY ACT**	
1. Medicines and Related Substances Control Act, 1965	
1. The amendment of section 22G— (a) by the substitution for subsection (1) of the following subsection: ‘‘(1) The Minister shall in consultation with the Office of Health Products Procurement established in section 38 of the National Health Insurance Act, 2019, appoint, for a period not exceeding five years, such persons as he or she may deem fit to be members of a committee to be known as the pricing committee.’’ ; and (b) by the substitution in subsection (3) for paragraph (a) of the following paragraph: ‘‘(a) The transparent pricing system contemplated in subsection (2)(a) shall include a single	

exit price which shall be published as prescribed by the Office of Health Products Procurement contemplated in subsection (1), and such price shall be the only price at which manufacturers shall sell medicines and Scheduled substances to [any person other than the State] the National Health Insurance Fund established by section 9 of the National Health Insurance Act, 2019, or any other person.''.	
2. Occupational Diseases in Mines and Works Act, 1973	
1. The amendment of section 36 by the substitution for subsection (1) of the following subsection: ''(1) The cost of any medical examination under this Act, and the cost incurred to keep a person under observation in accordance with any provision of this Act, shall be purchased and paid for by the National Health Insurance Fund established by section 9 of the National Health Insurance Act, 2019**[—** ***(a)* in the case of a person who works at a mine or works, or whom the owner of a mine or works intends to employ, be borne by the owner of the mine**	

or works; and ***(b)* in the case of any other person, be paid by the Director-General from moneys appropriated by Parliament for that purpose]**.''. 2. The deletion of sections 36A and 36B.	
3. Health Professions Act, 1974	
1. The amendment of section 53— *(a)* by the substitution for subsections (1) and (2) of the following subsections, respectively: ''(1) Every person registered under this Act (in this section referred to as the practitioner) shall, unless the circumstances render it impossible for him or her to do so, before rendering any **[professional]** services which are not covered by the National Health Insurance Fund established by section 9 of the National Health Insurance Act, 2019, inform the person to whom the services are to be rendered or any person responsible for the maintenance of such person, of the fee which he or she intends to charge for such services— *(a)* when so requested by the person concerned; or	

(b) when such fee exceeds that usually charged for such services, and shall in a case to which paragraph *(b)* relates, also inform the person concerned of the usual fee. (2) Any practitioner who in respect of any **[professional]** services rendered by him or her which are not covered by the National Health Insurance Fund established by section 9 of the National Health Insurance Act, 2019, claims payment from any person (in this section referred to as the patient) shall, subject to the provisions of section 32 of the Medical Schemes Act, 1998 (Act No. 131 of 1998), furnish the patient with a detailed account within a reasonable period.''; and *(b)* by the substitution in subsection (3) for paragraph *(a)* of the following paragraph: ''*(a)* The patient may, within three months after receipt of the account referred to in subsection (2), apply in writing to the professional board to determine the amount which in the opinion of the professional board should	

have been charged in respect of the services to which the account relates and which are not covered by the National Health Insurance Fund established by section 9 of the National Health Insurance Act, 2019, and the professional board shall, as soon as possible after receipt of the application, determine the said amount and notify the practitioner and the patient in writing of the amount so determined: Provided that before the professional board determines the said amount, it shall afford the practitioner concerned an opportunity to submit to it in writing his or her case in support of the amount charged.'	
4. **Allied Health Professions Act, 1982**	
1. The amendment of section 38A by the substitution in subsection (1) for the words preceding paragraph *(a)* of the following words: ''Every practitioner shall, unless the circumstances render it impossible for him to do so, and before rendering any professional services, inform the person to whom the services are to be rendered or any person responsible for the maintenance of such person,	

of the fee which he intends to charge for such services <u>that are not covered by the National Health Insurance Act, 2019</u>—''.	
5. **Compensation for Occupational Injuries and Diseases Act, 1993**	
1. The amendment of section 1— *(a)* by the substitution for the definition of ''compensation'' of the following definition: '' **'compensation'** means compensation in terms of this Act **[and, where applicable, medical aid or payment of the cost of such medical aid;]**''; and *(b)* by the deletion of the definition of ''medical aid''. 2. The amendment of section 16 by the substitution in subsection (1) for paragraph *(a)* of the following paragraph: ''*(a)* the payment of compensation, **[the cost of medical aid]** or other pecuniary benefits to or on behalf of or in respect of employees in terms of this Act where no other person is liable for such payment;''. . 3. The amendment of section 22 by the deletion in subsection (3) of paragraph *(a)*. 4. The amendment of section 42—	

(a) by the deletion of subsection (2); and *(b)* by the substitution for subsection (4) of the following subsection: ‘‘(4) An employee shall be entitled **[at his own expense]** to have a medical practitioner or chiropractor of his choice present at an examination by a designated medical practitioner.’’. . 5. The repeal of sections 73 and 75.	
6. **Road Accident Fund Act, 1996**	
1. The amendment of section 17— *(a)* by the substitution for subsection (4B) of the following subsection: ‘‘(4B) *(a)* The liability of the Fund or an agent regarding any tariff contemplated in subsections (4)*(a),* (5) and (6) shall be based on **[the tariffs]** the reimbursement strategy for health care services **[provided by public health establishments]** contemplated in the **[National Health Act, 2003 (Act No. 61 of 2003), and shall be prescribed after]** National Health Insurance Act, 2019, in consultation with the Minister of Health. *(b)* The tariff for emergency	

medical treatment provided by a health care provider **[contemplated in the National Health Act, 2003—** **[(i) shall be negotiated between the Fund and such health care providers; and** **(ii) shall be reasonable taking into account factors such as the cost of such treatment and the ability of the Fund to pay.** ***(c)* In the absence of a tariff for emergency medical treatment the tariffs contemplated in paragraph *(a)* shall apply]** <u>shall be determined, under the National Health Insurance Act, 2019</u>.''; and *(b)* by the deletion of subsections (5) and (6).	
7. Competition Act, 1998	
1. The amendment of section 3— *(a)* by the substitution in subsection (1) for paragraph *(b)* of the following paragraph: ''*(b)* a collective agreement, as defined in section 213 of the Labour Relations Act, 1995; **[and]**''; and *(b)* by the insertion in subsection (1)	

after paragraph *(b)* of the following paragraph: ''*(b*A*)* the operations of the National Health Insurance Fund established by section 9 of the National Health Insurance Act, 2019, as single public purchaser and single payer of health care services;''.	
8. Correctional Services Act, 1998	
1. The amendment of section 12— *(a)* by the substitution for subsection (1) of the following subsection: ''(1) The Department must provide, within its available resources provided by the National Health Insurance Fund established by section 9 of the National Health Insurance Act, 2019, adequate health care services, based on the principles of universal access to primary health care, in order to allow every inmate to lead a healthy life.''; and *(b)* by the substitution for subsection (3) of the following subsection: ''(3) Every inmate may be visited and examined by a medical practitioner of his or her choice and, subject to the permission of the Head of the Correctional	

Centre, may be treated by such practitioner**[, in which event the inmate is personally liable for the costs of any such consultation, examination, service or treatment]**.''.	
9. Medical Schemes Act, 1998	
1. The amendment of section 1— *(a)* by the substitution for the definition of ''business of a medical scheme'' of the following definition: '' **'business of a medical scheme'** means the business of undertaking, in return for a premium or contribution, the liability associated with one or more of the following activities: *(a)* Providing for the obtaining of any relevant health care service <u>that is not covered by the provisions of the National Health Insurance Act, 2019</u>; *(b)* granting assistance in defraying expenditure incurred in connection with the rendering of any relevant health care service <u>that is not covered by the provisions of the National Health Insurance Act, 2019;</u> <u>or</u> *(c)* rendering a relevant health	

care service that is not covered by the provisions of the National Health Insurance Act, 2019, either by the medical scheme itself, or by any supplier or group of suppliers of a relevant health service or by any person, in association with or in terms of an agreement with a medical scheme;''; and *(b)* by the substitution for the definition of ''relevant health service'' of the following definition: '' **'relevant health service'** means any health care treatment **[of any person by a person registered in terms of any law]** that is not covered by the provisions of the National Health Insurance Act, 2019, which treatment is complementary to health care services funded by the State and has as its object— *(a)* the physical or mental examination of that person; *(b)* the diagnosis, treatment or prevention of any physical or mental defect, illness or deficiency; *(c)* the giving of advice in relation to any such defect, illness or deficiency;	

[*(d)* the giving of advice in relation to, or treatment of, any condition arising out of a pregnancy, including the termination thereof;] *(e)* the prescribing or supplying of any medicine, appliance or apparatus in relation to any such defect, illness or deficiency **[or a pregnancy, including the termination thereof]**; or *(f)* nursing or midwifery, and **[includes an]** <u>subject to the provisions of the National Health Insurance Act, 2019, may include complementary and top up</u> and ambulance service, and the supply of accommodation in **[an]** <u>a</u> private institution established or registered in terms of any law as a hospital, maternity home, nursing home or similar institution where nursing is practised, or any other institution where surgical or other medical activities are performed, and such accommodation is necessitated by any physical or mental defect, illness or deficiency **[or by a pregnancy]**;''. 2. The amendment of section 2— *(a)* by the substitution for subsection	

(1) of the following subsection: ''(1) If any conflict, relating to the matters dealt with in this Act, arises between this Act and the provisions of any other law save the Constitution and the Public Finance Management Act, the National Health Insurance Act, 2019, or any Act expressly amending this Act, the provisions of this Act shall prevail.''; and *(b)* by the deletion of subsection (2). 3. The amendment of section 24 by the substitution for subsection (1) of the following subsection: ''(1) The Registrar shall, if he or she is satisfied that a person who carries on the business of a medical scheme which has lodged an application in terms of section 22, complies or will be able to comply with the provisions of this Act, as well as with the provisions of the National Health Insurance Act, 2019, register the medical scheme, with the concurrence of the Council, and impose such terms and conditions as he or she deems necessary.''. 4. The amendment of section 33 by the substitution for subsection (1) of the following subsection:	

‘‘(1) A medical scheme shall apply to the Registrar for the approval of any benefit option **[if such a medical scheme provides members with more than one benefit option]** that constitutes complementary or top up cover and that does not overlap with the personal health care service benefits purchased by the National Health Insurance Fund on behalf of users as provided for in the National Health Insurance Act, 2019.’’.	
10. National Health Act, 2003	
1. The amendment of section 1 by the substitution for paragraph *(c)* of the definition of ‘‘health agency’’ of the following paragraph: ‘‘*(c)* who procures health care personnel or health services for the benefit of a user excluding the National Health Insurance Fund established by section 9 of the National Health Insurance Act, 2019, and its functionaries;’’. 2. The amendment of section 21— *(a)* by the insertion in subsection (2)*(b)* after subparagraph (vi) of the following subparagraph: ‘‘(viA) develop and manage the national health *(b)* by the substitution in subsection (2)	

for paragraph *(c)* of the following paragraph: ''*(c)* promote adherence to norms and standards for the training of human resources for the health sector for purposes of rendering health services;''; *(c)* by the substitution in subsection (2) for paragraph *(k)* of the following paragraph: ''*(k)* facilitate and promote the provision of health services for the management, prevention and control of communicable and non-communicable diseases; **[and]**;''; *(d)* by the substitution in subsection (2) for paragraph *(l)* of the following paragraphs: ''*(l)* co-ordinate the health services rendered by the national department with **[the health services]** those rendered **[by]** through provinces and District Health Management Office, and **[provide]** such additional health services as may be necessary to establish a comprehensive national health system;	

(m) plan the development of public and private hospitals, other health establishments and health agencies; *(n)* control and manage the cost and financing of public health establishments and public health agencies; *(o)* develop a national policy framework for the procurement and use of health technology; *(p)* develop guidelines for the management of health districts; *(q)* assist the District Health Management Office in controlling the quality of all health services and facilities; and *(r)* together with the District Health Management Office promote community participation in the planning, provision and evaluation of health services in a health district.''; and *(e)* by the substitution for subsection (5) of the following subsection: ''(5) The Director-General must integrate the health plans of the national department **[and]**, provincial departments and districts annually and submit the	

integrated health plans to the National Health Council.''. 3. The amendment of section 25— *(a)* by the substitution in subsection (2) for the words preceding paragraph *(a)* of the following words: ''The head of a provincial department must, in accordance with national health policy and **[the]** relevant provincial health policy **[in respect of or]** perform such health functions within the relevant province as may be prescribed—''; *(b)* by the deletion in subsection (2) of paragraph *(b)*; *(c)* by the deletion in subsection (2) of paragraph *(f)*; *(d)* by the deletion in subsection (2) of paragraphs *(h)* to *(l)*; *(e)* by the substitution in subsection (2) for paragraph *(n)* of the following paragraph: ''*(n)* **[control]** <u>assist the District Health Management Office in controlling</u> the quality of all health services and facilities;''; *(f)* by the deletion in subsection (2) of paragraph *(s)*; and *(g)* by the deletion of subsection (3). 4. The amendment of section 27— *(a)* by the deletion in subsection (1)*(a)*	

of subparagraphs (i) and (ii); *(b)* by the deletion in subsection (1)*(a)* of subparagraphs (iv), (v) and (vi); *(c)* by the deletion in subsection (1)*(a)* of subparagraph (viii); and *(d)* by the deletion in subsection (1) of paragraphs *(c)* and *(d)*. 5. The amendment of section 31— *(a)* by the substitution in subsection (2)*(a)* for subparagraph (iv) of the following subparagraph: ''(iv) not more than five other persons, appointed by the relevant member of the Executive Council after consultation with the municipal council of the municipality or District Health Management Office, as the case may be.''; *(b)* by the substitution in subsection (3) for paragraph *(b)* of the following paragraph: ''*(b)* ensure co-ordination of planning, budgeting, provisioning and monitoring of all health services that affect residents of the health district for which the council was established;**[and]**''; *(c)* by the insertion in subsection (3) after paragraph *(b)* of the following	

paragraph: ‘‘*(b*A*)* promote community participation in the planning, provision and evaluation of health care services.’’; *(d)* by the substitution in subsection (5) for paragraph *(b)* of the following paragraph: ‘‘*(b)* the approval, after consultation with the relevant district health council, by the relevant member of the Executive Council and the municipal council of the metropolitan or district municipality, as the case may be, of the detailed **[budget and]** performance targets for health services in the health district to which both the provincial and municipal spheres of government must contribute; and’’; and *(e)* by the substitution in subsection (5)*(c)* for subparagraph (i) of the following subparagraph: ‘‘(i) deadlock-breaking mechanisms for cases where agreement between the relevant member of the **[Executive**	

Council] District Health Council and the municipal council on the **[budget or]** performance targets contemplated in paragraph *(b)* cannot be reached within a period specified in the legislation; and''. 6. The insertion of the following sections after section 31: ''**Establishment of District Health Management Offices** **31A.** (1) District Health Management Offices are hereby established as national government components. (2) The Offices established in section (1) above must facilitate and coordinate the provision of primary health care services at district level in compliance with national policy guidelines and relevant law. (3) The District Health Management Office must— *(a)* prepare annual strategic mediumterm health and human resources plans to provide for the exercise of the powers the performance of the duties and the provision of health care services in the district; *(b)* develop annual district health	

care plans that identify health care service needs in terms of the demographic and epidemiological profile of a particular district; *(c)* submit plans contemplated in subparagraph *(a)* and *(b)* to the Director-General within the timeframes and in accordance with the guidelines determined by the National Health Council; *(d)* manage provision of non-personal health services in the district; *(e)* interact with community representatives through district health councils; *(f)* coordinate and manage the functioning of primary health care within the district, including district specialist support teams, primary health care teams and agents, and school health services; *(g)* provide information on the disease profile in a particular district that would inform the design of the health care service benefits for that district; *(h)* improve access to health care services at health care facilities and in the community in a particular district; *(i)* ensure that the user referral system	

referred to in section 44 is functional, including the transportation of users between the different levels of care and between public and private facilities accredited by the Fund established by section 9 of the National Health Insurance Act, 2019, if necessary; *(j)* facilitate the certification of public health care facilities and accreditation of health care service providers, health establishments and suppliers at district level, including municipal clinics; *(k)* facilitate the integration of public and private health care services such as emergency medical services but excluding public ambulance services; *(l)* receive and resolve complaints from users in the district in relation to the delivery of health care services; *(m)* liaise with and report on a monthly basis to the national office of the Fund established by section 9 of the National Health Insurance Act, 2019, concerning— (i) difficulties experienced by users relating to access to	

health care services; (ii) challenges experienced by the Office in respect of service providers; (iii) health needs of users that are not met; and (iv) any other matter required for the efficient functioning of health care services in the relevant district; *(n)* cooperate with the Investigating Units established in terms of section 20(2)*(e)* of the National Health Insurance Act, 2019, in order to facilitate the investigation of complaints in the district; *(o)* control the quality of all health services and facilities within a district to comply with the norms and standards of the Office of Health Standards Compliance; *(p)* develop, procure, use, maintain and protect health technology within the district; and *(q)* liaise with provincial and municipal health authorities on any matter relevant to users within the relevant district. (4) The Director-General must together with the District Health Management Office ensure that each	

health district and each health subdistrict is effectively and efficiently managed. **Establishment of Contracting Units for Primary Health Care** **31B.** (1) The District Health Management Office must establish Contracting Units for Primary Health Care operating within a framework stipulated by the National Department of Health. (2) The Units established in terms of subsection (1) must be directly contracted by the Fund established by section 9 of the National Health Insurance Act, 2019, to ensure the provision of primary health care services, including prevention, promotion, curative, rehabilitative ambulatory, home-based care and community care. (3) The Fund must transfer funds to the Contracting Units for Primary Heath Care guided by district health resource allocation formulae or capitation formulae prescribed by the Fund established by section 9 of the National Health Insurance Act, 2019. (4) Each Unit must be responsible for the population in its designated	

sub-district as determined by regulation and must ensure that the required human resources are in place to provide primary health care services. (5) Contracting Units for Primary Health Care must identify certified and accredited public and private health care providers at primary care facilities that fulfil all requirements to receive funding for services within the relevant district. (6) To the extent that the Contracting Units for Primary Heath Care are not adequately capacitated, the District Health Management Office must perform these functions on its behalf until such time as the Units have been sufficiently capacitated to fulfil their purpose as provided for in this section.'' 7. The amendment of section 41— *(a)* by the substitution in subsection (1) for the words preceding paragraph *(a)* of the following words: ''The Minister, in respect of a central hospital, and the relevant member of the Executive Council and District Health Management Office, in respect of all other public health establishments within the province and district in question, may—''; 	

(b) by the deletion in subsection (1) of paragraphs *(c)* and *(d)*; and *(c)* by the deletion of subsections (2) and (3). 8. The amendment of section 90— *(a)* by substitution in subsection (1) for the words preceding paragraph *(a)* of the following words: ''The Minister, after consultation with the National Health Council **[or the Office, as the case may be]**, may make regulations regarding—''; *(b)* by the substitution in subsection (1)*(b)* for subparagraph (i) of the following subparagraph: ''(i) the fees to be paid to public health establishments for health services rendered in consultation with the Fund established by section 9 of the National Health Insurance Act, 2019;''; and *(c)* by the substitution in subsection (1) for paragraphs *(d)* and *(e)* of the following paragraphs, respectively: ''*(d)* the development of an essential drugs list and medical and other assistive devices list together with the Office of Health Products Procurement;	

(e) human **[resource]** resources planning, development and management;	
11. Prevention of and Treatment for Substance Abuse Act, 2008	
9. The substitution for section 7 of the following section: ''**Support for services delivered by service providers** **7.** (1) The Minister may— *(a)* from funds **[appropriated by Parliament for that purpose]** received from the National Health Insurance Fund , provide financial assistance to service providers that provide services in relation to substance abuse; *(b)* for the purposes of paragraph *(a)* prioritise certain needs of and services for persons affected by substance abuse; **[*(c)* in the prescribed manner enter into contracts with service providers to ensure that the services contemplated in paragraph *(b)* are provided; and 2) The Minister must—** ***(a)* prescribe conditions for the receiving of financial assistance referred to in subsection (1)*(a)*, including accounting and compliance measures;** ***(b)* prescribe remedies for failure to**	

comply with the conditions contemplated in paragraph *(a)*; ***(c)* establish and maintain a register of all assets bought by service providers with Government funds; and** ***(d)* prescribe conditions for the management and disposal of assets contemplated in paragraph *(c)*.** **(3) Service providers who procure any immovable property with the funds appropriated in terms of subsection (1) must ensure that the Registrar of Deeds makes the necessary entries in the title deed indicating the state ownership of such property.]**	

END.